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Paroxetine

A Multicenter, Open-label, Six-Month Extension Study to Assess the Long-Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD)

716

Interim Clinical Report

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Signature Page

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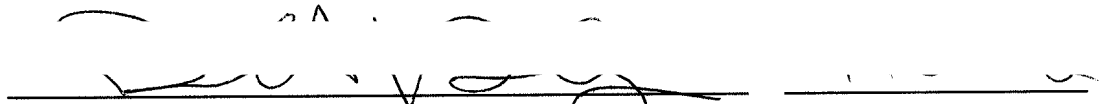
I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.



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Report Synopsis

Study Title: A Multicenter, Open-label, Six-Month Extension Study to Assess the Long-Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD) (29060/716).

Investigators and Centers: This interim report includes data from 43 centers in the United States and 2 centers in Canada. All investigators were experienced in the treatment of child and adolescent patients. The study center of Dr. xxxxxxxxxx, xxxxxxxxxxx xx (center 055) was terminated because of significant compliance violations.

Publication: No publications as of January 2002.

Study Dates: The first dose of open-label study medication was administered on May 13, 2000. This interim report includes data for all patients who entered the open-label extension study from acute studies 701 (patients with MDD) and 704 (patients with OCD) and had a completed 716 week 4 CRF or a 716 CRF study conclusion page received in-house by GlaxoSmithKline by October 1, 2001. Data from patients who entered this extension study after completing study 715 (open-label, forced-titration, steady state pharmacokinetic evaluation in patients with MDD or OCD) are not included in this interim report as the database for 715 was finalized after the study 716 database. These data will be included in the 716 final clinical study report.

Objectives: The objectives were to:

Assess the long-term (6-month) safety of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine study 701, 704, or 715, and chose to enter this study.

Monitor the long-term (6-month) efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine study 701, 704, or 715, and chose to enter this study.

Study Design: This was a multicenter, open-label, 6-month extension study in children (aged 7 to 11 years inclusive) and adolescents (aged 12 to 17 years inclusive) who completed acute paroxetine study 701, 704 or 715, and who chose to enter this study.

Study Population: Children and adolescents who completed paroxetine study 701, 704, or 715, and who met all other inclusion and none of the exclusion criteria were eligible to enter this study. Data from patients who entered this extension study after completing study 715 are not included in this interim report.

Treatment and Administration: Paroxetine was supplied in the form of white, oval, film-coated tablets for oral administration once daily. Each tablet contained 10 mg of paroxetine (batch number U00001).

Patients were to receive paroxetine (10 to 50 mg/day) for a period of 24 weeks during the treatment phase of study 716. Patients entering study 716 from acute study 701 or 704 were to be started on therapy at 10 mg/day. Patients entering study 716 from study 715 could, at the investigator's discretion, be initiated at a higher dosage level (e.g., the dosage level achieved at 715 endpoint). Starting at week 2, the dose of paroxetine could be increased by 10 mg/day up to a maximum dose of 50 mg/day, according to clinical response and tolerability. Dose reductions of 10 mg/day at weekly intervals were permitted at the discretion of the investigator. During the taper phase, patients who completed the treatment phase or were prematurely withdrawn at a dosage of $\geq$ 20 mg/day were down-titrated at a rate of 10 mg/day/week for a period of up to 4 weeks until they finished one week of taper phase dosing at 10 mg/day.

Evaluation Criteria

Safety Parameters: Safety, of primary interest in this study, was assessed via AE monitoring, vital sign measurements, laboratory evaluations, serum pregnancy tests, electrocardiograms (ECGs) and physical examinations.

Efficacy Parameters: There was no primary efficacy variable in this study.

Secondary efficacy variables were change from baseline in the Children's Depression Rating Scale-Revised (CDRS-R) total score, assessed only in patients with a primary diagnosis of MDD; change from baseline in the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) total score, assessed only in patients with a primary diagnosis of OCD; the proportion of responders based on the Clinical Global Impressions (CGI) Global Improvement item (where response was defined as a score of 1 [very much improved] or 2 [much improved]), assessed in patients with a primary diagnosis of either MDD or OCD; and change from baseline in the CGI Severity of Illness item score, assessed in patients with a primary diagnosis of either MDD or OCD.

Statistical Methods: This is an open label study and no hypothesis testing was performed. Efficacy data were summarized descriptively, both overall and by acute study treatment group at each visit, with inferences based on the week 24 observed cases (OC) and last observation carried forward (LOCF) datasets. Categorical data were summarized by counts and percentages. Continuous data were summarized by the mean, median, standard deviation and range (minimum, maximum). Two patient populations were evaluated. The intention-to-treat (ITT) population consisted of all patients who received at least one dose of open-label medication and for whom at least one valid post-baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available. The pure paroxetine (PPX) population consisted of all patients who received paroxetine in their acute study, received at least one dose of open-label medication, and for whom at least one valid post-baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available.

Patient Disposition and Key Demographic Data

A total of 261 patients were entered into this open-label study. Of these, 223 patients met the criteria for inclusion in this interim analysis (117 patients from acute study 701 and 106 patients from acute study 704). Of these, 221 patients were included in the ITT population [94 patients who received paroxetine in their acute study (referred to as acute study paroxetine patients) and 127 patients who received placebo in their acute study (referred to as acute study placebo patients)]. Two patients were not included in the ITT population as they had no post 716 baseline assessments.

Patient Disposition (All Patients)

Study Stage/Population	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
716 Baseline Only	0	-	0	-	0	-
Entered	96	(100.0)	127	(100.0)	223	(100.0)
Completed *	40	(41.7)	33	(26.0)	73	(32.7)
Ongoing**	11	(11.5)	15	(11.8)	26	(11.7)
Early Withdrawal	45	(46.9)	79	(62.2)	124	(55.6)
Intention-to-Treat	94	(97.9)	127	(100.0)	221	(99.1)
Pure Paroxetine	94	(97.9)	-	-	94	(42.2)

*A patient was considered to have completed the study if they completed a week 24 visit CRF.

** Ongoing patients were patients who did not have a study conclusion page, but had a completed week 4 CRF in-house by October 1, 2001

The acute study paroxetine group includes two patients who entered study 716, but had no post-baseline assessments

As of the clinical cut-off date of October 1, 2001, a total of 73 patients had completed the study, 124 had withdrawn early and 26 were continuing to receive open-label paroxetine having already completed a week 4 CRF. Overall, of all patients entered into study 716, more patients from the acute study placebo group withdrew early (62.2%, 79/127) compared to patients from the acute study paroxetine group (46.9%, 45/96). The primary reasons for withdrawal in the overall population were 'adverse event' (14.9%), 'other' reason (13.6%), and 'lack of efficacy' (11.8%). In patients who had received paroxetine in the acute study, 'other' was the primary reason leading to withdrawal (13.8%), whereas in patients who had received placebo in the acute study 'adverse event' was the primary reason leading to withdrawal (18.9%). The withdrawal rate was slightly higher for children than adolescents, but independent of primary diagnosis.

Baseline demographic and efficacy parameters are presented below. Demographic data were collected at acute study baseline; efficacy parameters, CDRS-R and CY-BOCS, are presented for study 716 baseline. Mean age, height, weight and BMI were similar between acute study treatment groups for the ITT population. There were more male patients (57.0%, 126/221) than female patients (43.0%, 95/221). The proportion of females in patients from the acute study paroxetine group (47.9%, 45/94) was higher than in patients from the acute study placebo group (39.4%, 50/127). The proportion of males from the acute study paroxetine group (52.1%, 49/94) was lower than in patients who had received placebo in the acute study (60.6%, 77/127).

There were slightly more children than adolescents in the ITT population, 53.8% (119/221) compared to 46.2% (102/221), respectively. This imbalance was most prominent in the patients who received placebo in their acute study.

Demography and Baseline Characteristics (ITT Population)

	Acute Study Treatment Group		
	Paroxetine	**Placebo**	**Total**
Total Patients Age Group: Total			
Females: Males	45:49	50:77	95:126
Mean age (SD): years	11.5 (3.00)	11.6 (2.83)	11.5 (2.90)
White: n (%)	77 (81.9)	109 (85.8)	186 (84.2)
Total Patients Age Group: Children			
Females: Males	27:22	26:44	53:66
Mean age (SD): years	9.0 (1.42)	9.4 (1.32)	9.3 (1.37)
White: n (%)	40 (81.6)	61 (87.1)	101 (84.9)
Total Patients Age Group: Adolescents			
Females: Males	18:27	24:33	42:60
Mean age (SD): years	14.2 (1.49)	14.2 (1.73)	14.2 (1.62)
White: n (%)	37 (82.2)	48 (84.2)	85 (83.3)
Patients with MDD Age Group: Total			
Females: Males	23:27	29:37	52:64
Mean age (SD): years	11.6 (2.82)	11.6 (2.94)	11.6 (2.88)
White: n (%)	39 (78.0)	54 (81.8)	93 (80.2)
716 Baseline CDRS-R Total Score: Mean	36.7 (13.26)	37.3 (13.93)	37.1(13.60)
Patients with MDD Age Group: Children			
Females: Males	14:11	14:22	28:33
Mean age (SD): years	9.2 (1.34)	9.4 (1.29)	9.3 (1.31)
White: n (%)	9 (76.0)	30 (83.3)	49 (80.3)
716 Baseline CDRS-R Total Score: Mean	37.8 (15.12)	35.3 (12.92)	36.2 (13.72)
Patients with MDD Age Group: Adolescents			
Females: Males	9:16	15:15	24:31
Mean age (SD): years	14.0 (1.50)	14.3 (1.86)	14.2 (1.70)
White: n (%)	20 (80.0)	24 (80.0)	44 (80.0)
716 Baseline CDRS-R Total Score: Mean	35.8 (11.55)	39.9 (14.92)	38.1 (13.54)
Patients with OCD Age Group: Total			
Females: Males	22:22	21:40	43:62
Mean age (SD): years	11.5 (3.22)	11.5 (2.73)	11.5 (2.93)
White: n (%)	38 (86.4)	55 (90.2)	93 (88.6)
716 Baseline CY-BOCS Total Score: Mean	16.5 (8.86)	19.9 (7.59)	18.5 (8.27)
Patients with OCD Age Group: Children			
Females: Males	13:11	12:22	25:33
Mean age (SD): years	8.9 (1.51)	9.5 (1.38)	9.2 (1.45)
White: n (%)	21 (87.5)	31 (91.2)	52 (89.7)
716 Baseline CY-BOCS Total Score: Mean	15.0 (9.65)	19.0 (8.38)	17.3 (9.06)
Patients with OCD Age Group: Adolescents			
Females: Males	9:11	9:18	18:29
Mean age (SD): years	14.6 (1.47)	14.1 (1.59)	14.3 (1.54)
White: n (%)	17 (85.0)	24 (88.9)	41 (87.2)
716 Baseline CY-BOCS Total Score: Mean	18.4 (7.65)	20.9 (6.50)	19.1 (7.03)

Safety Results

Adverse Events: Overall, 72.9% (161/221) of patients reported a gender-non-specific adverse event during the open-label treatment phase: 75.5% (71/94) of patients who had received paroxetine in the acute study and 70.9% (90/127) of patients who had received placebo in the acute study. The most common (>10%) gender-non-specific adverse events for patients in the acute study paroxetine group were headache (25.5%), respiratory disorder (16.0%), infection (13.8%), trauma (12.8%), and nausea (10.6%), while the most common adverse events for patients in the acute study placebo group were respiratory disorder (19.7%), headache (18.9%), infection (11.8%), and nervousness (10.2%). Six female patients reported a female-specific emergent adverse event during the open label treatment phase. There were no male specific adverse events during the open label treatment phase.

The overall frequency of gender-non-specific adverse events was slightly higher among children compared to adolescents. A total of 77.3% (92/119) of children reported gender-non-specific adverse events during the open-label treatment phase; 79.6% (39/49) of patients from the acute study paroxetine group and 75.7% (53/70) of patients from the acute study placebo group. A total of 67.6% (69/102) of adolescents reported gender-non-specific adverse events during the open-label treatment phase; 71.1% (32/45) of patients from the acute study paroxetine group and 64.9% (37/57) of patients from the acute study placebo group.

The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 70.7% (82/116). A total of 76.0% (38/50) of patients with a primary diagnosis of MDD from the acute study paroxetine group and 66.7% (44/66) of patients from the acute study placebo group reported at least one gender-non-specific adverse event during the open label treatment phase. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD was 75.2% (79/105). A total of 75.0% (33/44) of patients with a primary diagnosis of OCD from the acute study paroxetine group and 75.4% (46/61) of patients from the acute study placebo group reported at least one gender-non-specific adverse event during the open label treatment phase. The nature of the adverse events were similar among patients with a primary diagnosis of MDD and patients with a primary diagnosis of OCD.

Overall, 11.3% (25/221) patients reported a severe gender-non-specific adverse event during the open-label treatment phase. The proportion of patients reporting at least one severe gender-non-specific adverse event during the open-label treatment phase was 9.6% (9/94) of patients from the acute study paroxetine group and 12.6% (16/127) of patients from the acute study placebo group. The only severe adverse events occurring in more than one patient in either acute study treatment group were hostility (4 patients), emotional lability (3 patients) and infection (3 patients). There were no severe gender-specific adverse events. The majority of open-label treatment phase-emergent severe adverse events were considered unrelated to study medication. One patient from the acute study paroxetine group and 6 patients from the acute study placebo group had severe adverse events during the open-label treatment phase that were considered by the investigator to be related or possibly related to open-label study medication.

Overall, 47.1% (104/221) of patients reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the open-label treatment phase: 47.9% (45/94) of patients from the acute study paroxetine group and 46.5% (59/127) of patients from the acute study placebo group. The most common (>5% in patients from either acute study treatment group) gender-non-specific adverse events judged to be related or possibly related to open-label study medication were headache, nervousness, hyperkinesia, weight gain, nausea, insomnia and decreased appetite. The only gender-specific adverse event judged to be related or possibly related to open-label study medication was female genital disorders, which occurred in 1 patient from the acute study placebo group.

Serious Adverse Events: No deaths were reported prior to the clinical cut-off for this interim report (October 1, 2001).

Overall, 5.4% (12/223) of all patients enrolled experienced at least one serious adverse event during the open-label treatment phase, taper phase, or within 30 days of the last dose of open-label study medication. The proportion of patients with at least one serious adverse event was similar between patients from the two acute study treatment groups: 5.2% (5/96) of patients from the acute study paroxetine group and 5.5% (7/127) of patients from the acute study placebo group. (Note: the total number of patients includes two patients who had no post-716 baseline assessments). Of the 14 serious adverse events reported, 12 were reported during the open-label treatment phase. The majority of serious adverse events were judged as moderate or severe in intensity and unrelated to open-label study medication. No gender-specific serious adverse events were reported for either acute study treatment group.

Withdrawals Due to Adverse Events:
Overall, 14.9% (33/221) of patients were withdrawn from the study during the open-label treatment phase because of an adverse event (31 patients during the open-label treatment phase and 2 patients during the taper phase). Of the 33 patients withdrawn from the study because of an adverse event 15.1% (18/119) were children and 14.7% (15/102) were adolescents. The proportion of patients withdrawn because of an adverse event was lower in patients who received paroxetine in their acute study (9.6%, 9/94) compared to patients who received placebo in their acute study (18.9%, 24/127). The majority of the adverse events leading to withdrawal were judged moderate or severe in intensity by the investigator.

Adverse events leading to withdrawal during the open-label treatment phase (excluding taper) occurring in more than 1% of the total population were hostility (3.6%, 8/221), emotional lability (1.8%, 4/221), hyperkinesia (1.8%, 4/221) and nervousness (1.4%, 3/221). Two patients in the acute study placebo group reported a gender specific adverse event leading to withdrawal (libido decreased and abnormal ejaculation).

Vital Signs: Overall, 40 patients (20 patients from the acute study paroxetine group and 20 patients from the acute study placebo group) had vital sign values that met the sponsor's definition of potential clinical concern during the open-label treatment phase of the study. The majority of these patients, 12 from the acute study paroxetine group and 9 from the acute study placebo group, had an increase in body weight, which was ≥ 7% and were above the normal weight range for their age. Changes in vital signs values from acute study baseline to week 24 and endpoint were small for both acute study treatment groups and age groups and of no clinical concern.

Laboratory Data : In total, 53 patients had laboratory values that met the sponsor's definition of potential clinical concern during the course of the study (27 patients from the acute study paroxetine group and 26 patients from the acute study placebo group). The majority of these patients had low hematocrit values of potential clinical concern. No remarkable mean changes in laboratory parameters were observed in patients from either acute study treatment group or age group.

Electrocardiograms : No patients had abnormal ECG findings at the study 716 baseline visit or the week 24/early withdrawal visit. One patient who had received paroxetine in the acute study had an abnormal ECG assessment (as assessed by the investigator) during the taper phase, and one patient who had received placebo in the acute had an abnormal ECG assessment (as assessed by the investigator) during the follow-up phase. One patient who had received paroxetine in the acute had an abnormal ECG assessment (as assessed by the investigator) during the follow-up phase that was associated with an adverse event. In addition, one patient who had received placebo in the acute study had an ECG during the open-label treatment phase of the study that was associated with an adverse event.

Efficacy Results

Datasets : Two datasets were used to summarize the results: an observed case (OC) dataset and a last observation carried forward (LOCF) dataset. For both the ITT population and PPX population, descriptive summaries were produced based on the OC data set at each visit and the LOCF data set, with primary inferences based on the protocol defined week 24 endpoint.

Primary Efficacy Variable : There was no primary efficacy variable defined in this study as this study was not formally designed to assess efficacy.

Secondary Efficacy Variables: Results of the secondary endpoints suggest that MDD and OCD patients who respond to paroxetine during acute treatment generally will continue to respond during long term (i.e, 6 month) treatment. The mean CDRS-R total score remained substantially decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints in patients with a primary diagnosis of MDD. Similarly, the mean CY-BOCS total score remained substantially decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints for patients with a primary diagnosis of OCD. The majority of patients with a primary diagnosis of MDD or OCD met the CGI-Global Improvement item responder criteria at the week 24 OC and week 24 LOCF endpoints.

Conclusions

Data from this study demonstrate that paroxetine (10-50 mg/day) is safe and generally well-tolerated when used to treat children and adolescents with MDD or OCD for a period of up to 24 weeks. The adverse event profile with longer term dosing was comparable to that observed during acute (short term) dosing in earlier studies. As was the case in the prior acute studies, the long term safety data suggest that the common adverse event profile may differ somewhat between children and adolescents.

The efficacy results suggest that patients who responded to paroxetine in the acute study are likely to continue to respond to paroxetine during long term administration, however this study was not designed to evaluate this.

List of Abbreviations & Definitions

Abbreviation	Unabridged Term(s)
ADECS	Adverse Drug Experience Coding System (based on COSTART system)
AE	adverse event
ALT	alanine aminotransferase (SGPT)
AP	alkaline phosphatase
ART	Adverse Reaction Terminology
AST	aspartate aminotransferase (SGOT)
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
BP	blood pressure
bpm	beats per minute
BUN	blood urea nitrogen
CDRS-R	Children's Depression Rating Scale – Revised
CFR	Code of Federal Regulation
CGI	Clinical Global Impression
CRF	case report form
CV	Curriculum Vitae
CY-BOCS	Children's Yale-Brown Obsessive Compulsive Scale
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth
ECDEU	Early Clinical Drug Evaluation Unit
ECG	electrocardiogram
GAD	Generalized Anxiety Disorder
GCP	Good Clinical Practice
GSK	GlaxoSmithKline
HCG	human chorionic gonadotropin
HDPE	high-density polyethylene
ICH	International Conference on Harmonization
IRB	Institutional Review Board
ITT	Intention-to-Treat
LOCF	last observation carried forward
umol	micromole

MDD	Major Depressive Disorder
mmol	millimole
mg	milligrams
mmHg	millimeters of mercury
mU	milliunit
N (n)	number in population (sample)
NOS	not otherwise specified
OC	observed cases
OCD	Obsessive Compulsive Disorder
PPX	pure paroxetine population
PTSD	Posttraumatic Stress Disorder
RBC	red blood cell
SAD	Social Anxiety Disorder
SAE	serious adverse event
SAS	Statistical Analysis System
SB	SmithKline Beecham (a GlaxoSmithKline Company)
SD	standard deviation
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
SOPs	Standard Operating Procedures
SSRI	selective serotonin reuptake inhibitor
TSH	thyroid stimulating hormone
WBC	white blood cell
WHO	World Health Organization
WRC-GCP	Worldwide Regulatory Compliance-GCP
yr	year

1 Introduction

Paroxetine (Paxil®, Seroxat®, Deroxat®, Aropax®), a phenylpiperidine compound, is a selective serotonin reuptake inhibitor (SSRI) registered for use in adults in the treatment of Obsessive-Compulsive Disorder (OCD), Major Depressive Disorder (MDD), Panic Disorder, Social Anxiety Disorder (SAD), Generalized Anxiety Disorder (GAD), and Posttraumatic Stress Disorder (PTSD). Because of the success of paroxetine in the treatment of these psychiatric disorders in adults, studies have been conducted in children and adolescents with MDD or OCD.

Major Depression is one of the behavioral disorders that can emerge during childhood and adolescence. Depression in children can lead to school failure, alcohol or other drug use, and even suicide. The prevalence of MDD is estimated to be approximately 2% in children and 4 to 8% in adolescents [1].

Studies 329, 377 and 701 assessed the safety and efficacy of paroxetine in children and adolescent patients with depression. Studies 329 and 377 were randomized, double-blind, placebo-controlled studies in adolescent patients, 13 to 18 years of age and 12 to 18 years, respectively, with unipolar major depression [2], [3], [4]. These studies yielded equivocal results. Study 329 suggested that paroxetine was efficacious, achieving statistical significance on four of eight secondary measures of efficacy, but there was little evidence of benefit in study 377. The third study, study 701, was a randomized double-blind, placebo-controlled study in children and adolescents 7 to 17 years of age with MDD [5]. This study failed to provide evidence that paroxetine was more efficacious than placebo in treating pediatric patients with MDD.

OCD is a severe, and chronically disabling condition characterized by recurrent, ritualized thought patterns (obsessions) and associated repetitive, intentional behavior patterns (compulsions) performed in response to the obsession. The obsessions and compulsions cause marked distress, are time-consuming and may significantly interfere with the person's normal routine, occupational functioning, or usual social activities or relationships.

Studies 453 and 704 assessed the safety and efficacy of paroxetine in children and adolescent patients with OCD. Study 453 was a multicenter, two-phase, 32-week, relapse-prevention study in children and adolescents, 8 to 17 years of age, with moderate to severe OCD [6]. The mean reduction from baseline in Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) total score for the 16

week, flexible dose (10 to 60 mg/day paroxetine), open-label phase was 13.0, and the majority of patients enrolled (69%) met the response criteria and therefore were eligible to enter the double-blind relapse prevention phase. The proportion of patients who met the criteria for relapse during the 16 week, randomized (placebo or 10 to 60 mg/day paroxetine), relapse prevention phase was lower in the paroxetine group (34.7%) than in the group of patients switched to placebo (43.9%), suggesting that paroxetine is beneficial in the treatment of children and adolescents with OCD.

Study 704 was a 10-week multicenter, randomized, double-blind, placebo-controlled, flexible-dose (10 to 50 mg/day paroxetine or placebo) study in children and adolescents (7 to 17 years of age) with OCD [7]. A statistically significant difference was demonstrated in favor of paroxetine for the primary variable, change from baseline in CY-BOCS total score at the week 10 LOCF endpoint. This was supported by statistically significant results for three of the six secondary efficacy variables, and numerical results indicating a benefit of paroxetine over placebo for all other secondary efficacy variables.

Overall, safety data from these five studies indicate hat paroxetine is safe and generally well tolerated when used in children and adolescents for up to 12 weeks in duration. However, there is limited information on the long-term safety and efficacy of paroxetine in the pediatric population. Psychiatric disorders may occur in childhood, continue into adulthood, and require long-term treatment. It is therefore imperative that studies assessing the long-term safety of SSRIs in children and adolescents be undertaken. Study 329 included a 6 month extension phase and study 453 was a 32 week study. Therefore in both studies patients were exposed to paroxetine for up 8 months. A preliminary review of the long-term data from these studies indicated that there were no significant new or unexpected adverse events emerging upon long-term dosing, however, additional long-term safety data in children and adolescents are needed.

This 6-month, open-label extension study was conducted to assess the long-term safety and efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD. Children and adolescents, 7 to 17 years of age, meeting DSM-IV criteria for either MDD or OCD, who completed paroxetine studies 701, 704 or, 715 (paroxetine forced titration open-label pharmacokinetic study) were eligible for entry into study 716. Patients who entered study 716 from study 715 are not included in this interim report because the database for 715 was finalized after the study 716 database. Patients from study 715 will be included in the final clinical study report for study 716.

2 Objectives

2.1 Primary Objective

The primary objective of this study was to assess the long-term (6-month) safety of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine study 701, 704, or 715.

2.2 Secondary Objective

The secondary objective was to monitor the long-term (6-month) efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine study 701, 704, or 715.

3 Methodology

3.1 Study Design

This was a multicenter, open-label, 6-month extension study. Children and adolescents who completed paroxetine study 701, 704, or 715, and who chose to enter this study were considered eligible if they met all the inclusion criteria and none of the exclusion criteria (Section 3.4.1 and Section 3.4.2). Patients who entered 716 from the 715 paroxetine forced titration open-label pharmacokinetic study are not included in this interim report because the database for 715 was finalized after the clinical cut-off point for this report. Patients from 715 will be included in the final clinical study report for 716.

Eligibility was assessed at the study 716 baseline visit (day 0). For patients who entered a taper phase upon completing study 701, 704 or 715, the taper end visit was the study 716 baseline visit. For patients who did not enter a taper phase upon completion of study 701, 704 or 715, the treatment end visit was the study 716 baseline visit.

Paroxetine was administered according to a flexible-dosage regimen (10 to 50 mg/day). Patients entering study 716 from study 701 or 704 were to be started on therapy at 10 mg/day, (however, several patients started at a higher dose). Patients entering 716 from study 715 could, at the investigator's discretion, be initiated at a higher dosage level (e.g., the dosage level achieved at 715 endpoint). For all patients, the study 716 starting dosage could thereafter be increased at each clinic visit by 10 mg/day at intervals no more frequently than every 7 days. This increase in dose was at the discretion of the investigator, and was based on clinical response and tolerability. The maximum dose allowed was 50 mg/day.

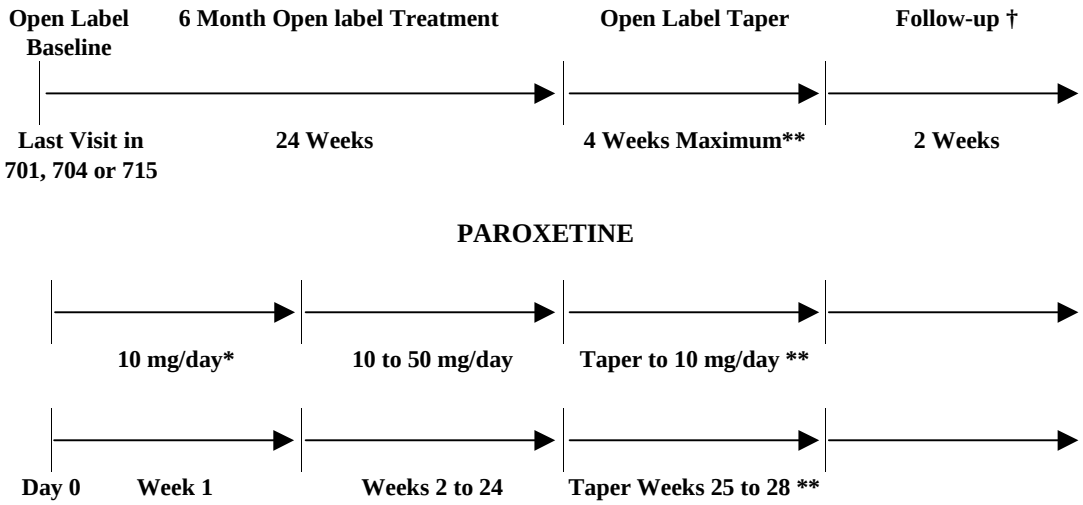
Dose reductions of 10 mg/day at weekly intervals were permitted at the discretion of the investigator. Patients unable to tolerate a paroxetine dosage of 10 mg/day were withdrawn from the study. It was recommended that dosage reductions be initiated at clinic visits. If the dose reduction was because of an adverse event, the patient could return to the previous dosage level upon resolution of the adverse event.

Gradual reduction of dosing at the conclusion of the 6-month open-label treatment phase (for patients who completed the study as well as for early withdrawals) was

required for all patients except for those who terminated at the 10 mg/day level. Patients were down-titrated at a rate of 10 mg/day/week until they finished one week of taper phase dosing at 10 mg/day. The duration of the taper phase, therefore, varied for each patient, depending on their dosage level upon completion of the open-label treatment phase. A follow-up visit was scheduled 14 days after the last dose of study medication (including any taper phase dosing).

An overview of the study design is presented in Figure 1.

Figure 1 Study Design for 716



* Patients entering from open-label study 715 may have started at a higher dosage level at the investigator's discretion.
** The duration of the taper phase was dependent on the final dosage level at week 24 or the early withdrawal visit.
†14 days after the last dose of study medication

3.1.1 Protocol Amendments

No amendments were made to the protocol.

3.2 Investigators

This interim report includes data from 43 centers in the United States and 2 centers in Canada. A list of principal investigators, their center numbers, affiliated institutions and geographic locations are provided in Table 1. Appendix

A contains copies of the curricula vitae (CVs) of all principal investigators, which provide details of the investigator's qualifications and experience.

The study center (number 055) of Dr. XXXXXXXXXXXXXXXXXXXX, who entered 9 patients, was terminated by the sponsor following an internal audit that detected significant compliance violations. Of these 9 patients, 7 were withdrawn from the study when the site was closed and 2 were withdrawn due to protocol violations (including non-compliance). For purposes of this report, the results are presented including Dr. XXXXXXXX patients.

Investigators were selected based on previous experience with the patient population under study, their ability to recruit eligible patients, and their ability to conduct the study according to Good Clinical Practice (GCP).

Table 1 Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States			
			Minneapolis, MN
		School	Dallas, TX
		Center of Dallas	
			Charlotte, NC
		Neuropsychiatry	Charlotte, NC
		Neuropsychiatry	Salem, OR
			Piscataway, NJ
			Lake Jackson, TX
		Research Inc.	

xxxxxxxxxxxxxxxxxxxxxxxxxx	012	Madison, WI
xxxxxxxxxxxxxxxxxxxxxxxxxx	014	Boise, MD
xxxxxxxxxxxxxxxxxxxxxxxxxx	015	Lexington, KY
xxxxxxxxxxxxxxxxxxxxxxxxxx	016	Phoenix, AZ
xxxxxxxxxxxxxxxxxxxxxxxxxx	017	Cincinnati, OH
xxxxxxxxxxxxxxxxxxxxxxxxxx	019	Galveston, TX

Source: Appendix A, Investigator CV's

Continued…

Table 1 Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States			
xxxxxxxxxxxxxxxxxxxxxxxxxx	020	University of	Gainesville, FL
xxxxxxxxxxxxxxxxxxxxxxxxxx M.D.	020	University of Group Practice	Gainesville, FL
xxxxxxxxxxxxxxxxxxxxxxxxxx	025		Terre Haute, IN
xxxxxxxxxxxxxxxxxxxxxxxxxx	026		Medina, OH
Axxxxxxxxxxxxxxxxxxxxxxxxxx	027		Washington, DC
xxxxxxxxxxxxxxxxxxxxxxxxxx	028		Richmond, VA
xxxxxxxxxxxxxxxxxxxxxxxxxx	028	Associates, Inc.	Richmond, VA
xxxxxxxxxxxxxxxxxxxxxxxxxx	040	Associates, Inc. Research, Inc.	Baltimore MD

Investigator	Center	Affiliated Institute	City/State
xxxxxxxxxxxxxxxxxxxxxxxx	040		Baltimore MD
xxxxxxxxxxxxxxxxxxxxxxxx	43		Clearwater, FL
xxxxxxxxxxxxxxxxxxxxxxxx	044		Maitland, FL
xxxxxxxxxxxxxxxxxxxxxxxx	047		Elkins Park, PA
xxxxxxxxxxxxxxxxxxxxxxxx	049		Hershey, PA
xxxxxxxxxxxxxxxxxxxxxxxx	049		Hershey, PA

Source: Appendix A, Investigator CV's

Continued…

Table 1 Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States			
xxxxxxxxxxxxxxxxxxxxxxxx	052	, Inc.	Mobile, AL
xxxxxxxxxxxxxxxxxxxxxxxx	055		New Orleans, LA
M.D.	148		Alburquerque, NM
xxxxxxxxxxxxxxxxxxxxxxxx	151		Cleveland, OH
xxxxxxxxxxxxxxxxxxxxxxxx	154		Charleston, SC
xxxxxxxxxxxxxxxxxxxxxxxx	159		Lake Oswego, OR
xxxxxxxxxxxxxxxxxxxxxxxx	164		Columbia, MO
xxxxxxxxxxxxxxxxxxxxxxx	165		Long Beach, CA
xxxxxxxxxxxxxxxxxxxxxxxx	167	Institute xxxxxxxxxxxxx	St Paul, MN

Investigator	Center	Affiliated Institute	City/State
xxxxxxxxxxxxxxxxxxxxxx	167		St Paul, MN
xxxxxxxxxxxxxxxxxxxxxx	168		Seattle, WA
xxxxxxxxxxxxxxxxxxxxxx	169		Lynn, MA
xxxxxxxxxxxxxxxxxxxxx, M.D.	170		Atlanta, GA
xxxxxxxxxxxxxxxxxxxxxx	171		St Simons Island, GA
xxxxxxxxxxxxxxxxxxxxxx	172	System xxxxxxxxxxxx	Reno, NV
xxxxxxxxxxxxxxxxxxxxxx	173		Los Angeles, CA
xxxxxxxxxxxxxxxxxxxxxx	176	Inc.	Prairie Village, KS

Source: Appendix A, Investigator CV's

Continued…

Table 1 Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location (Continued)

Investigator	Center	Affiliated Institute	City/State
United States			
xxxxxxxxxxxxxxxxxxxxx	179		Philadelphia, PA
xxxxxxxxxxxxxxxxxxxxxx	180		Orlando, FL
xxxxxxxxxxxxxxxxxxxxxx	183		Houston , TX
xxxxxxxxxxxxxxxxxxxxxx	186	Research xxxxxxxxxxxxxxxx	Hialeah, FL
Canada			
xxxxxxxxxxxxxxxxxxxxxx	031	Center	Halifax, Nova Scotia
xxxxxxxxxxxxxxxxxxxxxx	192	Center	Halifax, Nova Scotia

Source: Appendix A, Investigator CV's

3.3 Ethics

This study was conducted in accordance with GCP, the Declaration of Helsinki as amended in Somerset West, Republic of South Africa (1996), and US 21 CFR (Code of Federal Regulations) for studies filed to the US IND. The protocol and statement of informed consent and/or assent were approved by an Institutional Review Board (IRB) prior to each center's initiation[1]. The IRB was to be informed by the investigator of protocol amendments and of serious or unexpected adverse events occurring during the study that were likely to affect the safety of the subjects or the conduct of the study.

Written informed consent and/or assent was obtained from each parent/guardian and/or patient prior to entry into the study. Case report forms (CRFs) were provided for each patient's data to be recorded. A sample CRF is provided in Appendix A.

3.4 Eligibility Criteria

This study enrolled male and female outpatients who completed paroxetine studies 701, 704, or 715 and chose to enter the open-label extension study. Children and adolescents, 7 to 17 years of age at acute study screening, meeting DSM IV criteria for either MDD or OCD [2] as their predominant psychiatric diagnosis were eligible for entry into the acute studies 701 or 704, respectively. Patients participating in the paroxetine forced titration open-label pharmacokinetic study (715) could meet diagnostic criteria for either MDD or OCD. All parents (or legal guardians) signed informed consent, and all patients provided written informed consent or assent prior to participation in study 716 and the preceding study.

The inclusion and exclusion criteria for study 716 are listed in Section 3.4.1 and Section 3.4.2, respectively.

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[1] A sample informed consent / assent is provided in the protocol; Appendix A.

[2] The DSM-IV Diagnostic Criteria for Major Depressive Disorder, Single Episode (296.2) or Recurrent (296.3); and for Obsessive-Compulsive Disorder (300.30) may be found in Appendices E, F, and H, respectively, of the protocol.

3.4.1 Inclusion Criteria

Patients were considered eligible for the study if they satisfied all of the following inclusion criteria:

- children or adolescents completing paroxetine study 701 (MDD), 704 (OCD) or 715 (pharmacokinetic study in patients with OCD or MDD);
- patients who were otherwise determined medically healthy by physical examination, medical history and laboratory screening;
- written informed consent of parent (or legal guardian) and assent of patient (where required) prior to any specific study procedures.

3.4.2 Exclusion Criteria

Patients were considered ineligible for the study if they met any of the following exclusion criteria:

- patients not completing paroxetine study 701, 704 or 715;
- patients who posed a current suicidal or homicidal risk in the investigator's judgement;
- patients, who in the opinion of the investigator, would be non-compliant with the visit schedule or other study procedures;
- patients with clinically significant abnormalities in hematology, blood chemistry, ECG or physical examination at acute study endpoint which had not resolved;
- patients who in the opinion of the investigator had a serious medical condition which would preclude the administration of paroxetine;
- female patients who had a positive dipstick or serum human chorionic gonadotropin (HCG) pregnancy test at acute study endpoint or who were lactating;
- sexually active female patients who were not using a reliable method of contraception (e.g., oral contraception, condom in conjunction with spermicidal foam).

3.5 Study Medication and Administration

3.5.1 Study Medication

Open-label medication was supplied as oval, white, film-coated tablets containing 10 mg of paroxetine (batch number U00001). All paroxetine tablets were identical in appearance. A certificate of analysis is provided in Appendix A.

All open-label study medication was provided in white opaque high-density polyethylene (HDPE) bottles with white, opaque, plastic, child-resistant caps with coated polyester film bonded aluminum foil inner seal. Each bottle contained 34 tablets. Open-label study medication was dispensed at each scheduled visit during the treatment phase, with medication for the taper phase dispensed at the week 24 or early withdrawal visit. The total number of bottles dispensed at any given visit was dependent on the required dosage and the protocol-stipulated time interval before the next scheduled visit.

All open-label study medication bottles were labeled according to the protocol. The label text contained the following information: protocol number, job number, batch and lot number, contents, medication number, tablets strength, dosage directions, storage instructions, "Keep out of reach of children", "FOR CLINICAL TRIAL USE ONLY", sponsor's address and any other information required by local law. The tear-off portion of the label was affixed to the patient's CRF.

All study medication was to be stored in a secure (locked) area at ambient temperature (15 to 30°C).

3.5.2 Drug Accountability

Study medication was dispensed according to the protocol to enrolled patients under the supervision of the investigator or his/her designee. Records of all study medication shipped to the center, dispensed to the patients, returned by patients, and returned to the sponsor were to be maintained at each study center. Unused study medication was to be returned to SmithKline Beecham (a GlaxoSmithKline company) at the end of the study.

3.5.3 Dosage and Administration

Patients, under parental supervision, were instructed to take from 1 to 5 (dependent on dosage) 10 mg paroxetine tablets each morning, with food, throughout the treatment phase of the study (weeks 1-24), and the taper phase, if

necessary (weeks 25-28). Written dosage instructions were to be provided on the label of each bottle since the number of 10 mg paroxetine tablets to be taken per day varied as each patient's daily dosage was increased and/or decreased based on clinical response and tolerability.

Patients were to receive paroxetine (10 to 50 mg/day) for a period of 24 weeks during the open-label treatment phase of study 716. Patients entering study 716 from study 701 or 704 were to be started on therapy at 10 mg/day (however, several patients were started on a higher dose). Patients entering study 716 from study 715 could, at the investigator's discretion, be initiated at a higher dosage level (e.g., the dosage level achieved at 715 endpoint). Starting at week 2, the dose of paroxetine could be increased by 10 mg/day up to a maximum dose of 50 mg/day, according to clinical response and tolerability. It was recommended that dose increases were initiated at clinic visits. Dose increases of 10 mg/day at weekly intervals were permitted at the discretion of the investigator.

Dose reductions of 10 mg/day at weekly intervals were also permitted at the discretion of the investigator. Patients unable to tolerate a paroxetine dose of 10 mg/day were withdrawn from the study. It was recommended that dose reductions were initiated at clinic visits. If the dose reduction was due to an adverse event, the patient could return to the previous dose level upon resolution of the adverse event.

During the taper phase, open-label study medication was reduced by 10 mg/day/week for a period of up to 4 weeks for patients who completed the treatment phase or were prematurely withdrawn at a dosage of $\geq$ 20 mg/day. Patients completing or withdrawing at 10 mg/day did not enter the taper phase. Patients completing or withdrawing at $\geq$ 20 mg/day commenced taper phase dosing at a dosage of 10 mg/day below the dose of their final open-label treatment phase dose and ended the taper phase as shown in Table 2.

Table 2 Study Medication Dosing Instructions During the Taper Phase

Dosage*	Week 25**	Week 26**	Week 27**	Week 28**
10 mg	**No Taper medication**			
20 mg	10 mg	**No further Taper medication**		
30 mg	20 mg	10 mg	**No further Taper medication**	
40 mg	30 mg	20 mg	10 mg	**No further Taper medication**
50 mg	40 mg	30 mg	20 mg	10 mg

* Dosage level at the end of the 6 month open-label treatment phase.
** Or corresponding weeks 1,2,3 or 4 following early withdrawal.

Open-label study medication for the taper phase was dispensed at the week 24 or early withdrawal visit. Written dosage instructions were provided on the label of each bottle since the number of 10 mg paroxetine tablets to be taken per day was dependent on the dosage of paroxetine at the end of the open-label treatment phase.

3.5.4 Blinding

There was no blinding as this was an open-label study. All 10 mg paroxetine tablets were identical in appearance and packaged in bottles containing 34 tablets.

3.6 Compliance with Study Medication

Every effort was made to encourage patient compliance with the dosing regimen as per protocol. All patients were instructed to return their medication bottles, with any unused drug, to the investigator at their next clinic visit. All medication dispensed to the patient, taken by the patient and returned by the patient was recorded in the patient's CRF at each visit. The tear-off portion of the medication bottle label was affixed to the patient's CRF.

If, in the opinion of the investigator, there were any significant irregularities in compliance, the patient was to be withdrawn from the study. Patients who missed more than three consecutive days of medication on more than one occasion were to be withdrawn from the study.

3.7 Concomitant Medication

The concomitant use of psychotropic drugs, other than open-label study medication, was contraindicated during this study.

All concomitant medications taken during the study were to be recorded in the patient's CRF with the total daily dose, route of administration, indication, start date and end date or notation that medication was continuing.

3.8 Study Procedures

3.8.1 Schedule of Assessments

An overview of the schedule of assessments and study procedures is presented in Table 3.

All patients were assessed at the open-label baseline visit (day 0), which coincided with the taper end visit in paroxetine studies 701 and 704 or with the last treatment phase visit if there was no taper phase. The open-label treatment phase started on the first day that open-label study medication was administered, day 1, and continued through to completion of the week 24 visit (or early withdrawal visit, if applicable). The open-label taper phase started following the week 24 visit or the early withdrawal visit, and continued for a maximum of 4 weeks. The length of the taper phase was dependent on the dosage at the week 24 or early withdrawal visit. The follow-up visit was scheduled for 14 days after the last dose of study medication (including taper phase dosing) for all patients.

Table 3 Outline of Study Procedures for Study 29060/716 Continued…

	Baseline Visit (Day 0)	Week 1	2	3	4	6	8	12	16	20	24	Early Withdrawal	Taper Phase End Visit	Follow-up Visit [d]
Screen/Baseline Evaluations														
Informed Consent/Assent	X													
Patient Demography	X[a]													
Inclusion/Exclusion Criteria	X													
Psychiatric Interview	X[a]													
MDD criteria (DSM-IV)	X[a]													
OCD criteria (DSM-IV)	X[a]													
Medical/Surgical History	X[a]													
Efficacy Parameters														
CDRS-R	X[c]										X	X		
CY-BOCS	X[c]										X	X		
CGI (Severity of Illness)	X	X	X	X	X		X	X	X	X	X	X		
CGI (Global Improvement)	X	X	X	X	X		X	X	X	X	X	X		
Safety Evaluations														
12 Lead ECG	X[b]										X	X	X[e]	X[e]
Vital Signs[f]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height and Weight	X							X			X	X		
Adverse Event	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Laboratory Evaluations[h]	X[b]				X			X			X	X	X[e]	X[e]
Physical Examination	X[b]										X	X		
Pregnancy Dipstick/Serum Test [g]	X[j]							X			X	X		

Table 3 Outline of Study Procedures for Study 29060/716

	Baseline Visit (Day 0)	Week 1	2	3	4	6	8	12	16	20	24	Early Withdrawal	Taper Phase End Visit	Follow-up Visit [d]
Miscellaneous Records														
Prior and Concomitant Meds	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dispense Study Medication	X	X	X	X	X	X	X	X	X	X	X[i]	X[i]		
Medical Procedures Record	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study Medication Record		X	X	X	X	X	X	X	X	X	X	X	X	
Study Conclusion Record											X	X		

(Investigator's could schedule a clinic visit outside the protocol defined visit schedule for handling a dosage adjustment)

CY-BOCS: Children's Yale-Brown Obsessive-Compulsive Scale; CDRS-R: Children's Depression Rating Scale - Revised; CGI, Clinical Global Impression.

(a) Information was captured in the previous acute study 701 or 704.

(b) Last laboratory assessments, ECG, and physical examination from the previous acute study (within 3 weeks and with no clinically significant abnormalities) were taken as baseline data for 716.

(c) CDRS-R assessed for patients from 701; CY-BOCS assessed for patients from 704; these assessments were not repeated if the patient's 701 or 704 treatment end visit coincided with their 716 baseline visit.

(d) Follow-up visit was completed 14 days after the last dose of study medication including taper for all patients.

(e) Repeat laboratory evaluations or ECG assessments were performed only if results were clinically significantly abnormal at previous visit, and with the investigator's agreement

(f) 3-minutes sitting systolic and diastolic blood pressure and heart rate.

(g) Dipstick and HCG serum pregnancy test for females of child-bearing potential.

(h) Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], electrolytes); dipstick urinalysis (if positive for blood or protein, full microscopy was performed).

(i) Taper medication dispensed for all patients ending open-label treatment phase or withdrawing at a dosage of 20 to 50 mg/day.

(j) The serum HCG pregnancy test was not repeated for patients in 701 or 704 whose treatment end visit coincided with the baseline visit in 716.

3.8.2 Baseline Visit (Day 0)

The open-label study 716 baseline visit (day 0) coincided with the last visit in the acute studies 701 and 704. Those patients meeting all the inclusion criteria and none of the exclusion criteria were administered open-label paroxetine. The following assessments and procedures were performed at the 716 baseline visit.

- written informed consent by parent (or legal guardian), or by patient if emancipated minor, and assent by minor patient (when required) obtained before any study procedures were conducted;
- assessment with respect to all other inclusion/exclusion criteria (Section 3.4.1 and Section 3.4.2);
- Children's Depression Rating Scale - Revised (CDRS-R) for patients from study 701;
- CY-BOCS for patients for patients from study 704;
- Clinical Global Impression (CGI) – Severity of Illness item;
- CGI – Global Improvement item;
- vital signs (3 minute sitting systolic and diastolic blood pressure, and heart rate). Blood pressure was measured in the same arm and, where possible, by the same person throughout the study;
- height (cm) and weight (kg) measurements without shoes;
- 12-lead ECG (the last assessment from study 701 or 704 was acceptable if taken within 3 weeks of the 716 baseline assessment and not clinically significant);
- pregnancy urine dipstick test and serum HCG pregnancy test for females of child bearing potential. Patients with confirmatory positive results from serum HCG pregnancy test were withdrawn from the study;
- laboratory evaluations (last assessments from study 701 or 704 were acceptable if taken within 3 weeks of the 716 baseline assessment and not clinically significant). Laboratory evaluations consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST] and electrolytes); and dipstick

urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed). Laboratory evaluations were interpreted and deemed clinically non-significant by the investigator;

- concomitant medications;
- Medical Procedures Record completed;
- adverse events;
- study medication dispensed.

3.8.3 Open-label Treatment Phase (Weeks 1 - 24)

Study assessments during the open-label treatment phase were scheduled for weeks 1 to 4, 6, 8, 12, 16, 20, and 24 or at early withdrawal, if applicable. An investigator could schedule a clinic visit outside the protocol-defined visit schedule for handling a dosage adjustment. Each study visit included the following evaluations unless otherwise specified:

- vital signs (3 minute sitting systolic and diastolic blood pressure, and heart rate);
- height (cm) and weight (kg) measurements without shoes at the 12 and 24 week visits (or early withdrawal visit, if applicable);
- CGI – Global Improvement item at the 1, 2, 3, 4, 8, 12, 16, 20, and 24 week visits (or early withdrawal visit, if applicable);
- CGI – Severity of Illness item at the 1, 2, 3, 4, 8, 12, 16, 20, and 24 week visits (or early withdrawal visit, if applicable);
- CDRS-R at the week 24 visit (or early withdrawal visit, if applicable) for patients from the acute study 701;
- CY-BOCS at the week 24 visit (or early withdrawal visit, if applicable) for patients from the acute study 704;
- adverse events;
- concomitant medications;

- open-label study medication dispensed. At the open-label study 716 baseline and at weeks 1, 2, and 3 a supply of open-label treatment medication sufficient for a 1-week period was dispensed; at weeks 4 and 6, a supply of open-label treatment medication sufficient for a 2-week period was dispensed; at weeks 8, 12, 16, and 20, open-label treatment medication sufficient for a 4-week period was dispensed; and at week 24 or early withdrawal, open-label taper medication was dispensed;

- physical examination at week 24 (or early withdrawal visit, if applicable);

- pregnancy urine dipstick test and serum HCG pregnancy test for females of child bearing potential at weeks 12 and 24 (or early withdrawal visit, if applicable). Patients with confirmatory positive results from serum HCG pregnancy test were withdrawn from the study;

- laboratory evaluations at weeks 4, 12, and 24 (or early withdrawal visit, if applicable). Laboratory evaluations consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST] and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed);

- 12-lead ECG at week 24 (or early withdrawal visit, if applicable);

- Study Medication Record completed;

- Medical Procedures Record completed;

- Study Conclusion Record completed at week 24 (or early withdrawal visit, if applicable).

3.8.4 Open-label Taper Phase (Weeks 25 - 28)

For patients on ≥ 20 mg/day paroxetine at completion of the open-label treatment phase, or at early withdrawal, study medication was gradually reduced by 10 mg/day at intervals of approximately 7 days during the taper phase. All patients completed the taper phase at 10 mg/day.

3.8.5 Taper End Visit

Following completion of the taper phase, patients returned to the clinic for a taper end visit. Study medication was returned and patients underwent a safety

evaluation, which was planned to coincide with the last study medication dose taken in the taper phase. The following evaluations were performed at the taper end visit:

- vital signs;
- adverse events;
- concomitant medications;
- repeat laboratory evaluation or 12-lead ECG, if clinically significantly abnormal values were noted at previous visit;
- Taper Medication Record completed;
- Medical Procedures Record completed.

3.8.6 Follow-up Visit

All patients returned for a safety follow-up visit 14 days after the last dose of study medication (including taper phase medication). The following evaluations were performed at the follow-up visit:

- vital signs;
- concomitant medications;
- adverse events;
- repeat laboratory evaluation or 12-lead ECG if clinically significantly abnormal values were noted at previous visit;
- Medical Procedures Record completed.

3.9 Patient Completion and Early Withdrawal

3.9.1 Definition

A patient was considered to have completed the study if he/she completed the week 24 visit. A premature withdrawal was any patient who did not complete the week 24 visit.

3.9.2 Reasons for Withdrawal

Patients could withdraw or be withdrawn from the study at any time. The primary reason for withdrawal was categorized as one of the following:

- adverse event;
- lack of efficacy;
- protocol deviation (including non-compliance);
- lost to follow-up;
- other (reason specified).

The reason for withdrawal was recorded in the study conclusion section of the patient's CRF. If a patient withdrew, every attempt was made to carry out the assessments scheduled for the week 24 visit at the patient's last visit.

3.10 Efficacy Assessments

There was no primary efficacy parameter in this open-label study. The following instruments were used to monitor the severity of the patient's MDD or OCD symptoms, the patient's overall clinical condition, and the patient's response to open-label medication:

- CDRS-R total score for patients from study 701;
- CY-BOCS total score for patients from study 704;
- CGI-Severity of Illness item for all patients;
- CGI-Global Improvement item for all patients.

Descriptions of the efficacy assessments are provided in Section 3.10.1 to Section 3.10.3. Copies of the CDRS-R, CY-BOCS, CGI-Severity of Illness, and CGI-Global Improvement are provided in the protocol in Appendix G, Appendix I, Appendix J, and Appendix K, respectively.

All the efficacy assessments were to be conducted by a Psychiatrist, Clinical Psychologist or Psychometrician with 2-3 years of experience with pediatric patients. For consistency, it was recommended that the same person, where possible, should perform the assessments on individual patients.

3.10.1 Children's Depression Rating Scale-Revised (CDRS-R)

The CDRS-R is a clinician-rated instrument initially designed to measure the severity of depression in children aged 6 to 12 years. It has also been used successfully in adolescents in measuring the severity of depression. The CDRS-R has high inter-rater reliability, good test-retest reliability, good internal consistency, and good convergent and discriminant validity [8]. The CDRS–R captures slight, but notable changes in a child's symptoms, thus making the scale useful for monitoring symptoms during illness or remission.

The CDRS–R assesses 17 symptom areas including those that serve as the criteria in the DSM-IV [9] for the diagnosis of depressive disorders. It can be administered by a clinician or trained rater in a semi-standard fashion to the child or adolescent, parent(s), teacher, or guardian in approximately 30 minutes. The first 14 items of the scale are rated on the basis of the patient's verbal responses to interview questions. The remaining 3 symptom areas of the CDRS–R (depressed facial affect, listless speech, and hypoactivity) are rated by the clinician on the basis of the patient's nonverbal behavior for signs of depression. Fifteen of the symptom areas are rated on a 7-point scale, with two on a 5-point scale. Following separate CDRS-R evaluation sessions with the patient and parent or guardian, the clinician summarized the best overall description of the patient and entered the data on the patient's CRF.

The CDRS–R summary score ranges from 17 to 113. A summary score of 45 or above on the CDRS–R is a strong indicator of the presence or potential for a MDD. Although the score of 45 is a reliable indicator of depression, it should serve as a heuristic, not as a criterion by which the child is diagnosed with MDD or not.

The procedure for conducting the CDRS-R and recording data was reviewed with all attendees during a multicenter investigator meeting prior to the start of the acute study 701, as well as with site personnel unable to attend the meeting. Rater training was also conducted to insure proper use of the scale during the studies.

Treatment of missing values in the calculation of CDRS-R total scores is detailed in Appendix H of this report.

3.10.2 Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS)

The CY-BOCS is a clinician-rated scale designed to rate the severity of obsessive and compulsive symptoms in children and adolescents [10]. It is identical in form

and scoring to the widely used adult Yale-Brown Obsessive Compulsive Scale, except that the questions are slightly modified for age appropriateness.

The clinician or rater first reviews the definitions of obsessions and compulsions with the parent(s) or guardian and the patient. The clinician or rater then proceeds with detailed questioning about the patient's symptoms using the compulsions checklist and obsessions checklist as guides. Following completion of the obsessions and compulsions checklists, the four most severe obsessions and four most severe compulsions are listed on the target symptom lists.

After completion of the compulsions and obsessions checklists, and target symptom lists for obsessions and compulsions, the clinician reviews the severity of the symptoms. For both obsessions (items 1 to 5) and compulsions (items 6 to 10), the specific questions relate to: time spent with obsessions or compulsions, interference due to obsessions or compulsions, distress associated with the obsessions or compulsions, resistance against obsessions or compulsions, and degree of control over obsessions or compulsions. These items are rated on a severity scale ranging from 0 ('none', 'no symptoms', 'always resists', or 'complete control') to 4 ('extreme', 'extremely short', 'completely yields', or 'no control'). Scores for these items reflect the rater's best estimate from all available information from the past week, with special emphasis on the target symptoms.

The total CY-BOCS score is the sum of items 1-10 (not including items 1b or 6b); the obsession and compulsion subtotals are the sums of items 1-5 and 6-10, respectively (not including items 1b and 6b). The total CY-BOCS score ranges from 0 to 40, with a score of 20 indicating moderate severity of obsessive and compulsive symptoms and a score of 10 or below indicating subclinical OCD.

CY-BOCS raters were required to attend the training sessions offered at the investigator meeting prior to the start of acute study 704 or to complete follow-up training requirements. Follow-up training for raters included reviewing the scoring conventions for the CY-BOCS and assessing an OCD patient on video through completion of the CY-BOCS score sheet. The rater's scores were then compared with an acceptable score range set for the OCD patient. This documentation was reviewed by the sponsor. Confirmation of an acceptable passing score was sent to the rater.

Treatment of missing values in the calculation of CY-BOCS total scores is detailed in Appendix H of this report.

3.10.3 Clinical Global Impression (CGI) - Severity of Illness and Global Improvement Items

The CGI is a widely accepted measure of clinical improvement in a variety of psychiatric disorders. These items have been extensively used in psychopharmacologic trials since their introduction into the Early Clinical Drug Evaluation Unit (ECDEU) Assessment Manual for Psychopharmacologic Trials published by the US National Institute of Mental Health [11]. The CGI scales are rated by the clinician based on all information available at the time of rating.

The CGI-Global Improvement item is rated on a scale of 1 to 7: not assessed (0); very much improved (1); much improved (2); minimally improved (3); no change (4); minimally worse (5); much worse (6); very much worse (7). The clinician indicates their assessment of the patient's total improvement or worsening compared with that individual's condition at acute study baseline (whether or not the change is judged to be due to drug treatment). Typically, a score of 1 "very much improved" or 2 "much improved" is considered a responder.

The CGI-Severity of Illness item is rated on a scale of 1 to 7: not assessed (0); normal, not at all ill (1); borderline mentally ill (2); mildly ill (3); moderately ill (4); markedly ill (5); severely ill (6) and among most extremely ill patients (7). The clinician indicates his/her assessment of the patient's severity of illness considering their total clinical experience with the particular population being studied.

3.11 Safety Assessments

Safety was primarily assessed through routine adverse event monitoring, vital sign determinations (systolic and diastolic blood pressure, and heart rate), physical examination (including height and weight), clinical laboratory evaluations (hematology, blood chemistry, and urinalysis), urine dipstick and serum HCG pregnancy tests (where applicable), and 12-Lead ECGs.

3.11.1 Adverse Events

An adverse event was any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical study and whether or not considered to be drug related. This included exacerbation of a pre-existing condition or event, intercurrent illness, drug interaction or the significant worsening of the disease under investigation that was not recorded

elsewhere in the CRF under specific efficacy assessments. Anticipated day-to-day fluctuations of pre-existing conditions, including the disease under study, that did not represent a clinically significant exacerbation or worsening were not considered adverse events. Discrete episodes of chronic conditions occurring during the study were reported as adverse events in order to assess changes in frequency or severity.

All (serious and non-serious) adverse events, whether observed by the investigator or reported by the patient (or parent or legal guardian), were evaluated by the investigator and recorded in the adverse event section of the patient's CRF. Adverse events were elicited by the investigator asking the patient (parent or legal guardian, as appropriate) a non-leading question such as ***"Do you feel different in any way since starting the new treatment or since the last visit?"*** If the patient (parent or legal guardian) responded "yes," details of the adverse event and its severity, including any change in study drug administration, investigator attribution to study drug, any corrective therapy given and outcome status, were documented in the CRF.

The maximum severity of an adverse event was assigned to one of the following categories:

Mild:	an adverse event which was easily tolerated, caused minimal discomfort and did not interfere with everyday activities.
Moderate:	an adverse event which was sufficiently discomforting to interfere with normal everyday activities.
Severe:	an adverse event which prevented normal everyday activities.

Every effort was made to explain each adverse event and assess its relationship, if any, to study medication. Causality was assessed using the following categories:

Unrelated:	the adverse event was definitely not related to the test drug.
Probably unrelated:	cause and effect relationship between the drug and the adverse event was not demonstrated, was improbable but not impossible.

Possibly related: a direct cause and effect relationship between the drug and the adverse event was not demonstrated but was possible or likely.

Related: there was a direct cause and effect relationship between the adverse event and the study drug.

All adverse events were coded from the verbatim term according to the World Health Organization (WHO) Adverse Reaction Terminology (ART) dictionary and then mapped by body system and preferred term according to the COSTART-based Adverse Drug Experiences Coding System (ADECS).

3.11.2 Serious Adverse Events

A serious adverse event was any event which was fatal, life threatening, disabling/incapacitating or resulted in hospitalization, prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional)[3]. In addition, any event which the investigator regarded as serious or which suggested any significant hazard, contraindication, side effect or precaution that was associated with the use of the drug was documented as a serious event. Pregnancy was captured as a serious adverse event for the purpose of tracking the status of pregnancies to term.

Any serious adverse event which occurred at any time during the study or within 30 days of receiving the last dose of study medication, whether or not related to study medication, was to be reported to the sponsor within 24 hours. Instances of death, cancer or congenital abnormality if brought to the attention of the investigator and considered by the investigator to be possibly related to study medication, were to be reported to the sponsor.

Serious adverse events were documented on a serious adverse event form, and the event captured on the adverse events page of the subject's CRF.

In the safety tabulations, serious adverse events were coded by the WHO ART dictionary and mapped by ADECS for preferred term. Corresponding terms are provided in Section 5.4. In the separate database used for preparing the clinical narratives, serious adverse events were coded by the WHO ART dictionary.

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[3] Elective surgery or routine clinical procedures which required hospitalization but were not the result of an AE, and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the patient's CRF

3.11.3 Physical Examination

Physical examinations were conducted at the open-label study 716 baseline visit (the last assessment from study 701 or 704 was acceptable if taken within 3 weeks of the open-label baseline assessment and no clinically significant abnormalities), week 12 and week 24 or early withdrawal visit. The physical examination included height (cm) and weight (kg) measurements plus any other examination deemed necessary by the investigator. Any adverse changes were to be recorded in the adverse event section of the patient's CRF.

3.11.4 Vital Signs

Vital signs consisted of systolic and diastolic blood pressure, and heart rate. Vital sign readings were taken after the patient had been sitting for at least 3 minutes. Readings were taken at each visit. Any clinically significant adverse changes were to be recorded in the adverse event section of the patient's CRF.

3.11.5 Electrocardiograms (ECGs)

An ECG was conducted at the open-label study 716 baseline visit (the last assessment from study 701 or 704 was acceptable if taken within 3 weeks of the open-label baseline assessment and not clinically significant), and the week 24 or early withdrawal visit. Any clinically significant adverse changes were to be recorded in the adverse event section of the patient's CRF. If an ECG assessment revealed a clinically significant finding, a repeat ECG was required.

3.11.6 Laboratory Values

Laboratory evaluations were assessed at the open-label study 716 baseline visit (the last assessment from study 701 or 704 was acceptable if taken within 3 weeks of the open-label baseline assessment and not clinically significant), and at weeks 4, 12, and 24 (or early withdrawal visit if applicable). The laboratory evaluation consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count), blood chemistry (BUN, creatinine, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], and electrolytes), and dipstick urinalysis (if dipstick method was positive for blood or protein, a full microscopy was performed).

Any abnormalities considered clinically significant were to be recorded in the adverse event pages of the patient's CRF. Laboratory assessments were to be repeated if clinically significant abnormalities were detected and followed up until the abnormality had resolved or stabilized.

All laboratory assessments were carried out centrally by Quest Diagnostics Ltd.

3.11.7 Pregnancy Tests

Pregnancy urine dipstick and serum HCG pregnancy tests were performed at the open-label baseline visit (only if the study 701 or 704 endpoint visit did not coincide with the 716 baseline visit) and at weeks 12 and 24 (or early withdrawal if applicable) for patients of child-bearing potential.

Patients who became pregnant during the study were to be withdrawn from the study immediately. Patients were instructed to notify the investigator if it was determined after completion of the study that they became pregnant either during the study or within 30 days of the last dose of study medication (including taper phase medication). Whenever possible a pregnancy was to be followed to term, any premature terminations reported, and the status of the mother and child was to be reported to SmithKline Beecham (a GlaxoSmithKline company) after delivery.

3.12 Pharmacokinetic Assessments

No Pharmacokinetic assessments were made in this study.

3.13 Data Quality Assurance

To ensure that study procedures were correctly and consistently carried out across all investigator sites, the protocol, CRFs and safety reporting were reviewed with the investigator and his/her personnel responsible for the conduct of the study by a SmithKline Beecham (a GlaxoSmithKline company) representative(s) at the investigator site. In addition, a multicenter Investigators' meeting was held on February 24 to 25, 2000 in New Orleans, Louisiana, USA for study 701, and December 8 to 9, 1999 in St. Louis, Missouri, USA for study 704.

Adherence to the protocol requirements and verification of data generation accuracy was achieved through monitoring visits to each study site by sponsor personnel at periodic intervals during the study and at the completion of the study. The monitor verified CRF entries by comparing them with the source documents (hospital/clinic/office records). Subsequent data handling and reporting processes were subject to in-process quality control and this final clinical report has, in addition, been subject to an end-stage quality control review. All the above procedures were performed according to methodologies detailed in SmithKline Beecham (a GlaxoSmithKline company) Standard Operating Procedures (SOPs).

This study was subject to audit by GlaxoSmithKline's department of Worldwide Regulatory Compliance-GCP (WRC-GCP). To date no study specific audits have been performed for this study.

3.14 Statistical Evaluation

The study center of Dr. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx who entered 9 patients, was terminated by the sponsor following an internal audit that detected significant compliance violations. All 9 patients from this site were included in the intention-to-treat (ITT) population.

3.14.1 Target Sample Size

No sample size calculations were performed for this study. Sample size was determined by the number of patients who completed studies 701, 704, or 715 and continued into this extension study. It was estimated that approximately 250 patients would complete their acute study and choose to enter this extension study.

3.14.2 Method of Randomization

There was no randomization as this was an open-label extension study and all patients were taking paroxetine.

3.14.3 Population/Data Sets to be Evaluated

Two patient populations were evaluated:

- The ITT population consisted of all patients who received at least one dose of open-label medication and for whom at least one valid post-baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available. Primary inference was based on the OC and LOCF datasets at the protocol-defined week 24 endpoint. The summaries using the ITT population are intended to describe the long term effect of paroxetine.

- The pure paroxetine population (PPX) population consisted of all patients who received paroxetine in their acute study, received at least one dose of open-label medication, and for whom at least one valid post baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available. Primary inference was based on the OC and LOCF datasets at the protocol-

defined week 24 endpoint. The summaries using the PPX population are intended to describe the maintenance effect of paroxetine.

3.14.4 Planned Efficacy Evaluations

As this is an open label extension study no formal hypothesis testing was performed. Descriptive summaries were provided for the observed case (OC) data set at each visit and the last observation carried forward (LOCF) data set, with primary inference based on the protocol defined week 24 endpoint. In the OC data set, efficacy data were assessed at the time point at which they were collected; no data were carried forward to estimate missing data. In the LOCF datasets for change in CY-BOCS total score and change in CDRS-R total score, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in CGI-Severity of Illness, and proportion of responders based on the CGI-Global Improvement item, the last non zero post baseline score for each patient was carried forward to estimate missing data points. The LOCF dataset contains all data from the week 24 visit, plus the last on-treatment assessment for patients who withdrew before week 24

Based on primary diagnosis from the acute study, the following instruments were used in this study in order to monitor the intensity of the patient's MDD or OCD symptoms, the patient's overall clinical condition and the patient's response to open-label treatment:

- CDRS-R at 716 baseline and week 24 (or early withdrawal if applicable) for patients from study 701 and 715 (if primary diagnosis was MDD);
- CY-BOCS at 716 baseline and week 24 (or early withdrawal if applicable) for patients from study 704 and 715 (if primary diagnosis was OCD);
- CGI-Severity of Illness item at 716 baseline and weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24 (or early withdrawal, if applicable) for all patients;
- CGI-Global Improvement item at 716 baseline and weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24 (or early withdrawal, if applicable) for all patients.

3.14.4.1 Primary Efficacy Variable

There was no primary measure of efficacy in this study.

3.14.4.2 Secondary Efficacy Variables

The following efficacy variables were summarized descriptively for the ITT and PPX populations, except for the CGI Global Improvement item which was summarized for the ITT population only since it is relative to the acute study baseline.

- change from baseline in the CDRS-R total score at the week 24 visit (OC and LOCF) for patients entering study 716 from study 701;
- change from baseline in the CY-BOCS total score at the week 24 visit (OC and LOCF) for patients entering study 716 from study 704;
- proportion of responders based on the CGI-Global Improvement item at the week 24 visit (OC and LOCF) for patients entering study 716 from study 701 or 704 (separately by indication, MDD or OCD). Global improvement was rated by comparing the patient's condition at a particular visit to their condition at the acute study baseline. Response was defined as a score of 1 (very much improved) or 2 (much improved) ;
- change from baseline in the CGI-Severity of Illness item score at each OC visit and week 24 LOCF for patients entering study 716 from study 701 or 704 (separately by indication, MDD or OCD).

For comparisons involving the ITT population (see Section 3.14.3) the baseline assessment was defined as the patient's acute study baseline visit. For comparisons involving the PPX population (see Section 3.14.3), the baseline assessment was defined as the patient's final on treatment assessment (excluding taper phase medication) from their acute study. The PPX population is a subset of the ITT population.

3.14.4.3 Other Variables of Interest

The following efficacy variables were summarized by acute study treatment group, and dose level at the end of the acute study treatment phase (pre-taper); these summaries are intended to describe the effect of taper in patients treated with paroxetine:

- for all patients entering 716 from 701, the change from 701 treatment phase endpoint to 716 visit 1 (pre to post taper) in CDRS-R total score. Patients who completed the acute study 701 at dosage level 1 (or 10 mg/day) were

excluded from this evaluation as their treatment phase endpoint was on the same day as their 716 visit 1 assessment;

- for all patients entering 716 from 704, the change from 704 treatment phase endpoint to 716 visit 1 (pre to post taper) in CY-BOCS total score. Patients who completed the acute study 704 at dosage level 1 (or 10 mg/day) were excluded from this evaluation as their treatment phase endpoint was on the same day as their 716 visit 1 assessment.

3.14.5 Methods of Analyses

This is an open label study and no hypothesis testing was performed. Efficacy data were summarized descriptively, both overall and by acute study treatment group. Categorical data were summarized by counts and percentages. Continuous data were summarized by the mean, median, standard deviation and range (minimum, maximum).

3.14.6 Safety Evaluations

The safety population was identical to the ITT population. All patients who received at least one dose of open-label study medication and who had at least one valid post-dose assessment (including any adverse events) were included in the safety population and assessed for clinical safety and tolerability. All safety evaluations were assessed relative to the baseline assessment of the acute study.

3.14.6.1 Adverse Events

Adverse events were coded from the verbatim term using the WHO adverse reaction WHO ART dictionary, and then mapped to the ADECS (COSTART based) classification to give a body system and preferred term. Serious adverse events were coded from the verbatim term according to the WHO ART dictionary and mapped by ADECS for preferred term.

Adverse event data were listed by acute study treatment group, age group and patient number. The number (%) of patients with treatment emergent adverse events were summarized for overall incidence by acute study paroxetine group, and by body system and preferred term. Tables of adverse events are presented for the pre-acute study treatment phase, acute study treatment phase adverse events ongoing into 716, open-label treatment phase, taper phase and follow-up phase. The number (%) of adverse events are presented by primary diagnosis and age group for each diagnosis subgroup and overall.

Numbers and percentages are also presented for patients with adverse events by severity and adverse events by relationship to study medication, for patients with serious adverse events and adverse events leading to withdrawal.

Adverse events were summarized into five phases as follows:

- *Pre-acute study treatment phase adverse events* were defined as all adverse events where the onset date was prior to the first day of acute study treatment. All pre-acute study treatment adverse events were classified as screening emergent;

- *Acute study treatment (including taper) phase adverse events* were defined as all adverse events where the onset date was on or after the first day of acute study treatment and prior to the first day of open-label study treatment. Adverse events that started and stopped in this phase were reported in the acute study only;

- *Open-label treatment phase adverse events* were defined as all adverse events where the onset date was on or after the first day of open-label treatment and before or on the last day of open-label treatment (excluding taper medication);

- *Taper phase adverse events* were defined as all adverse events where the onset date was on or after the first day of taper medication and on or prior to last day of taper medication. Some patients may not have this phase;

- *Follow-up phase adverse events* were defined as all adverse events where the onset date was after the last date of open-label treatment (or taper medication) but less than 14 days (or 30 days if a serious adverse event) after this date;

In addition, a post follow-up phase was defined for the listing of serious adverse events where the onset date was >30 days after the last date of open-label medication (or taper medication).

Adverse events were categorized as emergent according to International Conference on Harmonization (ICH) E9 guidelines, which gives the following definition of a treatment emergent adverse event: "An event that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state".

However, this is an open-label treatment study and is divided into 5 phases: pre-acute study treatment, acute study treatment (including taper), open-label treatment, taper and follow-up. Hence the definition has been modified to: "An

event that emerges during the open-label treatment phase having been absent pre-acute study treatment, or worsens relative to the pre-acute study treatment state".

3.14.6.2 Vital Signs

Vital signs data were listed by acute study treatment group, age group and patient number. Summary statistics were produced for changes from acute study baseline for blood pressure, heart rate, weight, height and body mass index (BMI). In addition, the number and percentage of patients with a significant increase or decrease in any vital sign from acute-study baseline, which was of potential clinical concern, during the study was tabulated by parameter by acute study treatment group for each age group. Table 4 shows these pre-determined levels of potential clinical concern for vital signs.

Table 4 Criteria for Assessment of Vital Signs

Parameter	Age	Absolute Value of Clinical Concern	Change from Acute Study Baseline of Clinical Concern	
			Decrease	Increase
Systolic BP (mmHg)	-	< 95 or >145	≥ 30	≥ 40
Diastolic BP (mmHg)	-	< 50 or > 85	≥ 20	≥ 30
Pulse Rate (bpm)	7-12	< 65 or > 115	≥ 30	≥ 30
	13-18	< 55 or > 110	≥ 30	≥ 30
Weight (kg) (Boys)*	7-8	< 18.2 or > 36.8	≥ 7%	≥ 7%
	9	< 20.0 or > 41.8	≥ 7%	≥ 7%
	10	< 21.8 or > 47.2	≥ 7%	≥ 7%
	11	<24.5 or > 53.6	≥ 7%	≥ 7%
	12	< 27.2 or > 60.4	≥ 7%	≥ 7%
	13	< 31.3 or > 67.2	≥ 7%	≥ 7%
	14	< 35.9 or > 74.5	≥ 7%	≥ 7%
	15	< 40.9 or > 81.3	≥ 7%	≥ 7%
	16	< 45.4 or > 89.9	≥ 7%	≥ 7%
	17-18	<49.0 or > 93.5	≥ 7%	≥ 7%
Weight (kg) (Girls)*	7-8	< 17.3 or > 36.8	≥ 7%	≥ 7%
	9	< 19.5 or > 42.7	≥ 7%	≥ 7%
	10	< 21.8 or > 49.5	≥ 7%	≥ 7%
	11	<25.0 or > 56.3	≥ 7%	≥ 7%
	12	< 28.1 or > 63.1	≥ 7%	≥ 7%
	13	< 31.8 or > 69.5	≥ 7%	≥ 7%
	14	< 35.4 or > 75.4	≥ 7%	≥ 7%
	15	< 38.6 or > 79.9	≥ 7%	≥ 7%
	16	< 40.9 or > 83.1	≥ 7%	≥ 7%
	17-18	< 42.2 or > 84.4	≥ 7%	≥ 7%

*For weight, the last pre-acute study treatment value was considered to be the acute study baseline value

3.14.6.3 Electrocardiograms (ECGs)

ECG assessments were listed by acute study treatment group, age group and patient number. ECGs were repeated at taper end and/or follow-up if results at the 24 week visit were clinically significantly abnormal. The number and percentage of patients with an abnormal ECG and those with a normal ECG are

tabulated for acute study screening, acute study baseline, open-label study 716 baseline, last study 716 treatment/early withdrawal, taper and follow-up.

3.14.6.4 Laboratory Values

Laboratory data (hematology, blood chemistry and urinalysis) were listed by acute study treatment group and patient number.

Summary statistics for the changes from acute study baseline to endpoint in laboratory values are presented by parameter by acute study treatment group. Baseline for laboratory data was defined as the last acute study baseline assessment. Endpoint was defined as the last on-treatment open-label laboratory assessment, including the taper phase. Follow-up was the last open-label laboratory assessment up to 14 days after the last open-label treatment date (including taper).

The number and percentage of patients with a significant increase or decrease in any laboratory parameter from acute study baseline, which was of potential clinical concern, during the study was tabulated by parameter by acute study treatment group for each age group. Table 5 shows these pre-determined levels of potential clinical concern for laboratory values. In addition, the number and percentage of patients with transitions (e.g. from normal to abnormal) from baseline to endpoint and/or follow-up were tabulated by parameter by acute study treatment group.

Table 5 Laboratory Values of Potential Clinical Concern

Laboratory Parameters		Units	Values of Potential Clinical Concern
Hematology			
Hemoglobin	Males	g/L	< 115
	Females	g/L	< 95
Hematocrit	6-11 years	%	< 35
	12-17 years	%	< 36
	18-64 years males	%	< 35
	18-64 years females	%	< 41
RBC	Male	$x10^{12}$/L	> 8
	Female	$x10^{12}$/L	>10
WBC	All	$x10^{9}$/L	< 2.8 or >16
Lymphocytes	All	$x10^{9}$/L	< 0.53 or > 4.43
Monocytes	All	$x10^{9}$/L	> 1.38
Basophils	All	$x10^{9}$/L	> 0.40
Eosinophils	All	$x10^{9}$/L	> 0.79
Neutophil	All	$x10^{9}$/L	< 1.58 or > 8.64
Platelet Count	All	$x10^{9}$/L	<75 or >700
Liver Function			
AST (SGOT)	All	IU/L	> 150
ALT (SGPT)	All	IU/L	> 165
Total Bilirubin	All	micromol/L	> 34.2
Renal Function			
Creatinine	All	micromol/L	> 176.8
BUN	All	mmol/L	> 10.71
Others			
Sodium	All	mmol/L	< 126 or >156
Potassium	All	mmol/L	< 3 or > 6
TSH	All	MU/L	> 10

Source Table 15.3.2, Section 13

3.14.7 Defined Visit Timepoints

The protocol stipulated that patients' visits during the open-label treatment phase were to occur at specific timepoints. However, because of schedule problems, patient visits could not always occur on the exact day in question. Therefore, where possible, data were slotted into the following time windows depending on

the frequency with which the assessment was recorded as per protocol, with days relative to the first dose of open-label medication. Unscheduled visits were also slotted according to the visit windows specified in Table 6.

Table 6 Visit Windows

Visit	Proposed Day Relative to the First Dose of Open-Label Medication	Visit Window
716 Baseline (Visit 1)	0	—
Week 1 (Visit 2)	7	Days 1* to 10
Week 2 (Visit 3)	14	Days 11 to 17
Week 3 (Visit 4)	21	Days 18 to 24
Week 4 (Visit 5)	28	Days 25 to 35
Week 6 (Visit 6)	42	Days 36 to 49
Week 8 (Visit 7)	56	Days 50 to 70
Week 12 (Visit 8)	84	Days 71 to 98
Week 16 (Visit 9)	112	Days 99 to 126
Week 20 (Visit 10)	140	Days 127 to 154
Week 24 (Visit 11)	168	Days 155 to 196
Post-Week 24	—	Greater than 196 days

* Day 1 is included as open-label baseline (visit 1) if data are recorded before open-label study medication is taken; however, day 1 is included as week 1 (visit 2) if data are recorded after open-label study medication is taken.

Baseline (visit 1) data are all data that were collected on the baseline page of the 716 CRF, prior to the first dose of open-label medication.

Data recorded at specific visits only were slotted according to the intervals given above. All data were listed, but only data slotted into intervals corresponding to the protocol-defined assessment time were tabulated. For example, only CDRS-R and CY-BOCS assessments that fell into baseline and week 24 intervals were tabulated; however, all data are displayed in the listings.

If more than one assessment occurred in the same time window (or at the same visit for non-slotted data), then the latest assessment was used in the data summaries; however, all assessments are displayed in the listings.

Where efficacy data were recorded at the early withdrawal visit, they were handled in the same way as scheduled data and were slotted using the pre-defined

visit windows. Thus, for example if a patient withdrew at week 8 their final CDRS-R data would not be tabulated since week 8 was not a scheduled visit for collection of this endpoint. However, these data would be listed and contribute to the LOCF summary statistics.

Efficacy assessments performed more than 7 days after the last dose of open-label medication (excluding taper phase) and safety assessments performed more than 14 days after the last dose of taper medication, or more than 14 days after the last dose of open-label study medication if the patient did not enter the taper phase, were excluded from the summary tables. However, all data were listed.

3.14.8 Phases of the Study

3.14.8.1 Baseline

All safety evaluations were assessed relative to the baseline assessment of the acute study. For efficacy comparisons involving the ITT population, the baseline assessment was defined as the patient's acute study baseline visit. For efficacy comparisons involving the PPX population, the baseline assessment was defined as the patient's final on treatment assessment (excluding taper period medication) from their acute study.

3.14.8.2 Open-Label Treatment Phase

An efficacy assessment was defined as occurring during the open-label treatment phase if the assessment date was on or after the first dose of open-label study medication and up to and including 7 days after the last dose of open-label study medication, as long as it was prior to the start of open-label taper medication. For all other data, the open-label treatment phase started on the date of the first dose of open-label study medication and ended on either:

- the date of the last dose of open-label study medication, if no open-label taper medication was taken or;

- the day prior to the date of first open-label taper medication taken.

Once the taper phase commenced, no assessments after the last dose of open-label study medication were classified as occurring during the open label treatment phase.

3.14.8.3 Open-Label Taper Phase

The open-label taper phase was defined as from the first dose date of taper medication to the last dose date of taper medication. No efficacy assessments were made during the open-label taper phase.

3.14.8.4 Follow-up Phase

The follow-up phase was defined as any evaluable data that were collected after the last dose of study medication (including taper). No efficacy assessments were made during the follow-up phase.

3.14.9 Interim Analysis

This interim summary has been produced to meet reporting obligations for an sNDA for paroxetine pediatric use planned for April 2002.

3.14.10 Data Irregularities

Eleven patients had paroxetine listed as a concomitant medication during the open-label treatment phase. For patients 716.005.25409, 716.016.7018, 716.017.25495, 716.020.25458, 716.025.25806, 716.025.25822, and 716.025.2594 the date given in the CRF as the date the patient started taking paroxetine as a concomitant medication is incorrect. These seven patients received paroxetine as a concomitant medication starting the day after the end of open-label treatment. Patients 716.019.25752 and 716.159.25628 received paroxetine as a concomitant medication during the open-label treatment phase. Data for the other two patients (716.028.27079 and 716.169.25781) has been queried.

Patient 716.169.25781 in the acute study placebo group completed the week 24 visit CRF, but because the visit occurred less than 155 days after the first dose of open-label study medication, completion of the study was slotted to week 20.

Patient 716.172.25619 in the acute study paroxetine group did not complete CDRS-R or CGI scales at study 716 baseline and patient 716.055.28171 in the acute study placebo group did not complete CGI scales at study 716 baseline. These patients did complete these scales at the acute study treatment phase endpoint. For all efficacy tables, change is only calculated on the number of patients that have both required assessments.

Patient 716.019.25943 failed one of the inclusion/exclusion criteria for this study. The patient had high lymphocyte values at acute screening and study 716 baseline, but was entered into the study.

4 Study Population

Patients who entered study 716 from the 715 paroxetine forced titration open-label pharmacokinetic study are not included in this interim report as the database for 715 was finalized after the study 716 database. Patients from 715 will be included in the final clinical study report for study 716. In addition, the interim database does not include patients from acute study 704 who did not have a 716 CRF study conclusion page or did not have a completed study 716 week 4 CRF received in-house at GlaxoSmithKline by the clinical cut-off date of October 1, 2001. All patients from study 701 who entered 716 are included in this interim report.

4.1 Study Dates

The first dose of open-label study medication was administered on May 13, 2000. This interim report includes data for all patients who entered the open-label extension study from acute studies 701 and 704 and had a 716 CRF study conclusion page or a completed study 716 week 4 CRF received in-house by GSK by October 1, 2001.

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 261 patients were entered into this open-label extension study. Of these 223 were included in this interim report: 117 patients entered from acute study 701 and 106 patients from acute study 704. No patient who chose to enter study 716 failed the inclusion/exclusion criteria. A summary of the numbers and disposition of patients by primary diagnosis (OCD or MDD), age group (child or adolescent), and acute study treatment group (paroxetine or placebo) is presented in Table 7.

The ITT population consisted of all patients who received at least one dose of open-label medication and for whom at least one valid post-baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available. Two patients who entered study 716 are not included in the ITT population (Listing 13.1.1, Appendix B). One patient (716.020.25462) from acute study 704 moved to another state and one patient (716.154.25767) from acute study 701 was lost to

follow-up; both patients had no post baseline assessments in study 716 and received paroxetine in their acute study.

The interim report ITT population, therefore, consisted of a total of 221 patients: 94 patients who received paroxetine in their acute study (referred to as acute study paroxetine patients) and 127 patients who received placebo in their acute study (referred to as acute study placebo patients). The PPX population consisted of all patients who received paroxetine in their acute study, received at least one dose of open-label medication, and for whom at least one post-baseline (study 716, visit 1) open-label evaluation (including any adverse event) was available. The PPX population consisted of 94 acute study paroxetine patients.

Of the ITT population, 52.5% (116/221) had a primary diagnosis of MDD, and 47.5% (105/221) had a primary diagnosis of OCD. Of those with MDD, 52.6% (61/116) were children and 47.4% (55/116) were adolescents; 43.1% (50/116) had received paroxetine in their acute study and 56.9% (66/116) had received placebo in their acute study. Of those with OCD, 55.2% (58/105) were children and 44.8% (47/105) were adolescents; 41.9% (44/105) had received paroxetine in their acute study and 58.1% (61/105) had received placebo in their acute study.

As of the clinical cut-off date of October 1, 2001, a total of 73 patients had completed the study, 124 had withdrawn early and 26 were continuing to receive open label paroxetine having already completed a week 4 CRF. Overall, of all patients entered into study 716 who are included in this interim report, more patients from the acute study placebo group withdrew early (62.2%, 79/127) compared to patients from the acute study paroxetine group (46.9%, 45/96). Further, slightly more children (59.7%, 71/119) withdrew early compared to adolescents (51.0%, 53/104). The number of early withdrawals was similar in patients with MDD (56.4%, 66/117) and OCD (54.7%, 58/106).

Table 7 Number (%) and Disposition of Patients by Primary Diagnosis, Age Group, and Acute Study Treatment Group (All Patients) Continued…

Study Stage / Population	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: Total	**(N=96)**		**(N=49)**		**(N=47)**		**(N=127)**		**(N=70)**		**(N=57)**		**(N=223)**		**(N=119)**		**(N=104)**	
716 Baseline Only	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Number Entered	96	(100.0)	49	(100.0)	47	(100.0)	127	(100.0)	70	(100.0)	57	(100.0)	223	(100.0)	119	(100.0)	104	(100.0)
Completed*	40	(41.7)	21	(42.9)	19	(40.4)	33	(26.0)	16	(22.9)	17	(29.8)	73	(32.7)	37	(31.1)	36	(34.6)
Ongoing**	11	(11.5)	4	(8.2)	7	(14.9)	15	(11.8)	7	(10.0)	8	(14.0)	26	(11.7)	11	(9.2)	15	(14.4)
Early Withdrawal	45	(46.9)	24	(49.0)	21	(44.7)	79	(62.2)	47	(67.1)	32	(56.1)	124	(55.6)	71	(59.7)	53	(51.0)
ITT Population	94	(97.9)	49	(100.0)	45	(95.7)	127	(100.0)	70	(100.0)	57	(100.0)	221	(99.1)	119	(100.0)	102	(98.1)
PPX Population	94	(97.9)	49	(100.0)	45	(95.7)	-	-	-	-	-	-	94	(42.2)	49	(41.2)	45	(43.3)
Primary Diagnosis: MDD	**(N=51)**		**(N=25)**		**(N=26)**		**(N=66)**		**(N=36)**		**(N=30)**		**(N=117)**		**(N=61)**		**(N=56)**	
716 Baseline Only	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Number Entered	51	(100.0)	25	(100.0)	26	(100.0)	66	(100.0)	36	(100.0)	30	(100.0)	117	(100.0)	61	(100.0)	56	(100.0)
Completed*	26	(51.0)	13	(52.0)	13	(50.0)	24	(36.4)	11	(30.6)	13	(43.3)	50	(42.7)	24	(39.3)	26	(46.4)
Ongoing**	1	(2.0)	0	-	1	(3.8)	0	-	0	-	0	-	1	(0.9)	0	-	1	(1.8)
Early Withdrawal	24	(47.1)	12	(48.0)	12	(46.2)	42	(63.6)	25	(69.4)	17	(56.7)	66	(56.4)	37	(60.7)	29	(51.8)
ITT Population	50	(98.0)	25	(100.0)	25	(96.2)	66	(100.0)	36	(100.0)	30	(100.0)	116	(99.1)	61	(100.0)	55	(98.2)
PPX Population	50	(98.0)	25	(100.0)	25	(96.2)	-	-	-	-	-	-	50	(42.7)	25	(41.0)	25	(44.6)

Source Table 13.1.1, Section 10; Listings 13.1.1, 13.1.2 and 13.3.1b, Appendix B

* A patient was considered to have completed the study if they completed a week 24 visit CRF. One patient in the acute study placebo group completed the study at the week 24 visit, but the completion was slotted to week 20 because their last dose of non-taper study medication was taken in the week 20 visit window (see Section 3.14.10, Data Irregularities)

** Ongoing patients were patients who did not have a study conclusion page, but had a completed week 4 CRF in-house by October 1, 2001.

The acute study paroxetine group includes two patients who entered study 716, but had no post-baseline assessments.

Table 7 Number (%) and Disposition of Patients by Primary Diagnosis, Age Group, and Acute Study Treatment Group (All Patients)

Study Stage / Population	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: OCD	**(N=45)**		**(N=24)**		**(N=21)**		**(N=61)**		**(N=34)**		**(N=27)**		**(N=106)**		**(N=58)**		**(N=48)**	
716 Baseline Only	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Number Entered	45	(100.0)	24	(100.0)	21	(100.0)	61	(100.0)	34	(100.0)	27	(100.0)	106	(100.0)	58	(100.0)	48	(100.0)
Completed*	14	(31.1)	8	(33.3)	6	(28.6)	9	(14.8)	5	(14.7)	4	(14.8)	23	(21.7)	13	(22.4)	10	(20.8)
Ongoing**	10	(22.2)	4	(16.7)	6	(28.6)	15	(24.6)	7	(20.6)	8	(29.6)	25	(23.6)	11	(19.0)	14	(29.2)
Early Withdrawal	21	(46.7)	12	(50.0)	9	(42.9)	37	(60.7)	22	(64.7)	15	(55.6)	58	(54.7)	34	(58.6)	24	(50.0)
ITT Population	44	(97.8)	24	(100.0)	20	(95.2)	61	(100.0)	34	(100.0)	27	(100.0)	105	(99.1)	58	(100.0)	47	(97.9)
PPX Population	44	(97.8)	24	(100.0)	20	(95.2)	-	-	-	-	-	-	44	(41.5)	24	(41.4)	20	(41.7)

Source Table 13.1.1, Section 10; Listings 13.1.1, 13.1.2 and 13.3.1b, Appendix B.

* A patient was considered to have completed the study if they completed a week 24 visit CRF. One patient in the acute study placebo group completed the study at the week 24 visit, but the completion was slotted to week 20 because their last dose of non-taper study medication was taken in the week 20 visit window (see Section 3.14.10, Data Irregularities)

** Ongoing patients were patients who did not have a study conclusion page, but had a completed week 4 CRF in-house by October 1, 2001.

The acute study paroxetine group includes two patients who entered study 716, but had no post-baseline assessments.

This interim report includes data from 43 centers in the United States and 2 centers in Canada. The numbers and disposition of patients by age group and acute study treatment group is presented by country (USA or Canada) in Table 13.1.2, Section 11.

Table 8 presents the number of patients entered and completed by center. Investigator name(s) at each center and affiliation may be found in Table 1, Section 3.2. The number of patients enrolled per center ranged from a single patient at 10 centers to 16 patients at center 025. A total of 12 centers each entered at least 8 patients.

Table 8 Number (%) of Patients Entered and Completed by Center and Acute Study Treatment Group (ITT Population) Continued…

Center No.	Acute Study Treatment Group											
	Paroxetine (N=94)				Placebo (N=127)				Total (N=221)			
	Entered		Completed*		Entered		Completed*		Entered		Completed*	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
002	0	-	0	-	2	(1.6)	0	-	2	(0.9)	0	-
004	3	(3.2)	2	(2.1)	3	(2.4)	0	-	6	(2.7)	2	(0.9)
005	4	(4.3)	1	(1.1)	4	(3.1)	1	(0.8)	8	(3.6)	2	(0.9)
006	3	(3.2)	1	(1.1)	1	(0.8)	0	-	4	(1.8)	1	(0.5)
008	3	(3.2)	0	-	1	(0.8)	0	-	4	(1.8)	0	-
009	1	(1.1)	0	-	1	(0.8)	0	-	2	(0.9)	0	-
010	6	(6.4)	4	(4.3)	6	(4.7)	2	(1.6)	12	(5.4)	6	(2.7)
012	1	(1.1)	1	(1.1)	0	-	0	-	1	(0.5)	1	(0.5)
014	3	(3.2)	1	(1.1)	6	(4.7)	1	(0.8)	9	(4.1)	2	(0.9)
015	3	(3.2)	1	(1.1)	3	(2.4)	0	-	6	(2.7)	1	(0.5)
016	4	(4.3)	3	(3.2)	5	(3.9)	0	-	9	(4.1)	3	(1.4)
017	1	(1.1)	1	(1.1)	0	-	0	-	1	(0.5)	1	(0.5)
019	4	(4.3)	1	(1.1)	5	(3.9)	1	(0.8)	9	(4.1)	2	(0.9)
020	3	(3.2)	3	(3.2)	6	(4.7)	1	(0.8)	9	(4.1)	4	(1.8)
025	7	(7.4)	3	(3.2)	9	(7.1)	4	(3.1)	16	(7.2)	7	(3.2)
026	1	(1.1)	0	-	2	(1.6)	0	-	3	(1.4)	0	-
027	1	(1.1)	0	-	2	(1.6)	1	(0.8)	3	(1.4)	1	(0.5)
028	3	(3.2)	1	(1.1)	6	(4.7)	2	(1.6)	9	(4.1)	3	(1.4)
031	0	-	0	-	3	(2.4)	2	(1.6)	3	(1.4)	2	(0.9)
040	1	(1.1)	0	-	1	(0.8)	0	-	2	(0.9)	0	-

Source Table 13.4.1, Section 10; Listing 13.3.1b, Appendix B

* A patient was considered to have completed the study if they completed the week 24 visit CRF

Table 8 Number (%) of Patients Entered and Completed by Center and Acute Study Treatment Group (ITT Population)

Center No.	Acute Study Treatment Group											
	Paroxetine (N=94)				Placebo (N=127)				Total (N=221)			
	Entered		Completed*		Entered		Completed*		Entered		Completed*	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
043	2	(2.1)	1	(1.1)	1	(0.8)	0	-	3	(1.4)	1	(0.5)
044	2	(2.1)	1	(1.1)	5	(3.9)	2	(1.6)	7	(3.2)	3	(1.4)
047	1	(1.1)	0	-	2	(1.6)	0	-	3	(1.4)	0	-
049	2	(2.1)	0	-	3	(2.4)	0	-	5	(2.3)	0	-
052	0	-	0	-	1	(0.8)	0	-	1	(0.5)	0	-
055	4	(4.3)	0	-	5	(3.9)	0	-	9	(4.1)	0	-
148	1	(1.1)	0	-	0	-	0	-	1	(0.5)	0	-
151	0	-	0	-	2	(1.6)	1	(0.8)	2	(0.9)	1	(0.5)
154	1	(1.1)	0	-	0	-	0	-	1	(0.5)	0	-
159	3	(3.2)	1	(1.1)	5	(3.9)	3	(2.4)	8	(3.6)	4	(1.8)
164	1	(1.1)	0	-	1	(0.8)	0	-	2	(0.9)	0	-
165	0	-	0	-	2	(1.6)	0	-	2	(0.9)	0	-
167	1	(1.1)	1	(1.1)	2	(1.6)	2	(1.6)	3	(1.4)	3	(1.4)
168	4	(4.3)	1	(1.1)	3	(2.4)	1	(0.8)	7	(3.2)	2	(0.9)
169	0	-	0	-	1	(0.8)	1	(0.8)	1	(0.5)	1	(0.5)
170	0	-	0	-	2	(1.6)	1	(0.8)	2	(0.9)	1	(0.5)
171	0	-	0	-	1	(0.8)	0	-	1	(0.5)	1	-
172	1	(1.1)	1	(1.1)	0	-	0	-	1	(0.5)	1	(0.5)
173	1	(1.1)	1	(1.1)	0	-	0	-	1	(0.5)	1	(0.5)
176	6	(6.4)	3	(3.2)	8	(6.3)	2	(1.6)	14	(6.3)	5	(2.3)
179	0	-	0	-	1	(0.8)	1	(0.8)	1	(0.5)	1	(0.5)
180	2	(2.1)	0	-	1	(0.8)	0	-	3	(1.4)	0	-
183	4	(4.3)	3	(3.2)	8	(6.3)	2	(1.6)	12	(5.4)	5	(2.3)
186	3	(3.2)	2	(2.1)	3	(2.4)	1	(0.8)	6	(2.7)	3	(1.4)
192	3	(3.2)	2	(2.1)	4	(3.1)	1	(0.8)	7	(3.2)	3	(1.4)
Total	94	(100.0)	40	(42.6)	127	(100.0)	33	(26.0)	221	(100.0)	73	(33.0)

Source Table 13.4.1, Section 10, Listing 13.3.1b Appendix B

* A patient was considered to have completed the study if they completed the week 24 visit CRF

4.2.2 Number of Patients Present at Each Visit

Table 9 presents the number and percentage of patients remaining in this study at the conclusion of each study visit. The percentages shown in this table are based

on the numbers of patients in the ITT population. A total of 73/221 patients (33.0%) had completed study 716 (completed the week 24 visit measurements: 72 patients at week 24 and 1 patient at relative week 20) as of the cut-off date for this interim report. The percentage of patients who completed study 716 was higher for patients who had received paroxetine in their acute study (42.6%, 40/94: all patients completed at week 24) than for those who had received placebo (26.0%, 33/127: 32 patients completed at week 24 and 1 patient completed at relative week 20).

Table 9 Number (%) of Patients Remaining in the Study at Each Visit by Acute Study Treatment Group (ITT Population)

Visit	Acute Study Treatment Group					
	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
	n	(%)	n	(%)	n	(%)
716 Baseline	94	(100.0)	127	(100.0)	221	(100.0)
Week 1	91	(96.8)	122	(96.1)	213	(96.4)
Week 2	91	(96.8)	119	(93.7)	210	(95.0)
Week 3	89	(94.7)	114	(89.8)	203	(91.9)
Week 4	85	(90.4)	106	(83.5)	191	(86.4)
Week 6	81	(86.2)	91	(71.7)	172	(77.8)
Week 8	66	(70.2)	73	(57.5)	139	(62.9)
Week 12	58	(61.7)	62	(48.8)	120	(54.3)
Week 16	44	(46.8)	46	(36.2)	90	(40.7)
Week 20*	42	(44.7)	34	(26.8)	76	(34.4)
Week 24**	40	(42.6)	32	(25.2)	72	(32.6)

Source Table 13.3.2, Section 10; Listing 13.3.1b, Appendix B.
Percentages for patients still in the study at each visit are based on the total number of patients at study 716 baseline.
* One patient in the acute study placebo group completed the study at the week 24 visit, but the completion was slotted to week 20 because of the visit windows (Section 3.14.7).
**These numbers represent patients who completed the study at the week 24 visit window and do not include one acute study placebo patient who completed at the week 20 visit window.

4.2.3 Withdrawal Reasons

A summary of the number and percentage of patients not completing the study and the reason for withdrawal by primary diagnosis, age group, and acute study treatment group is presented in Table 10. A total of 55.2% (122/221) of ITT patients were withdrawn during the open-label treatment phase of study 716. Overall, the percentage of patients who were withdrawn prematurely was lower in patients who received paroxetine in their acute study (45.7%, 43/94) compared with patients who received placebo in their acute study (62.2%, 79/127). The

primary reason for withdrawal in patients receiving paroxetine in their acute study was 'other' [includes unknown and non-study related personal reasons] (13.8%, 13/94). In patient who had received placebo in their acute study the primary reason for withdrawal was 'adverse event' (18.9%, 24/127).

A total of 30 patients withdrew for 'other' reasons which included:

- withdrew consent (10 patients);
- site was prematurely closed (7 patients);
- scheduling conflict (2 patients);
- family wanted to seek additional treatment;
- patient choice;
- did not want to give blood;
- patient's mother wanted the patient off all medication before beginning new therapy;
- mother and child desired to withdraw from the study;
- issues at school override therapeutic effects of study;
- patient needed to take excluded medication;
- patient/family decision;
- early termination as principal investigator moving out of state;
- did not want to continue;
- patient wished to withdraw due to lack of time;

A slightly higher percentage of children (59.7%, 71/119) were withdrawn prematurely compared to adolescents (50.0%, 51/102). The main reason for withdrawal among children in the acute study paroxetine group was 'other' (18.4%, 9/49). The main reasons for withdrawal in the acute study placebo group among children were 'adverse event' (20.0%, 14/70) or 'other' (18.6%, 13/70). The primary reason for withdrawal among adolescents was 'adverse event' (11.1%, 5/45 of acute study paroxetine patients; 17.5%, 10/57 of acute study placebo patients).

Overall, a total of 56.0% (65/116) of patients with a primary diagnosis of MDD were withdrawn during the open-label treatment phase of study. In MDD patients receiving paroxetine in their acute study the main reason for withdrawal was 'adverse event' (14.0%, 7/50). In MDD patients receiving placebo in their acute study the main reasons for withdrawal were 'adverse event' (15.2%, 10/66), 'lack of efficacy' (16.7%, 11/66) or 'other' (16.7%, 11/66).

Overall, a total of 54.3% (57/105) of patients with a primary diagnosis of OCD were withdrawn during the open-label treatment phase of the study. In OCD patients receiving paroxetine in their acute study the main reason for withdrawal was 'other' (22.7%, 10/44). In MDD patients receiving placebo in their acute study the primary reason for withdrawal was 'adverse event' (23.0%, 14/61).

Table 10 Number (%) of Patients who Completed the Study or were Withdrawn from Study by Reason for Withdrawal by Primary Diagnosis, Age Group, and Acute Study Treatment Group (ITT Population) Continued…

Study Stage/Population	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: Total	**(N=94)**		**(N=49)**		**(N=45)**		**(N=127)**		**(N=70)**		**(N=57)**		**(N=221)**		**(N=119)**		**(N=102)**	
Completed Study*	40	(42.6)	21	(42.9)	19	(42.2)	33	(26.0)	16	(22.9)	17	(29.8)	73	(33.0)	37	(31.1)	36	(35.3)
Adverse Event	9	(9.6)	4	(8.2)	5	(11.1)	24	(18.9)	14	(20.0)	10	(17.5)	33	(14.9)	18	(15.1)	15	(14.7)
Lack of Efficacy	7	(7.4)	3	(6.1)	4	(8.9)	19	(15.0)	10	(14.3)	9	(15.8)	26	(11.8)	13	(10.9)	13	(12.7)
Protocol Deviation (Including Non-compliance)	6	(6.4)	3	(6.1)	3	(6.7)	7	(5.5)	3	(4.3)	4	(7.0)	13	(5.9)	6	(5.0)	7	(6.9)
Lost to Follow-up	8	(8.5)	5	(10.2)	3	(6.7)	12	(9.4)	7	(10.0)	5	(8.8)	20	(9.0)	12	(10.1)	8	(7.8)
Other +	13	(13.8)	9	(18.4)	4	(8.9)	17	(13.4)	13	(18.6)	4	(7.0)	30	(13.6)	22	(18.5)	8	(7.8)
Total withdrawn	43	(45.7)	24	(49.0)	19	(42.2)	79	(62.2)	47	(67.1)	32	(56.1)	122	(55.2)	71	(59.7)	51	(50.0)
Primary Diagnosis: MDD	**(N=50)**		**(N=25)**		**(N=25)**		**(N=66)**		**(N=36)**		**(N=30)**		**(N=116)**		**(N=61)**		**(N=55)**	
Completed Study*	26	(52.0)	13	(52.0)	13	(52.0)	24	(36.4)	11	(30.6)	13	(43.3)	50	(43.1)	24	(39.3)	26	(47.3)
Adverse Event	7	(14.0)	3	(12.0)	4	(16.0)	10	(15.2)	6	(16.7)	4	(13.3)	17	(14.7)	9	(14.8)	8	(14.5)
Lack of Efficacy	5	(10.0)	2	(8.0)	3	(12.0)	11	(16.7)	5	(13.9)	6	(20.0)	16	(13.8)	7	(11.5)	9	(16.4)
Protocol Deviation (Including Non-compliance)	4	(8.0)	1	(4.0)	3	(12.0)	3	(4.5)	1	(2.8)	2	(6.7)	7	(6.0)	2	(3.3)	5	(9.1)
Lost to Follow-up	4	(8.0)	3	(12.0)	1	(4.0)	7	(10.6)	3	(8.3)	4	(13.3)	11	(9.5)	6	(9.8)	5	(9.1)
Other +	3	(6.0)	3	(12.0)	0	-	11	(16.7)	10	(27.8)	1	(3.3)	14	(12.1)	13	(21.3)	1	(1.8)
Total withdrawn	23	(46.0)	12	(48.0)	11	(44.0)	42	(63.6)	25	(69.4)	17	(56.7)	65	(56.0)	37	(60.7)	28	(50.9)

Source Table 13.3.1b Section 10; Listing 13.3.1b, Appendix B

* Patients who completed a week 24 visit CRF. One patient in the acute study placebo group completed the study at the week 24 visit, but the completion was slotted to week 20 because of the visit windows (see Section 3.14.10, Data Irregularities).

+ Includes unknown and non-study related personal reasons.

Ongoing patients are not included in this table.

Table 10 Number (%) of Patients who Completed the Study or were Withdrawn from Study by Reason for Withdrawal Primary Diagnosis, Age Group, and Acute Study Treatment Group (ITT Population)

Study Stage/Population	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: OCD	**(N=44)**		**(N=24)**		**(N=20)**		**(N=61)**		**(N=34)**		**(N=27)**		**(N=105)**		**(N=58)**		**(N=47)**	
Completed Study*	14	(31.8)	8	(33.3)	6	(30.0)	9	(14.8)	5	(14.7)	4	(14.8)	23	(21.9)	13	(22.4)	10	(21.3)
Adverse Event	2	(4.5)	1	(4.2)	1	(5.0)	14	(23.0)	8	(23.5)	6	(22.2)	16	(15.2)	9	(15.5)	7	(14.9)
Lack of Efficacy	2	(4.5)	1	(4.2)	1	(5.0)	8	(13.1)	5	(14.7)	3	(11.1)	10	(9.5)	6	(10.3)	4	(8.5)
Protocol Deviation (Including Non-compliance)	2	(4.5)	2	(8.3)	0	-	4	(6.6)	2	(5.9)	2	(7.4)	6	(5.7)	4	(6.9)	2	(4.3)
Lost to Follow-up	4	(9.1)	2	(8.3)	2	(10.0)	5	(8.2)	4	(11.8)	1	(3.7)	9	(8.6)	6	(10.3)	3	(6.4)
Other +	10	(22.7)	6	(25.0)	4	(20.0)	6	(9.8)	3	(8.8)	3	(11.1)	16	(15.2)	9	(15.5)	7	(14.9)
Total withdrawn	20	(45.5)	12	(50.0)	8	(40.0)	37	(60.7)	22	(64.7)	15	(55.6)	57	(54.3)	34	(58.6)	23	(48.9)

Source Table 13.3.1b Section 10; Listing 13.3.1b, Appendix B

* Patients who completed a week 24 visit CRF. One patient in the acute study placebo group completed the study at the week 24 visit, but the completion was slotted to week 20 because of the visit windows (see Section 3.14.10, Data Irregularities).

+ Includes unknown and non-study related personal reasons.

Ongoing patients are not included in this table.

Table 11 presents a cumulative summary of patients withdrawing from the study by acute study treatment group, visit, and reason for withdrawal for both age groups combined, as well as for children and adolescents, separately.

The greatest percentage of withdrawals occurred at week 8, approximately half of all patients who withdrew did so before or at week 8. The predominant reason for withdrawal at week 8 for both acute study treatment groups combined was 'other' [includes protocol deviation (including non-compliance), lost to follow-up, unknown and non-study related personal reasons]. Of the 33 patients who withdrew due to an adverse event, 24 withdrew on or before week 8. The number of withdrawals was similar in children and adolescent. However, children withdrew earlier in the study compared to adolescents.

Table 11 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute Study Treatment Group (ITT Population) Continued…

	Acute Study Treatment Group																							
	Paroxetine (N=94)								Placebo (N=127)								Total (N=221)							
	AE		LOE		Other*		Total		AE		LOE		Other*		Total		AE		LOE		Other*		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total																								
Wk 1	0	-	1	(1.1)	2	(2.1)	3	(3.2)	1	(0.8)	1	(0.8)	3	(2.4)	5	(3.9)	1	(0.5)	2	(0.9)	5	(2.3)	8	(3.6)
Wk 2	0	-	1	(1.1)	2	(2.1)	3	(3.2)	2	(1.6)	2	(1.6)	4	(3.1)	8	(6.3)	2	(0.9)	3	(1.4)	6	(2.7)	11	(5.0)
Wk 3	2	(2.1)	1	(1.1)	2	(2.1)	5	(5.3)	4	(3.1)	2	(1.6)	6	(4.7)	12	(9.4)	6	(2.7)	3	(1.4)	8	(3.6)	17	(7.7)
Wk 4	2	(2.1)	1	(1.1)	6	(6.4)	9	(9.6)	8	(6.3)	2	(1.6)	9	(7.1)	19	(15.0)	10	(4.5)	3	(1.4)	15	(6.8)	28	(12.7)
Wk 6	4	(4.3)	2	(2.1)	7	(7.4)	13	(13.8)	13	(10.2)	4	(3.1)	17	(13.4)	34	(26.8)	17	(7.7)	6	(2.7)	24	(10.9)	47	(21.3)
Wk 8	6	(6.4)	4	(4.3)	13	(13.8)	23	(24.5)	18	(14.2)	8	(6.3)	20	(15.7)	46	(36.2)	24	(10.9)	12	(5.4)	33	(14.9)	69	(31.2)
Wk 12	6	(6.4)	5	(5.3)	20	(21.3)	31	(33.0)	20	(15.7)	14	(11.0)	23	(18.1)	57	(44.9)	26	(11.8)	19	(8.6)	43	(19.5)	88	(39.8)
Wk 16	9	(9.6)	6	(6.4)	24	(25.5)	39	(41.5)	20	(15.7)	17	(13.4)	30	(23.6)	67	(52.8)	29	(13.1)	23	(10.4)	54	(24.4)	106	(48.0)
Wk 20	9	(9.6)	7	(7.4)	25	(26.6)	41	(43.6)	24	(18.9)	19	(15.0)	34	(26.8)	77	(60.6)	33	(14.9)	26	(11.8)	59	(26.7)	118	(53.4)
Wk 24	9	(9.6)	7	(7.4)	27	(28.7)	43	(45.7)	24	(18.9)	19	(15.0)	35	(27.6)	78	(61.4)	33	(14.9)	26	(11.8)	62	(28.1)	121	(54.8)
Post Wk 24	9	(9.6)	7	(7.4)	27	(28.7)	43	(45.7)	24	(18.9)	19	(15.0)	36	(28.3)	79	(62.2)	33	(14.9)	26	(11.8)	63	(28.5)	122	(55.2)

Source Table 13.3.3 Section 11; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

*Other includes protocol deviations including non compliance, lost to follow-up, unknown, and non-study related personal reasons

Table 11 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute Study Treatment Group (ITT Population) Continued…

	Acute Study Treatment Group																							
	Paroxetine (N=49)								Placebo (N=70)								Total (N=119)							
	AE		LOE		Other*		Total		AE		LOE		Other*		Total		AE		LOE		Other*		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Children																								
Wk 1	0	-	1	(2.0)	1	(2.0)	2	(4.1)	0	-	0	-	2	(2.9)	2	(2.9)	0	-	1	(0.8)	3	(2.5)	4	(3.4)
Wk 2	0	-	1	(2.0)	1	(2.0)	2	(4.1)	0	-	0	-	3	(4.3)	3	(4.3)	0	-	1	(0.8)	4	(3.4)	5	(4.2)
Wk 3	1	(2.0)	1	(2.0)	1	(2.0)	3	(6.1)	2	(2.9)	0	-	4	(5.7)	6	(8.6)	3	(2.5)	1	(0.8)	5	(4.2)	9	(7.6)
Wk 4	1	(2.0)	1	(2.0)	3	(6.1)	5	(10.2)	5	(7.1)	0	-	5	(7.1)	10	(14.3)	6	(5.0)	1	(0.8)	8	(6.7)	15	(12.6)
Wk 6	2	(4.1)	1	(2.0)	4	(8.2)	7	(14.3)	8	(11.4)	1	(1.4)	9	(12.9)	18	(25.7)	10	(8.4)	2	(1.7)	13	(10.9)	25	(21.0)
Wk 8	3	(6.1)	2	(4.1)	10	(20.4)	15	(30.6)	11	(15.7)	3	(4.3)	10	(14.3)	24	(34.3)	14	(11.8)	5	(4.2)	20	(16.8)	39	(32.8)
Wk 12	3	(6.1)	2	(4.1)	15	(30.6)	20	(40.8)	12	(17.1)	8	(11.4)	13	(18.6)	33	(47.1)	15	(12.6)	10	(8.4)	28	(23.5)	53	(44.5)
Wk 16	4	(8.2)	2	(4.1)	15	(30.6)	21	(42.9)	12	(17.1)	9	(12.9)	17	(24.3)	38	(54.3)	16	(13.4)	11	(9.2)	32	(26.9)	59	(49.6)
Wk 20	4	(8.2)	3	(6.1)	16	(32.7)	23	(46.9)	14	(20.0)	10	(14.3)	21	(30.0)	45	(64.3)	18	(15.1)	13	(10.9)	37	(31.1)	68	(57.1)
Wk 24	4	(8.2)	3	(6.1)	17	(34.7)	24	(49.0)	14	(20.0)	10	(14.3)	22	(31.4)	46	(65.7)	18	(15.1)	13	(10.9)	39	(32.8)	70	(58.8)
Post Wk 24	4	(8.2)	3	(6.1)	17	(34.7)	24	(49.0)	14	(20.0)	10	(14.3)	23	(32.9)	47	(67.1)	18	(15.1)	13	(10.9)	40	(33.6)	71	(59.7)

Source Table 13.3.3 Section 10; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

*Other includes protocol deviations including non compliance, lost to follow-up, unknown, and non-study related personal reasons

Table 11 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group																					
	Paroxetine (N=45)								Placebo (N=57)								Total (N=102)					
	AE		LOE		Other*		Total		AE		LOE		Other*		Total		AE		LOE		Other*		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents																								
Wk 1	0	-	0	-	1	(2.2)	1	(2.2)	1	(1.8)	1	(1.8)	1	(1.8)	3	(5.3)	1	(1.0)	1	(1.0)	2	(2.0)	4	(3.9)
Wk 2	0	-	0	-	1	(2.2)	1	(2.2)	2	(3.5)	2	(3.5)	1	(1.8)	5	(8.8)	2	(2.0)	2	(2.0)	2	(2.0)	6	(5.9)
Wk 3	1	(2.2)	0	-	1	(2.2)	2	(4.4)	2	(3.5)	2	(3.5)	2	(3.5)	6	(10.5)	3	(2.9)	2	(2.0)	3	(2.9)	8	(7.8)
Wk 4	1	(2.2)	0	-	3	(6.7)	4	(8.9)	3	(5.3)	2	(3.5)	4	(7.0)	9	(15.8)	4	(3.9)	2	(2.0)	7	(6.9)	13	(12.7)
Wk 6	2	(4.4)	1	(2.2)	3	(6.7)	6	(13.3)	5	(8.8)	3	(5.3)	8	(14.0)	16	(28.1)	7	(6.9)	4	(3.9)	11	(10.8)	22	(21.6)
Wk 8	3	(6.7)	2	(4.4)	3	(6.7)	8	(17.8)	7	(12.3)	5	(8.8)	10	(17.5)	22	(38.6)	10	(9.8)	7	(6.9)	13	(12.7)	30	(29.4)
Wk 12	3	(6.7)	3	(6.7)	5	(11.1)	11	(24.4)	8	(14.0)	6	(10.5)	10	(17.5)	24	(42.1)	11	(10.8)	9	(8.8)	15	(14.7)	35	(34.3)
Wk 16	5	(11.1)	4	(8.9)	9	(20.0)	18	(40.0)	8	(14.0)	8	(14.0)	13	(22.8)	29	(50.9)	13	(12.7)	12	(11.8)	22	(21.6)	47	(46.1)
Wk 20	5	(11.1)	4	(8.9)	9	(20.0)	18	(40.0)	10	(17.5)	9	(15.8)	13	(22.8)	32	(56.1)	15	(14.7)	13	(12.7)	22	(21.6)	50	(49.0)
Wk 24	5	(11.1)	4	(8.9)	10	(22.2)	19	(42.2)	10	(17.5)	9	(15.8)	13	(22.8)	32	(56.1)	15	(14.7)	13	(12.7)	23	(22.5)	51	(50.0)
Post Wk 24	5	(11.1)	4	(8.9)	10	(22.2)	19	(42.2)	10	(17.5)	9	(15.8)	13	(22.8)	32	(56.1)	15	(14.7)	13	(12.7)	23	(22.5)	51	(50.0)

Source Table 13.3.3 Section 10; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

*Other includes protocol deviations including non compliance, lost to follow-up, unknown, and non-study related personal reasons

One patient (716.004.27702), age group children, was withdrawn during the post week 24 visit window and is therefore not included in ths summary

4.3 Protocol Violations

Protocol violations were not defined for this open-label extension study.

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics of the overall ITT population are summarized by acute study treatment group, primary diagnosis and age group in Table 12. All demographic data were collected at acute study baseline.

There were more male patients (57.0%, 126/221) than female patients (43.0%, 95/221). The mean age of patients was 11.5 years. Overall, 84.2% (186/221) of patients were white, 8.1% (18/221) were black and 7.7% (17/221) were categorized as other. Other included 11 Hispanic and 1 mixed Hispanic and white; 2 American Indian; 1 Indian; and 2 biracial patients.

The proportion of females in the acute study paroxetine group (47.9%, 45/94) was higher than in the acute study placebo group (39.4%, 50/127), and the proportion of males in the acute study paroxetine group (52.1%, 49/94) was lower than in the acute study placebo group (60.6%, 77/127).

The mean ages of children in both acute study treatment groups were similar (9.0 years and 9.4 years in the paroxetine and placebo groups, respectively), as were mean ages of adolescents (14.2 years in both acute study treatment groups), with an overall mean pediatric age of 11.5 years. The mean height, weight and BMI of children were similar in both acute study treatment groups, as were mean height, weight and BMI of adolescents.

The demographic characteristics of the population of patients with a primary diagnosis of MDD were similar to the population of patients with a primary diagnosis of OCD.

Table 12 Demographic Characteristics by Diagnosis, Age Group and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group								
		Paroxetine			Placebo			Total	
	Total	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents
Primary Diagnosis: Total	**(N=94)**	**(N=49)**	**(N=45)**	**(N=127)**	**(N=70)**	**(N=57)**	**(N=221)**	**(N=119)**	**(N=102)**
Gender [n (%)]									
Female	45 (47.9)	27 (55.1)	18 (40.0)	50 (39.4)	26 (37.1)	24 (42.1)	95 (43.0)	53 (44.5)	42 (41.2)
Male	49 (52.1)	22 (44.9)	27 (60.0)	77 (60.6)	44 (62.9)	33 (57.9)	126 (57.0)	66 (55.5)	60 (58.8)
Age (years)									
Mean (SD)	11.5 (3.00)	9.0 (1.42)	14.2 (1.49)	11.6 (2.83)	9.4 (1.32)	14.2 (1.73)	11.5 (2.90)	9.3 (1.37)	14.2 (1.62)
Range	6 –17	6 – 11	12 – 17	7 –17	7 – 11	12 – 17	6 –17	6 – 11	12 –17
Race [n (%)]									
White	77 (81.9)	40 (81.6)	37 (82.2)	109 (85.8)	61 (87.1)	48 (84.2)	186 (84.2)	101 (84.9)	85 (83.3)
Black	7 (7.4)	4 (8.2)	3 (6.7)	11 (8.7)	7 (10.0)	4 (7.0)	18 (8.1)	11 (9.2)	7 (6.9)
Oriental	-	-	-	-	-	-	-	-	-
Other*	10 (10.6)	5 (10.2)	5 (11.1)	7 (5.5)	2 (2.9)	5 (8.8)	17 (7.7)	7 (5.9)	10 (9.8)
Height (cm)									
Mean (SD)	152.43 (17.57)	139.83 (12.89)	166.15 (10.10)	150.80 (16.46)	138.80 (10.33)	165.79 (8.35)	151.50 (16.92)	139.23 (11.41)	165.95 (9.13)
Range	114.5 – 188.0	114.5 – 165.0	139.5 – 188.0	115.6 – 180.3	115.6 – 161.0	149.9 – 188.3	114.5 –188.0	114.5 – 165.0	139.5 – 188.0
Weight (kg)**									
Mean (SD)	55.16 (22.96)	41.73 (16.42)	69.78 (20.02)	51.54 (22.24)	38.82 (14.62)	67.45 (19.82)	53.09 (22.57)	40.02 (15.38)	68.49 (19.85)
Range	20.4 – 132.6	20.4 – 70.95	32.5 – 132.6	20.5 – 131.4	20.5 – 104.0	38.2 – 131.4	20.4 – 132.6	20.4 – 104.0	32.5 – 132.6
BMI (kg/m^2)									
Mean (SD)	22.84 (6.51)	20.72 (5.68)	25.16 (6.63)	21.80 (6.22)	19.73 (5.28)	24.73 (6.47)	22.25 (6.35)	20.14 (5.44)	24.73 (6.47)
Range	13.9 – 45.9	13.9 – 32.8	16.5 – 45.9	13.6 – 45.4	13.6 –40.1	16.4 – 45.9	13.6 – 45.9	13.6 – 40.1	16.4 – 45.9

Source Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B

*Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient) and biracial (2 patients)

**Weight measured in pounds was converted to kilograms using the conversion 1lb = 0.454 kg

Height, weight and BMI data are missing for one patient (placebo, adolescent, primary diagnosis of OCD)

Table 12 Demographic Characteristics by Diagnosis, Age Group and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group								
		Paroxetine			Placebo			Total	
	Total	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents
Primary Diagnosis: MDD	**(N=50)**	**(N=25)**	**(N=25)**	**(N=66)**	**(N=36)**	**(N=30)**	**(N=116)**	**(N=61)**	**(N=55)**
Gender [n (%)]									
Female	23 (46.0)	14 (56.0)	9 (36.0)	29 (43.9)	14 (38.9)	15 (50.0)	52 (44.8)	28 (45.9)	24 (43.6)
Male	27 (54.0)	11 (44.0)	16 (64.0)	37 (56.1)	22 (61.1)	15 (50.0)	64 (55.2)	33 (54.1)	31 (56.4)
Age (years)									
Mean (SD)	11.6 (2.82)	9.2 (1.34)	14.0 (1.50)	11.6 (2.94)	9.4 (1.29)	14.3 (1.86)	11.6 (2.88)	9.3 (1.31)	14.2 (1.70)
Range	7 – 17	7 – 11	12 – 17	7 – 17	7 - 11	12 – 17	7 – 17	7 – 11	12 – 17
Race [n (%)]									
White	39 (78.0)	19 (76.0)	20 (80.0)	54 (81.8)	30 (83.3)	24 (80.0)	93 (80.2)	49 (80.3)	44 (80.0)
Black	4 (8.0)	2 (8.0)	2 (8.0)	7 (10.6)	4 (11.1)	3 (10.0)	11 (9.5)	6 (9.8)	5 (9.1)
Oriental	-	-	-	-	-	-	0	-	-
Other*	7 (14.0)	4 (16.0)	3 (12.0)	5 (7.6)	2 (5.6)	3 (10.0)	12 (10.3)	6 (9.8)	6 (10.9)
Height (cm)									
Mean (SD)	152.93(16.34)	140.35 (12.59)	165.51 (7.53)	150.15 (16.36)	138.00 (10.36)	164.73 (8.21)	151.35 (16.34)	138.96 (11.29)	165.09 (7.85)
Range	120.0 – 180.3	120.0 - 165.0	143.5 – 180.3	119.4 – 180.3	119.4 – 160.0	149.9 – 180.3	119.4 – 180.3	119.4 – 165.0	143.5 – 180.3
Weight (kg)**									
Mean (SD)	57.63 (22.83)	44.41 (15.06)	70.86 (21.75)	52.91 (23.53)	40.20 (14.81)	68.15 (23.14)	54.94 (23.25)	41.93 (14.93)	69.38 (22.36)
Range	24.9 – 132.6	24.9 - 74.0	40.9 – 132.6	21.8 – 131.4	21.8 – 89.0	40.0 – 131.4	21.8 – 132.6	21.8 – 89.0	40.0 – 132.6
BMI (kg/m^2)									
Mean (SD)	23.90 (6.46)	22.13 (5.48)	25.66 (6.97)	22.56 (6.63)	20.68 (5.62)	24.83 (7.12)	23.14 (6.56)	21.27 (5.56)	25.21 (7.00)
Range	15.1 – 45.9	15.1 – 31.0	17.4 – 45.9	13.6 – 45.4	13.6 – 34.8	16.9 – 45.4	13.6 – 45.9	13.6 – 34.8	16.9 – 45.9

Source Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B

*Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient) and biracial (2 patients)

**Weight measured in pounds was converted to kilograms using the conversion 1lb = 0.454 kg

Height, weight and BMI data are missing for one patient (placebo, adolescent, primary diagnosis of OCD)

Table 12 Demographic Characteristics by Diagnosis, Age Group and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group								
		Paroxetine			Placebo			Total	
	Total	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents
Primary Diagnosis: OCD	**(N=44)**	**(N=24)**	**(N=20)**	**(N=61)**	**(N=34)**	**(N=27)**	**(N=105)**	**(N=58)**	**(N=47)**
Gender [n (%)]									
Female	22 (50.0)	13 (54.2)	9 (45.0)	21 (34.4)	12 (35.3)	9 (33.0)	43 (41.0)	25 (43.1)	18 (38.3)
Male	22 (50.0)	11 (45.8)	11 (55.0)	40 (65.6)	22 (64.7)	18 (66.7)	62 (59.0)	33 (56.9)	29 (61.7)
Age (years)									
Mean (SD)	11.5 (3.22)	8.9 (1.51)	14.6 (1.47)	11.5 (2.73)	9.5 (1.38)	14.1 (1.59)	11.5 (2.93)	9.2 (1.45)	14.3 (1.54)
Range	6 – 17	6 -11	12 - 17	7 – 17	7 – 11	12 –17	6 –17	6 – 11	12 – 17
Race [n (%)]									
White	38 (86.4)	21 (87.5)	17 (85.0)	55 (90.2)	31 (91.2)	24 (88.9)	93 (88.6)	52 (89.7)	41 (87.2)
Black	3 (6.8)	2 (8.3)	1 (5.0)	4 (6.6)	3 (8.8)	1 (3.7)	7 (6.7)	5 (8.6)	2 (4.3)
Oriental	-	-	-	-	-	-	-	-	-
Other*	3 (6.8)	1 (4.2)	2 (10.0)	2 (3.3)	-	2 (7.4)	5 (4.8)	1 (1.7)	4 (8.5)
Height (cm)									
Mean (SD)	151.87 (19.05)	139.30 (13.43)	166.96 (12.78)	151.51 (16.67)	139.66 (10.38)	167.02 (8.51)	151.66 (17.63)	139.51 (11.63)	166.9 (10.45)
Range	114.5 – 188.0	114.5 – 161.3	139.5 – 188.0	115.6 – 180.3	115.6 – 161.0	151.3 – 180.3	114.5 – 188.0	114.5 to 161.3	139.5 – 188.0
Weight (kg)**									
Mean (SD)	52.35 (23.05)	38.94 (17.60)	68.45 (18.09)	50.04 (20.83)	37.35 (14.48)	66.63 (15.55)	51.02 (21.72)	38.01 (15.72)	67.42 (16.54)
Range	20.4 – 110.9	20.4 – 79.5	32.5 – 110.9	20.5 – 104.0	20.5 – 104.0	38.2 – 100.9	20.4 – 110.9	20.4 – 104.0	32.5 – 110.9
BMI (kg/m^2)									
Mean (SD)	21.65 (6.44)	19.24 (5.60)	24.53 (6.31)	20.97 (5.67)	18.74 (4.78)	23.89 (5.49)	21.26 (5.99)	18.95 (5.09)	24.17 (5.80)
Range	13.9 – 41.9	13.9 – 32.8	16.5 – 41.9	13.7 – 40.1	13.7 – 40.1	16.4 – 37.7	13.7 – 41.9	13.7 – 40.1	16.4 – 41.9

Source Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B

*Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient) and biracial (2 patients)

**Weight measured in pounds was converted to kilograms using the conversion 1lb = 0.454 kg

Height, weight and BMI data are missing for one patient (placebo, adolescent, primary diagnosis of OCD)

4.4.2 Baseline Characteristics

Summary statistics for CDRS-R total scores at study 716 baseline by acute study treatment group and age group are presented in Table 13. At the study 716 baseline, the mean CDRS-R total scores were similar irrespective of acute study treatment group or age group. The overall mean CDRS-R total score was 37.1 (SD 13.60).

Summary statistics for CY-BOCS total scores at study 716 baseline by acute study treatment group and age group are presented in Table 14. At the study 716 baseline, patients who had received paroxetine in their acute study had lower mean CY-BOCS scores compared to patients who had received placebo in their acute study, reflecting the statistically significant positive effect of paroxetine demonstrated in study 704. The mean CY-BOCS total score for patients who had received paroxetine in their acute study was 16.5 (SD 8.86) and for patients who had received placebo in their acute study 19.9 (SD 7.59).

Table 13 Summary Statistics for CDRS-R Total Scores at Study 716 Baseline by Acute Study Treatment Group and Age Group (ITT Population with Primary Diagnosis of MDD)

716 Baseline	Acute Study Treatment Group											
	Paroxetine (N=50)				Placebo (N=66)				Total (N=116)			
	n	Mean	(SD)	Range	n	Mean	(SD)	Range	n	Mean	(SD)	Range
CDRS-R Total Scores												
Children	22	37.8	(15.12)	18 to 75	36	35.3	(12.92)	17 to 68	58	36.2	(13.72)	17 to 75
Adolescents	24	35.8	(11.55)	20 to 58	29	39.9	(14.92)	19 to 73	53	38.1	(13.54)	19 to 73
Total	46	36.7	(13.26)	18 to 75	65	37.3	(13.93)	17 to 73	111	37.1	(13.60)	17 to 75

Source Table 13.6.1b, Section 10; Listing 14.1.1, Appendix C

Table 14 Summary Statistics for CY-BOCS Total Scores at Study 716 Baseline by Acute Study Treatment and Age Group (ITT Population with Primary Diagnosis of OCD)

716 Baseline	Acute Study Treatment Group											
	Paroxetine (N=44)				Placebo (N=61)				Total (N=105)			
	n	Mean	(SD)	Range	n	Mean	(SD)	Range	n	Mean	(SD)	Range
CY-BOCS Total Scores												
Children	23	15.0	(9.65)	0 to 35	33	19.0	(8.38)	0 to 34	56	17.3	(9.06)	0 to 35
Adolescents	19	18.4	(7.65)	8 to 34	27	20.9	(6.50)	0 to 35	46	19.9	(7.03)	0 to 35
Total	42	16.5	(8.86)	0 to 35	60	19.9	(7.59)	0 to 35	102	18.5	(8.27)	0 to 35

Source Table 13.7.1b, Section 10; Listing 14.2.1, Appendix C

The number and percentage of patients in each category of the CGI-Severity of Illness item at study 716 baseline by primary diagnosis, age group, and acute study treatment group are presented in Table 15.

For patients with a primary diagnosis of MDD, the majority of patients in both acute study treatment groups and both age groups were rated as moderately ill (34.5%, 40/116) or mildly ill (25.9%, 30/116) at study 716 baseline. The majority of patients in the acute study paroxetine group were mildly ill (38%, 19/50), while the majority of patients in the acute study placebo group were moderately ill (42.4%, 28/66).

For patients with a primary diagnosis of OCD, the majority of patients in both acute study treatment groups were rated as moderately ill at study 716 baseline [43.2% (19/44) and 47.5% (29/61) of patients receiving paroxetine or placebo, respectively, in their acute study]. However, there was a greater percentage of normal or borderline mentally ill patients in the acute study paroxetine group (20.5%, 9/44) compared to the acute study placebo group (6.6%, 4/61). Further, there were no severely ill patients in the acute study paroxetine group, but 6.6% (4/61) of patients in the acute study placebo group were rated as severely ill. There were also notable differences between children and adolescents with OCD in CGI-Severity of illness scores at study 716 baseline. A greater percentage of children (19.0%, 11/58) were normal or borderline mentally ill compared to adolescents (4.3%, 2/47).

Table 15 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Study 716 Baseline by Primary Diagnosis, Age Group, and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: MDD	(N=50)		(N=25)		(N=25)		(N=66)		(N=36)		(N=30)		(N=116)		(N=61)		(N=55)	
Normal, not at all ill	7	(14.0)	4	(16.0)	3	(12.0)	10	(15.2)	5	(13.9)	5	(16.7)	17	(14.7)	9	(14.8)	8	(14.5)
Borderline mentally ill	7	(14.0)	4	(16.0)	3	(12.0)	14	(21.2)	7	(19.4)	7	(23.3)	21	(18.1)	11	(18.0)	10	(18.2)
Mildly ill	19	(38.0)	7	(28.0)	12	(48.0)	11	(16.7)	5	(13.9)	6	(20.0)	30	(25.9)	12	(19.7)	18	(32.7)
Moderately ill	12	(24.0)	6	(24.0)	6	(24.0)	28	(42.4)	17	(47.2)	11	(36.7)	40	(34.5)	23	(37.7)	17	(30.9)
Markedly ill	3	(6.0)	2	(8.0)	1	(4.0)	3	(4.5)	2	(5.6)	1	(3.3)	6	(5.2)	4	(6.6)	2	(3.6)
Severely ill	1	(2.0)	1	(4.0)	0	-	-	-	0	-	0	-	1	(0.9)	1	(1.6)	0	-
Among most extremely ill	-	-	0	-	0	-	-	-	0	-	0	-	0	-	0	-	0	-
Total	49	(98.0)	24	(96.0)	25	(100)	66	(100)	36	(100)	30	(100)	115	(99.1)	60	(98.4)	55	(100)
Primary Diagnosis: OCD	(N=44)		(N=24)		(N=20)		(N=61)		(N=34)		(N=27)		(N=105)		(N=58)		(N=47)	
Normal, not at all ill	3	(6.8)	3	(12.5)	0	-	3	(4.9)	2	(5.9)	1	(3.7)	6	(5.7)	5	(8.6)	1	(2.1)
Borderline mentally ill	6	(13.6)	5	(20.8)	1	(5.0)	1	(1.6)	1	(2.9)	0	-	7	(6.7)	6	(10.3)	1	(2.1)
Mildly ill	9	(20.5)	3	(12.5)	6	(30.0)	10	(16.4)	7	(20.6)	3	(11.1)	19	(18.1)	10	(17.2)	9	(19.1)
Moderately ill	19	(43.2)	10	(41.7)	9	(45.0)	29	(47.5)	13	(38.2)	16	(59.3)	48	(45.7)	23	(39.7)	25	(53.2)
Markedly ill	7	(15.9)	3	(12.5)	4	(20.0)	13	(21.3)	7	(20.6)	6	(22.2)	20	(19.0)	10	(17.2)	10	(21.3)
Severely ill	0	-	0	-	0	-	4	(6.6)	3	(8.8)	1	(3.7)	4	(3.8)	3	(5.2)	1	(2.1)
Among most extremely ill	0	-	0	-	0	-	-	-	0	-	0	-	0	-	0	-	0	-
Total	44	(100)	24	(100)	20	(100)	60	(98.4)	33	(97.1)	27	(100)	104	(99.0)	57	(98.2)	47	(100)

Source Table 13.8.1b, Section 10; Listing 14.4.1, Appendix C

4.5 Adverse Events Occurring Prior to the Open-Label 716 Baseline

Listing 15.1.1, Appendix D, presents adverse events for each patient by acute study treatment group and age group, and provides details of the onset, severity, relationship to study drug, and duration of the events.

Table 15.1.1.0.1, Section 12 summarizes adverse events occurring prior to the start of acute study treatment by body system, preferred term, and acute study treatment group. A total of 19.1% (18/94) of acute study paroxetine patients and 15.0% (19/127) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment. There were no gender-specific adverse events reported prior to the start of acute study treatment. The most frequent adverse event was headache, which occurred in 6.4% (6/94) of acute study paroxetine patients and 3.1% (4/127) of acute study placebo patients.

Among patients with a primary diagnosis of MDD a total of 12.0% (6/50) of acute study paroxetine patients and 12.1% (8/66) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment. Among patients with a primary diagnosis of OCD a total of 27.3% (12/44) of acute study paroxetine patients and 18% (11/61) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment.

Table 15.1.1.0.2, Section 12 summarizes adverse events occurring prior to the start of acute study treatment and continuing into study 716 by body system, preferred term, and acute study treatment group. A total of 1.1% (1/94) of acute study paroxetine patients and 3.1% (4/127) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment which were ongoing at the study 716 baseline. There were no gender-specific adverse events reported prior to the start of acute study treatment which were ongoing at the study 716 baseline. All adverse events were reported by only one patient each.

Among patients with a primary diagnosis of MDD a total of 2.0% (1/50) of acute study paroxetine patients and 3.0% (2/66) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment which were ongoing at the study 716 baseline. Among patients with a primary diagnosis of OCD 0.0% (0/44) of acute study paroxetine patients and

3.3% (2/61) of acute study placebo patients reported one or more gender non-specific adverse events prior to the start of acute study treatment which were ongoing at the study 716 baseline.

Table 15.1.1.0.3, Section 12 summarizes adverse events occurring during the acute study treatment phase (including taper) and ongoing into study 716 by body system, preferred term, and acute study treatment group. A total of 29.8% (28/94) of acute study paroxetine patients and 18.9% (24/127) of acute study placebo patients reported one or more gender non-specific adverse events during the acute study treatment phase (including taper) which were ongoing at the study 716 baseline. The most frequently reported adverse events were somnolence [4.3% (4/94) of acute study paroxetine patients and 2.4% (3/127) of acute study placebo patients] and nervousness [4.3% (4/94) of acute study paroxetine patients and 1.6% (2/127) of acute study placebo patients]. One male patient in the acute study placebo group and one female patient in the acute study paroxetine group reported gender-specific adverse events during the acute study treatment phase (including taper) which were ongoing at the study 716 baseline.

Among patients with a primary diagnosis of MDD, a total of 28.0% (14/50) of acute study paroxetine patients and 16.7% (11/66) of acute study placebo patients reported one or more gender non-specific adverse events during the acute study treatment phase (including taper) which were ongoing at the study 716 baseline. The most frequently reported adverse event was somnolence, which occurred in 6.0% (3/50) of acute study paroxetine patients and 4.5% (3/66) of acute study placebo patients.

Among patients with a primary diagnosis of OCD a total of 31.8% (14/44) of acute study paroxetine patients and 21.3% (13/61) of acute study placebo patients reported one or more gender non-specific adverse events during the acute study treatment phase (including taper) which were ongoing at the study 716 baseline. The most frequently reported adverse event was nervousness, which occurred in 6.8% (3/44) of acute study paroxetine patients and 3.3% (2/61) of acute study placebo patients.

4.6 Concomitant Medications

Table 16 presents a summary of the most frequently reported (≥5%) concomitant medications taken during the open-label treatment phase by therapeutic class. A total of 64.3% (142/221) of the ITT population were reported to have taken at least one concomitant medication, 64.9% (61/94) of patients in the acute study

paroxetine group and 63.8% (81/127) patients in the acute study placebo group. The proportion of patients taking each medication by therapeutic class was generally similar between the acute study treatment groups.

The most frequently reported concomitant medications by therapeutic class were central nervous system agents, primarily paracetamol and ibuprofen for pain, and respiratory agents, primarily pseudoephedrine hydrochloride, diphenhdramine hydrochloride, loratadine, paracetamol, and dextromethorphan hydrochloride for cold and flu symptoms and allergies. The most frequent single medication used was paracetamol, taken by 31.9% (30/94) of patients in the acute study paroxetine group and 19.7% (25/127) of patients in the acute study placebo group (Table 13.9.2, Section 10). The concomitant use of any psychotropic drug, other than paroxetine, was contraindicated during the study.

Eleven patients had paroxetine listed as a concomitant medication during the open-label treatment phase (Section 3.14.10 Data Irregularities).

A complete summary by WHO ATC generic names and the Level I drug classification system may be found in Table 13.9.1, Section 10, in which medications that are part of combination products may be counted in more than one ATC level. A complete summary by generic name in order of decreasing frequency may be found in Table 13.9.2, Section 10, in which components are counted only once. Per-patient details, including dosage, indication, and starting and ending days relative to start and end of open-label study medication may be found in Listing 13.9.1, Appendix B.

Table 16 Frequently Reported (≥5%) Concomitant Medications During the Open-Label Treatment Phase (Excluding Taper Phase) by Therapeutic Classes and Acute Study Treatment Group (ITT Population)

Therapeutic Class and Medication	Acute Study Treatment Group					
	Paroxetine (N= 94)		Placebo (N=127)		Total (N=221)	
	n	(%)	n	(%)	n	(%)
Total*	61	(64.9)	81	(63.8)	142	(64.3)
Alimentary tract/metab	18	(19.1)	28	(22.0)	46	(20.8)
Vitamins nos	8	(8.5)	6	(4.7)	14	(6.3)
Antiinfectives, systemic	22	(23.4)	26	(20.5)	48	(21.7)
Azithromycin	4	(4.3)	7	(5.5)	11	(5.0)
Central Nervous System	39	(41.5)	57	(44.9)	96	(43.4)
Paracetamol	30	(31.9)	25	(19.7)	55	(24.9)
Ibuprofen	19	(20.2)	26	(20.5)	45	(20.4)
Paroxetine	3	(3.2)	8	(6.3)	11	(5.0)
Pseudoephedrine hydrochloride	5	(5.3)	5	(3.9)	10	(4.5)
Dermatologicals	15	(16.0)	31	(24.4)	46	(20.8)
Diphenhydramine hydrochloride	7	(7.4)	11	(8.7)	18	(8.1)
Muscoskeletal	23	(24.5)	28	(22.0)	51	(23.1)
Ibuprofen	19	(20.2)	26	(20.5)	45	(20.4)
Respiratory	34	(36.2)	53	(41.7)	87	(39.4)
Pseudoephedrine hydrochloride	14	(14.9)	10	(7.9)	24	(10.9)
Diphenhydramine hydrochloride	8	(8.5)	13	(10.2)	21	(9.5)
Loratadine	10	(10.6)	10	(7.9)	20	(9.0)
Paracetamol	10	(10.6)	8	(6.3)	18	(8.1)
Dextromethorphan Hydrobromide	7	(7.4)	5	(3.9)	12	(5.4)

Source Table 13.9.1, Section 10; Listing 13.9.1, Appendix B

Medications sorted by descending frequency in the total group within each therapeutic class.

* Total patients with a concomitant medication. Patients taking multiple concomitant medications are counted only once.

See Data Irregularities, Section 3.14.10 for concomitant use of paroxetine

During the taper and follow-up phases, concomitant medication usage was reported for 102.0% (51/50) and 97.1% (67/69) of the acute study paroxetine and acute study placebo patients, respectively [Table 13.9.3 (by Level I classification and generic name) and Table 13.9.4 (by generic name in order of decreasing frequency), Section 10, and Listing 13.9.1, Appendix B]. (Note: Tables 13.9.3 and 13.9.4 may include concomitant medication usage for some patients that did not enter the follow-up phase but had a concomitant medication which was started before the last dose of open-label study/taper medication and had a missing stop date). The medications most frequently used (≥ 15% of patients in either acute study treatment group) during the follow-up phase, excluding paroxetine, were vitamins in the acute study paroxetine group [16.0% (8/50) compared with 8.7% (6/69) in the acute study placebo group] and ibuprofen in the acute study placebo group [15.9% (11/69) compared with 14.0% (7/50) patients in the acute study paroxetine group].

A total of 34.0% (17/50) of patients in the acute study paroxetine group and 23.2% (16/69) of patients in the acute study placebo group took paroxetine during the follow-up phase, or during the taper phase in addition to scheduled taper medication. This includes patients who did not taper and started taking paroxetine as a concomitant medication in the follow-up phase following the open-label treatment phase, patients who tapered and started taking paroxetine as a concomitant medication during the follow-up phase following the taper phase (Table 13.9.3, Section 10, Listing 13.9.1, Appendix B, and the nine patients with data irregularities described in Section 3.14.10.

4.7 Treatment Compliance and Titration

4.7.1 Treatment Compliance

A summary of compliance (patients who missed more than 3 consecutive days study medication at any time during the study) by each visit interval is presented in Table 17. Patients with unknown compliance and a duration of study medication of > 3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit. The majority of patients (75.5%, 166/221) did not miss > 3 consecutive days of study medication at any time during the study. The percentage of patients who missed > 3 consecutive days study medication at any time was slightly greater in the acute study paroxetine group, 28.7% (27/94) of patients, than in the acute study placebo group, 21.4% (27/127) of patients (Table 13.10.1, Section 10; Listing 13.10.1, Appendix B). This slight imbalance was more pronounced among adolescents:

31.1% (14/45) of patients in the acute study paroxetine group missed >3 consecutive days study medication at any time during the study, compared with 17.5% (10/57) in the acute study placebo group. The corresponding numbers in children were 26.5% (13/49) of patients in the acute study paroxetine group compared with 24.6% (17/70) of patients in the acute study placebo group.

Patients missing > 3 consecutive days of dosing on more than one occasion were to be withdrawn from the study. Of the 54 patients reported by the investigators as missing >3 consecutive days of dosing, 6 patients did so on more than one occasion (Listing 13.10.1, Appendix B). However, only two patients were withdrawn from the study for non-compliance. Patient 716.176.27170 in the acute study paroxetine group had unknown entered in response to the compliance question, missed > 3 consecutive days of study medication, at the week 8 visit and week 12 visit. This patient was withdrawn due to a protocol violation (including non-compliance) at the week 12 visit. Patient 716.004.27003 in the acute study placebo group was listed as non-compliant at the week 16 visit and week 20 visit. This patient was withdrawn due to a protocol violation (including non-compliance) at the week 20 visit.

As stated, six patients were reported by the investigators as missing >3 consecutive days of dosing on more than one occasion. Table 17 indicates, however, that 13 patients missed > 3 consecutive days on more than one occasion. This apparent discrepancy between the investigator's report and Table 17 results from the fact that compliance data was missing for a number of patients for at least one of the occasions recorded in Table 17, but the patient was not reported by the investigator as missing > 3 consecutive days of dosing on that occasion.

Table 17 Summary of Patients Missing >3 Consecutive Days Open-Label Study Medication at Each Visit and Overall, Excluding Taper Phase by Age Group and Acute Study Treatment Group (ITT Population) Continued…

Missed > 3 Consecutive Days	Acute Study Treatment Group								Total			
	Paroxetine				Placebo							
	No		Yes		No		Yes		No		Yes	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	**(N = 94)**				**(N = 127)**				**(N = 221)**			
Week 1	88	(93.6)	6	(6.4)	124	(98.4)	2	(1.6)	212	(96.4)	8	(3.6)
Week 2	84	(98.8)	1	(1.2)	118	(98.3)	2	(1.7)	202	(98.5)	3	(1.5)
Week 3	84	(94.4)	5	(5.6)	111	(95.7)	5	(4.3)	195	(95.1)	10	(4.9)
Week 4	85	(97.7)	2	(2.3)	105	(98.1)	2	(1.9)	190	(97.9)	4	(2.1)
Week 6	83	(98.8)	1	(1.2)	101	(98.1)	2	(1.9)	184	(98.4)	3	(1.6)
Week 8	74	(91.4)	7	(8.6)	87	(94.6)	5	(5.4)	161	(93.1)	12	(6.9)
Week 12	63	(94.0)	4	(6.0)	72	(93.5)	5	(6.5)	135	(93.8)	9	(6.3)
Week 16	54	(94.7)	3	(5.3)	62	(92.5)	5	(7.5)	116	(93.5)	8	(6.5)
Week 20	45	(100.0)	0	-	46	(95.8)	2	(4.2)	91	(97.8)	2	(2.2)
Week 24	38	(90.5)	4	(9.5)	32	(88.9)	4	(11.1)	70	(89.7)	8	(10.3)
Overall **	67	(71.3)	27	(28.7)	99	(78.6)	27	(21.4)	166	(75.5)	54	(24.5)

Source Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

** Overall number of patients who miss > 3 consecutive days at any point in the study. Patients missing > 3 consecutive days on more than one occasion are only counted once.

Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

Table 17 Summary of Patients Missing >3 Consecutive Days Open-Label Study Medication at Each Visit and Overall, Excluding Taper Phase by Age Group and Acute Study Treatment Group (ITT Population) Continued…

Missed > 3 Consecutive Days	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	No		Yes		No		Yes		No		Yes	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Children	(N = 49)				(N = 70)				(N = 119)			
Week 1	46	(93.9)	3	(6.1)	69	(100.0)	0	-	115	(97.5)	3	(2.5)
Week 2	42	(100.0)	0	-	66	(98.5)	1	(1.5)	108	(99.1)	1	(0.9)
Week 3	45	(97.8)	1	(2.2)	62	(95.4)	3	(4.6)	107	(96.4)	4	(3.6)
Week 4	43	(97.7)	1	(2.3)	58	(98.3)	1	(1.7)	101	(98.1)	2	(1.9)
Week 6	43	(100.0)	0	-	56	(98.2)	1	(1.8)	99	(99.0)	1	(1.0)
Week 8	38	(90.5)	4	(9.5)	48	(94.1)	3	(5.9)	86	(92.5)	7	(7.5)
Week 12	30	(93.8)	2	(6.3)	38	(90.5)	4	(9.5)	68	(91.9)	6	(8.1)
Week 16	25	(96.2)	1	(3.8)	32	(94.1)	2	(5.9)	57	(95.0)	3	(5.0)
Week 20	24	(100.0)	0	-	25	(96.2)	1	(3.8)	49	(98.0)	1	(2.0)
Week 24	20	(90.9)	2	(9.1)	16	(84.2)	3	(15.8)	36	(87.8)	5	(12.2)
Overall **	36	(73.5)	13	(26.5)	52	(75.4)	17	(24.6)	88	(74.6)	30	(25.4)

Source Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

** Overall number of patients who miss > 3 consecutive days at any point in the study. Patients missing > 3 consecutive days on more than one occasion are only counted once.

Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

Table 17 Summary of Patients Missing >3 Consecutive Days Open-Label Study Medication at Each Visit and Overall, Excluding Taper Phase by Age Group and Acute Study Treatment Group (ITT Population)

Missed > 3 Consecutive Days	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	No		Yes		No		Yes		No		Yes	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents	**(N = 45)**				**(N = 57)**				**(N = 102)**			
Week 1	42	(93.3)	3	(6.7)	55	(96.5)	2	(3.5)	97	(95.1)	5	(4.9)
Week 2	42	(97.7)	1	(2.3)	52	(98.1)	1	(1.9)	94	(97.9)	2	(2.1)
Week 3	39	(90.7)	4	(9.3)	49	(96.1)	2	(3.9)	88	(93.6)	6	(6.4)
Week 4	42	(97.7)	1	(2.3)	47	(97.9)	1	(2.1)	89	(97.8)	2	(2.2)
Week 6	40	(97.6)	1	(2.4)	45	(97.8)	1	(2.2)	85	(97.7)	2	(2.3)
Week 8	36	(92.3)	3	(7.7)	39	(95.1)	2	(4.9)	75	(93.8)	5	(6.3)
Week 12	33	(94.3)	2	(5.7)	34	(97.1)	1	(2.9)	67	(95.7)	3	(4.3)
Week 16	29	(93.5)	2	(6.5)	30	(90.9)	3	(9.1)	59	(92.2)	5	(7.8)
Week 20	21	(100.0)	0	-	21	(95.5)	1	(4.5)	42	(97.7)	1	(2.3)
Week 24	18	(90.0)	2	(10.0)	16	(94.1)	1	(5.9)	34	(91.9)	3	(8.1)
Overall **	31	(68.9)	14	(31.1)	47	(82.5)	10	(17.5)	78	(76.5)	24	(23.5)

Source Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

** Overall number of patients who miss > 3 consecutive days at any point in the study. Patients missing > 3 consecutive days on more than one occasion are only counted once.

Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

For each patient, counts of tablets dispensed and returned were recorded at each visit. Tablet accountability for each visit was determined according to the following calculation:

$$\left(\frac{\textit{No. of Tablets Dispensed - No. of Tablets Returned}}{\textit{No. of Days} \times \textit{No. of Tablets per Day}}\right) \times 100$$

If patients had a dose change(s) between visits, tablet accountability was summarized using the following calculation:

$$\left(\frac{\textit{Total No. of Tablets Dispensed for the Visit - Total No. of Tablets Returned for the Visit}}{\textit{Sum for Each Record in the CRF Corresponding to the Visit (No. of Days} \times \textit{No. of Tablets per Day)}}\right) \times 100$$

Overall tablet accountability was summarized using the following calculation:

$$\left(\frac{\textit{Total No. of Tablets Dispensed - Total No. of Tablets Returned}}{\textit{Sum for Each Visit (No. of Days} \times \textit{No. of Tablets per Day)}}\right) \times 100$$

If any of the data required to calculate tablet accountability were missing, accountability was not calculated.

Patients were tabulated according to whether or not the results of these calculations were ≥ 80% and ≤ 120% (Table 13.10.2, Section, 10).

Overall accountability was high with 92.9% (131/141) within the range of ≥ 80% to ≤ 120% accountability at each visit. Between 78.1% and 92.7% of patients in the acute study paroxetine group and between 83.1% and 89.0% of patients in the acute study placebo group fell within the range of ≥ 80% to ≤ 120% accountability at each visit (Table 18). The pattern of accountability was similar among acute study paroxetine patients and acute study placebo patients in both age groups with the following exceptions: week 6 where accountability fell to 75.0% (30/45) among adolescents in the acute study paroxetine group compared with 93.0% (40/57) for adolescents in the acute study placebo group, and week 12 where accountability fell to 78.8% (26/45) among adolescents in the acute study paroxetine group compared with 90.3% (28/57) for adolescents in the acute study placebo group.

Table 18 Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute Study Treatment Group (ITT Population) Continued…

	Acute Study Treatment Group											
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Total	**Paroxetine (N = 94)**				**Placebo (N = 127)**				**Total (N = 221)**			
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Week 1	75	(85.2)	13	(14.8)	105	(85.4)	18	(14.6)	180	(85.3)	31	(14.7)
Week 2	68	(84.0)	13	(16.0)	102	(86.4)	16	(13.6)	170	(85.4)	29	(14.6)
Week 3	74	(88.1)	10	(11.9)	97	(89.0)	12	(11.0)	171	(88.6)	22	(11.4)
Week 4	72	(84.7)	13	(15.3)	86	(84.3)	16	(15.7)	158	(84.5)	29	(15.5)
Week 6	62	(79.5)	16	(20.5)	87	(87.0)	13	(13.0)	149	(83.7)	29	(16.3)
Week 8	57	(78.1)	16	(21.9)	74	(83.1)	15	(16.9)	131	(80.9)	31	(19.1)
Week 12	50	(83.3)	10	(16.7)	60	(87.0)	9	(13.0)	110	(85.3)	19	(14.7)
Week 16	51	(92.7)	4	(7.3)	51	(85.0)	9	(15.0)	102	(88.7)	13	(11.3)
Week 20	33	(84.6)	6	(15.4)	39	(88.6)	5	(11.4)	72	(86.7)	11	(13.3)
Week 24	33	(86.8)	5	(13.2)	27	(84.4)	5	(15.6)	60	(85.7)	10	(14.3)
Overall**	53	(93.0)	4	(7.0)	78	(92.9)	6	(7.1)	131	(92.9)	10	(14.3)

Source Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit.

* Accountability is defined as the result of the following calculation falling within the 80%-120% band: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / sum for each record in the CRF corresponding to a visit (no. of days x no. of tablets per day)] x 100.

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band: [(total no. of tablets dispensed- total no. of tablets returned) / (sum for each visit (number of days x no. of tablets per day))] x 100

Accountability and overall accountability were calculated only if all data required were present

Table 18 Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute Study Treatment Group (ITT Population) Continued…

	Acute Study Treatment Group											
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Children	Paroxetine (N = 49)				Placebo (N = 70)				Total (N = 119)			
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Week 1	42	(89.4)	5	(10.6)	62	(93.9)	4	(6.1)	104	(92.0)	9	(8.0)
Week 2	37	(90.2)	4	(19.8)	59	(90.8)	6	(9.2)	96	(90.6)	10	(9.4)
Week 3	41	(93.2)	3	(6.8)	55	(88.7)	7	(11.3)	96	(90.6)	10	(9.4)
Week 4	36	(85.7)	6	(14.3)	48	(84.2)	9	(15.8)	84	(84.8)	15	(15.2)
Week 6	32	(84.2)	6	(15.8)	47	(82.5)	10	(17.5)	79	(83.2)	16	(16.8)
Week 8	29	(78.4)	8	(21.6)	39	(81.3)	9	(18.8)	68	(80.0)	17	(20.0)
Week 12	24	(88.8)	3	(11.1)	32	(84.2)	6	(15.8)	56	(86.2)	9	(13.8)
Week 16	24	(92.3)	2	(7.7)	24	(82.8)	5	(17.2)	48	(87.3)	7	(12.7)
Week 20	17	(85.0)	3	(15.0)	22	(91.7)	2	(8.3)	39	(88.6)	5	(11.4)
Week 24	16	(84.2)	3	(15.8)	12	(80.0)	3	(20.0)	28	(82.4)	6	(17.6)
Overall **	27	(96.4)	1	(3.6)	39	(88.6)	5	(11.4)	66	(91.7)	6	(8.3)

Source Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit.

* Accountability is defined as the result of the following calculation falling within the 80%-120% band: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / sum for each record in the CRF corresponding to a visit (no. of days x no. of tablets per day)] x 100.

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band: [(total no. of tablets dispensed- total no. of tablets returned) / (sum for each visit (number of days x no. of tablets per day))] x 100

Accountability and overall accountability were calculated only if all data required were present

Table 18 Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group											
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Adolescents	**Paroxetine (N = 45)**				**Placebo (N = 57)**				**Total (N = 102)**			
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Week1	33	(80.5)	8	(19.5)	43	(75.4)	14	(24.6)	76	(77.6)	22	(22.4)
Week 2	31	(77.5)	9	(22.5)	43	(81.1)	10	(18.9)	74	(79.6)	19	(20.4)
Week 3	33	(82.5)	7	(17.5)	42	(89.4)	5	(10.6)	75	(86.2)	12	(13.8)
Week 4	36	(83.7)	7	(16.3)	38	(84.4)	7	(15.6)	74	(84.1)	14	(15.9)
Week 6	30	(75.0)	10	(25.0)	40	(93.0)	3	(7.0)	70	(84.3)	13	(15.7)
Week 8	28	(77.8)	8	(22.2)	35	(85.4)	6	(14.6)	63	(81.8)	14	(18.2)
Week 12	26	(78.8)	7	(21.2)	28	(90.3)	3	(9.7)	54	(84.4)	10	(15.6)
Week 16	27	(93.1)	2	(6.9)	27	(87.1)	4	(12.9)	54	(90.0)	6	(10.0)
Week 20	16	(84.2)	3	(15.8)	17	(85.0)	3	(15.0)	33	(84.6)	6	(15.4)
Week 24	17	(89.5)	2	(10.5)	15	(88.2)	2	(11.8)	32	(88.9)	4	(11.1)
Overall**	26	(89.7)	3	(10.3)	39	(97.5)	1	(2.5)	65	(94.2)	4	(5.8)

Source Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit.

* Accountability is defined as the result of the following calculation falling within the 80%-120% band: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / sum for each record in the CRF corresponding to a visit (no. of days x no. of tablets per day)] x 100.

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band: [(total no. of tablets dispensed- total no. of tablets returned) / (sum for each visit (number of days x no. of tablets per day))] x 100

Accountability and overall accountability were calculated only if all data required were present

4.7.2 Titration of Dose

Patients entering study 716 from study 701 or 704 were to be started on therapy at 10 mg/day, however, not all patients were started at this dose. Starting at week 2, the dose of paroxetine could be increased by 10 mg/day up to a maximum dose of 50 mg/day, according to clinical response and tolerability. It was recommended that dose increases were initiated at clinic visits. Dose reductions of 10 mg/day at weekly intervals were also permitted at the discretion of the investigator.

The number and percentage of patients by maximum daily dosage of open-label study medication achieved at any time during the study is presented by primary diagnosis and age group for the ITT population in Table 19. In the overall population, 16.3% (36/221) of patients took a maximum dose of 50 mg/day. More adolescents than children were exposed to daily doses of paroxetine ≥ 40 mg/day. Among adolescents, 22.5% (23/102) took a maximum dose of 50 mg/day paroxetine for at least one dosing period compared with 10.9% (13/119) of children.

For patients with a primary diagnosis of MDD 10.3% (12/116) of patients took a maximum dose of 50 mg/day. There was no notable difference between age groups. For patients with a primary diagnosis of OCD 22.9% (24/105) of patients took a maximum dose of 50 mg/day. Of these patients, 10.3% (6/58) of children compared to 38.3% (18/47) of adolescents received a maximum dose of 50 mg/day. The proportion of adolescents receiving a maximum dose of 50 mg/day was higher in patients with a primary diagnosis of OCD (38.3%, 18/47) compared to patients with a primary diagnosis of MDD (9.1%, 5/55).

Table 19 Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication by Primary Diagnosis and Age Group (ITT Population)

Paroxetine Dosage	Age Group					
	Children		Adolescents		Total	
	n	(%)	n	(%)	n	(%)
Primary Diagnosis: Total	**(N=119)**		**(N= 102)**		**(N= 221)**	
10 mg/day	14	(11.8)	9	(8.8)	23	(10.4)
20 mg/day	38	(31.9)	16	(15.7)	54	(24.4)
30 mg/day	42	(35.3)	32	(31.4)	74	(33.5)
40 mg/day	12	(10.1)	22	(21.6)	34	(15.4)
50 mg/day	13	(10.9)	23	(22.5)	36	(16.3)
Primary Diagnosis: MDD	**(N= 61)**		**(N=55)**		**(N= 116)**	
10 mg/day	10	(16.4)	6	(10.9)	16	(13.8)
20 mg/day	17	(27.9)	10	(18.2)	27	(23.3)
30 mg/day	23	(37.7)	22	(40.0)	45	(38.3)
40 mg/day	4	(6.6)	12	(21.8)	16	(13.8)
50 mg/day	7	(11.5)	5	(9.1)	12	(10.3)
Primary Diagnosis: OCD	**(N=58)**		**(N=47)**		**(N=105)**	
10 mg/day	4	(6.9)	3	(6.4)	7	(6.7)
20 mg/day	21	(36.2)	6	(12.8)	27	(25.7)
30 mg/day	19	(32.8)	10	(21.3)	29	(27.6)
40 mg/day	8	(13.8)	10	(21.3)	18	(17.1)
50 mg/day	6	(10.3)	18	(38.3)	24	(22.9)

Source Table 13.10.4, Section 10; Listing 13.10.1, Appendix B

A summary of the number and percentage of patients with a primary diagnosis of MDD exposed to each study medication dosage of paroxetine by visit and age group is presented in Table 20. A total of 62.9% (73/116) of patients received a dose higher than 20 mg/day. Approximately half of the children (55.7%, 34/61) took a dose higher than 20 mg/day compared with 70.9% (39/55) of adolescents.

Table 20 Summary of the Number (%) of Patients with a Primary Diagnosis of MDD Exposed to Each Dosage of Paroxetine by Visit and Age Group (ITT Population) Continued…

Daily Dosage		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
	N*	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total											
Week 1	116	107	(92.2)	7	(6.0)	1	(0.9)	1	(0.9)	0	-
Week 2	109	42	(38.5)	60	(55.0)	6	(5.5)	1	(0.9)	0	-
Week 3	107	24	(22.4)	51	(47.7)	30	(28.0)	2	(1.9)	0	-
Week 4	104	19	(18.3)	47	(45.2)	31	(29.8)	7	(6.7)	0	-
Week 6	100	15	(15.0)	43	(43.0)	34	(34.0)	5	(5.0)	3	(3.0)
Week 8	94	12	(12.8)	36	(38.3)	35	(37.2)	11	(11.7)	0	-
Week 12	84	9	(10.7)	33	(39.3)	29	(34.5)	11	(13.1)	2	(2.4)
Week 16	75	9	(12.0)	24	(32.0)	30	(40.0)	8	(10.7)	4	(5.3)
Week 20	63	7	(11.1)	22	(34.9)	17	(27.0)	13	(20.6)	4	(6.3)
Week 24	55	6	(10.9)	21	(38.2)	16	(29.1)	6	(10.9)	6	(10.9)
Maximum**	116	16	(13.8)	27	(23.3)	45	(38.8)	16	(13.8)	12	(10.3)
Age Group: Children											
Week 1	61	56	(91.8)	4	(6.6)	0	-	1	(1.6)	0	-
Week 2	58	27	(46.6)	28	(48.3)	2	(3.4)	1	(1.7)	0	-
Week 3	56	16	(28.6)	25	(44.6)	14	(25.0)	1	(1.8)	0	-
Week 4	53	13	(24.5)	23	(43.4)	13	(24.5)	4	(7.5)	0	-
Week 6	52	11	(21.2)	21	(40.4)	15	(28.8)	4	(7.7)	1	(1.9)
Week 8	49	9	(18.4)	19	(38.8)	16	(32.7)	5	(10.2)	0	-
Week 12	43	7	(16.3)	17	(39.5)	13	(30.2)	5	(11.6)	1	(2.3)
Week 16	38	7	(18.4)	12	(31.6)	13	(34.2)	2	(5.3)	4	(10.5)
Week 20	31	5	(16.1)	10	(32.3)	9	(29.0)	4	(12.9)	3	(9.7)
Week 24	28	5	(17.9)	10	(35.7)	9	(32.1)	0	(0.0)	4	(14.3)
Maximum**	61	10	(16.4)	12	(27.9)	23	(37.3)	4	(6.6)	7	(11.5)

Source Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

* N is the number of patients in the study at each visit; percentages are based on N

** Represents the number of patients for whom the dosage was the maximum dosage during the study

Table 20 Summary of the Number (%) of Patients with a Primary Diagnosis of MDD Exposed to Each Dosage of Paroxetine by Visit and Age Group (ITT Population)

Daily Dosage		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
	N*	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents											
Week 1	55	51	(92.7)	3	(5.5)	1	(1.8)	0	-	0	-
Week 2	51	15	(29.4)	32	(62.7)	4	(7.8)	0	-	0	-
Week 3	51	8	(15.7)	26	(51.0)	16	(31.4)	1	(2.0)	0	-
Week 4	51	6	(11.8)	24	(47.1)	18	(35.3)	3	(5.9)	0	-
Week 6	48	4	(8.3)	22	(45.8)	19	(39.6)	1	(2.1)	2	(4.2)
Week 8	45	3	(6.7)	17	(37.8)	19	(42.2)	6	(13.3)	0	-
Week 12	41	2	(4.9)	16	(39.0)	16	(39.0)	6	(14.6)	1	(2.4)
Week 16	37	2	(5.4)	12	(32.4)	17	(45.9)	6	(16.2)	0	-
Week 20	32	2	(6.3)	12	(37.5)	8	(25.0)	9	(28.1)	1	(3.1)
Week 24	27	1	(3.7)	11	(40.7)	7	(25.9)	6	(22.2)	2	(7.4)
Maximum**	55	6	(10.9)	10	(18.2)	22	(40.0)	12	(21.8)	5	(9.1)

Source Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

* N is the number of patients in the study at each visit; percentages are based on N

** Represents the number of patients for whom the dose was the maximum dosage during the study

A summary of the number and percentage of patients with a primary diagnosis of OCD exposed to each study medication dosage of paroxetine by visit and age group is presented in Table 21. A total of 67.6% (71/105) of patients received a dose higher than 20 mg/day. Approximately half of the children (56.9%, 33/58) took a dose higher than 20 mg/day compared with 80.9% (38/47) of adolescents. Adolescents also reached higher doses earlier than children, with 44.4% (19/43) of adolescents receiving 30 mg/day at week 3 compared with 25.5% (14/55) of children.

Table 21 Summary of the Number (%) of Patients With a Primary Diagnosis of OCD Exposed to Each Dosage of Paroxetine by Visit and Age Group (ITT Population) Continued…

Daily Dosage		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
	N*	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total											
Week 1	105	100	(95.2)	5	(4.8)	0	-	0	-	0	-
Week 2	96	23	(24.0)	65	(67.7)	8	(8.3)	0	-	0	-
Week 3	98	11	(11.2)	48	(49.0)	33	(33.7)	6	(6.1)	0	-
Week 4	94	10	(10.6)	32	(34.0)	30	(31.9)	16	(17.0)	6	(6.4)
Week 6	91	8	(8.8)	26	(28.6)	27	(29.7)	17	(18.7)	13	(14.3)
Week 8	81	7	(8.6)	21	(25.9)	23	(28.4)	15	(18.5)	15	(18.5)
Week 12	60	3	(5.0)	19	(31.7)	15	(25.0)	7	(11.7)	16	(26.7)
Week 16	51	3	(5.9)	18	(35.3)	11	(21.6)	7	(13.7)	12	(23.5)
Week 20	32	4	(12.5)	13	(40.6)	6	(18.8)	4	(12.5)	5	(15.6)
Week 24	25	3	(12.0)	10	(40.0)	5	(20.0)	4	(16.0)	3	(12.0)
Maximum**	105	7	(6.7)	27	(25.7)	29	(27.6)	18	(17.1)	24	(22.9)
Age Group: Children											
Week 1	58	56	(96.6)	2	(3.4)	0	-	0	-	0	-
Week 2	51	16	(31.4)	32	(62.7)	3	(5.9)	0	-	0	-
Week 3	55	10	(18.2)	29	(52.7)	14	(25.5)	2	(3.6)	0	-
Week 4	52	7	(13.5)	24	(46.2)	14	(26.9)	5	(9.6)	2	(3.8)
Week 6	50	7	(14.0)	19	(38.0)	15	(30.0)	6	(12.0)	3	(6.0)
Week 8	44	6	(13.6)	13	(29.5)	16	(36.4)	4	(9.1)	5	(11.4)
Week 12	31	2	(6.5)	13	(41.9)	10	(32.3)	2	(6.5)	4	(12.9)
Week 16	24	2	(8.3)	11	(45.8)	5	(20.8)	4	(16.7)	2	(8.3)
Week 20	19	3	(15.8)	9	(47.4)	3	(15.8)	3	(15.8)	1	(5.3)
Week 24	15	3	(20.0)	7	(46.7)	2	(13.3)	3	(20.0)	0	-
Maximum**	58	4	(6.9)	21	(36.2)	19	(32.8)	8	(13.8)	6	(10.3)

Source Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

* N is the number of patients in the study at each visit; percentages are based on N

** Represents the number of patients for whom the dose was the maximum dosage during the study

Table 21 Summary of the Number (%) of Patients with a Primary Diagnosis of OCD Exposed to Each Dosage of Paroxetine by Visit and Age Group (ITT Population)

Daily Dosage		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
	N*	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents											
Week 1	47	44	(93.6)	3	(6.4)	0	-	0	-	0	-
Week 2	45	7	(15.6)	33	(73.3)	5	(11.1)	0	-	0	-
Week 3	43	1	(2.3)	19	(44.2)	19	(44.4)	4	(9.3)	0	-
Week 4	42	3	(7.1)	8	(19.0)	16	(38.1)	11	(26.2)	4	(9.5)
Week 6	41	1	(2.4)	7	(17.1)	12	(29.3)	11	(26.8)	10	(24.4)
Week 8	37	1	(2.7)	8	(21.6)	7	(18.9)	11	(29.7)	10	(27.0)
Week 12	29	1	(3.4)	6	(20.7)	5	(17.2)	5	(17.2)	12	(41.4)
Week 16	27	1	(3.7)	7	(25.9)	6	(22.2)	3	(11.1)	10	(37.0)
Week 20	13	1	(7.7)	4	(30.8)	3	(23.1)	1	(7.7)	4	(30.8)
Week 24	10	0	-	3	(30.0)	3	(30.0)	1	(10.0)	3	(30.0)
Maximum**	47	3	(6.4)	6	(12.8)	10	(21.3)	10	(21.3)	18	(38.3)

Source Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

* N is the number of patients in the study at each visit; percentages are based on N

** Represents the number of patients for whom the dose was the maximum dosage during the study

The mean daily dosage of paroxetine is presented for each visit and overall by primary diagnosis and age group for the ITT population in Table 22. The overall mean daily dose of paroxetine to which patients were exposed was 22.2 mg/day. The mean daily dose of paroxetine to which children were exposed was 20.5 mg/day and the mean daily dose of paroxetine to which adolescents were exposed was 24.3 mg/day.

For patients with a primary diagnosis of MDD the overall mean daily dose of paroxetine to which patients were exposed was 20.9 mg/day, and the mean daily dose at the week 24 LOCF endpoint was 26.5 mg/day. For patients with a primary diagnosis of OCD the overall mean dose of paroxetine to which patients were exposed was 23.7 mg/day and the mean dose at the week 24 LOCF endpoint was 25.7 mg/day. There was a greater difference between age groups in the OCD patients than in the MDD patients.

Overall duration of exposure to study medication may be found in Table 23, Section 5.1, and Tables 13.10.5.1b (excluding taper) and 13.10.5.2b (including taper).

Table 22 Mean Daily Dosage of Paroxetine by Primary Diagnosis and Age Group (ITT Population) Continued…

Visit	Total			Children			Adolescents		
	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)
Primary Diagnosis: Total									
Week 1	221	10.8	(3.28)	119	10.8	(3.48)	102	10.8	(3.05)
Week 2	205	17.6	(5.91)	109	16.7	(6.09)	96	18.6	(5.55)
Week 3	205	22.1	(7.69)	111	20.7	(7.71)	94	23.8	(7.35)
Week 4	198	24.8	(9.81)	105	23.0	(9.40)	93	27.0	(9.87)
Week 6	191	26.8	(10.94)	102	24.3	(10.20)	89	29.7	(11.12)
Week 8	175	27.8	(10.99)	93	25.4	(10.48)	82	30.5	(10.99)
Week 12	144	28.5	(11.42)	74	25.8	(10.47)	70	31.3	(11.79)
Week 16	126	28.5	(11.53)	62	26.3	(11.49)	64	30.6	(11.25)
Week 20	96	27.6	(11.63)	51	25.8	(11.59)	45	29.6	(11.47)
Week 24	80	27.4	(11.66)	43	24.9	(11.62)	37	30.3	(11.18)
Overall Mean	221	22.2	(7.83)	119	20.5	(7.36)	102	24.3	(7.89)

Source Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

Table 22 Mean Daily Dosage of Paroxetine by Primary Diagnosis and Age Group (ITT Population) Continued…

Visit	Total			Children			Adolescents		
	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)
Primary Diagnosis: MDD									
Week 1	116	11.0	(4.04)	61	11.1	(4.51)	55	10.9	(3.48)
Week 2	109	16.9	(6.19)	58	16.0	(6.47)	51	17.8	(5.77)
Week 3	107	20.9	(7.59)	56	20.0	(7.86)	51	22.0	(7.22)
Week 4	104	22.5	(8.33)	53	21.5	(8.86)	51	23.5	(7.70)
Week 6	100	23.8	(9.08)	52	22.9	(9.57)	48	24.8	(8.50)
Week 8	94	24.8	(8.64)	49	23.5	(9.03)	45	26.2	(8.06)
Week 12	84	25.7	(9.35)	43	24.4	(9.83)	41	27.1	(8.73)
Week 16	75	26.5	(10.07)	38	25.8	(11.77)	37	27.3	(8.04)
Week 20	64	27.4	(11.06)	32	26.4	(11.93)	32	28.4	(10.19)
Week 24	55	27.3	(11.46)	28	25.7	(12.30)	27	28.9	(10.50)
Overall Mean	116	20.9	(7.08)	61	20.0	(7.33)	55	22.0	(6.70)
Week 24 LOCF	82	26.5	(11.59)	41	24.9	(12.27)	41	28.0	(10.77)

Source Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

The week 24 LOCF endpoint corresponds to the visit making up each patients LOCF assessment for CDRS-R or CY-BOCS total score

Table 22 Mean Daily Dosage of Paroxetine by Primary Diagnosis and Age Group (ITT Population)

Visit		Total			Children			Adolescents	
	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)	N	Mean (mg/day)	(SD)
Primary Diagnosis: OCD									
Week 1	105	10.5	(2.14)	58	10.3	(1.84)	47	10.6	(2.47)
Week 2	96	18.4	(5.49)	51	17.5	(5.60)	45	19.6	(5.20)
Week 3	98	23.5	(7.61)	55	21.5	(7.56)	43	26.0	(6.95)
Week 4	94	27.4	(10.67)	52	24.4	(9.78)	42	31.2	(10.64)
Week 6	91	30.1	(11.88)	50	25.8	(10.71)	41	35.4	(11.20)
Week 8	81	31.2	(12.39)	44	27.5	(11.64)	37	35.7	(11.91)
Week 12	60	32.3	(12.94)	31	27.7	(11.17)	29	37.2	(13.06)
Week 16	51	31.4	(12.96)	24	27.1	(11.22)	27	35.2	(13.41)
Week 20	32	27.8	(12.89)	19	24.7	(11.24)	13	32.3	(14.23)
Week 24	25	27.6	(12.34)	15	23.3	(10.47)	10	34.0	(12.65)
Overall Mean	105	23.7	(8.38)	58	21.0	(7.41)	47	27.0	(8.40)
Week 24 LOCF	44	25.7	(11.89)	24	21.7	(8.68)	20	30.5	(13.56)

Source Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

The week 24 LOCF endpoint corresponds to the visit making up each patients LOCF assessment for CDRS-R or CY-BOCS total score

5 Safety Results

This section describes the safety data for the ITT population, which includes all patients who received at least one dose of open-label study medication and who had at least one valid post-dose assessment (including any adverse events). These patients were included in the safety population and assessed for clinical safety and tolerability. Therefore, for this study, the ITT population is identical to the safety population. The safety data summarized include all adverse events, vital signs, laboratory data, and ECGs.

5.1 Extent of Exposure

The overall duration of exposure to open-label study medication (excluding taper medication) by acute study treatment group is presented for the ITT population in Table 23.

The overall mean number of days of exposure to open-label study medication (excluding taper) was 106.9 days (range 2 to 197 days): 117.7 days for patients in the acute study paroxetine group and 98.8 days for patients in the acute study placebo group. The range of overall duration of exposure was similar between acute study treatment groups. Among children, the acute study paroxetine group had a higher overall mean duration (paroxetine, 114.2 days; placebo, 97.4 days). Similarly, among adolescents the acute study paroxetine group had a higher overall mean duration (paroxetine, 121.6 days; placebo, 100.6 days).

The overall duration of exposure to paroxetine study medication (excluding acute study taper medication and open-label taper medication) is presented for the PPX population in Table 13.10.5.1d, Section 10. The overall mean number of days of exposure to paroxetine during the acute study treatment phase and open label study treatment phase was 182.1 days (range 58 to 265 days). The mean number of days of exposure to paroxetine was similar between children and adolescents (children, 178.8 days; adolescents, 185.7 days).

The overall duration of exposure to open-label study medication (including taper medication) by acute study treatment group is presented for the ITT population in Table 13.10.5.2b, Section 10. The overall mean number of days exposure to open-label study medication (including taper medication) was 110.3 (range 2 to 211). The mean number of days exposure to open-label study medication (including taper medication) was 121.9 days for patients in the acute study

paroxetine group and 101.7 days for patients in the acute study placebo group. Among children, the acute study paroxetine group had a higher overall mean duration (paroxetine, 117.6 days; placebo, 100.6 days). Similarly, among adolescents the acute study paroxetine group had a higher overall mean duration (paroxetine, 126.7 days; placebo, 103.1 days).

The overall duration of exposure to paroxetine study medication (including all taper medication) is presented for the PPX population in Table 13.10.5.2d, Section 10. The overall mean number of days of exposure to paroxetine was 199.5 days (range 65 to 304). The mean number of days of exposure to paroxetine was 193.6 days in children and 206.0 days in adolescents.

Table 23 Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group (ITT Population) Continued…

	Acute Study Treatment Group					
Paroxetine Exposure	**Paroxetine**		**Placebo**		**Total**	
(Days)	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Total	**(N=94)**		**(N= 127)**		**(N= 221)**	
≥ 1	94	(100.0)	127	(100.0)	221	(100.0)
> 7	92	(97.9)	125	(98.4)	217	(98.2)
> 14	91	(96.8)	120	(94.5)	211	(95.5)
> 21	89	(94.7)	116	(91.3)	205	(92.8)
> 28	89	(94.7)	113	(89.0)	202	(91.4)
> 42	83	(88.3)	100	(78.7)	183	(82.8)
> 56	78	(83.0)	84	(66.1)	162	(73.3)
> 70	66	(70.2)	73	(57.5)	139	(62.9)
> 84	64	(68.1)	69	(54.3)	133	(60.2)
> 112	51	(54.3)	56	(44.1)	107	(48.4)
> 140	43	(45.7)	39	(30.7)	82	(37.1)
> 168	26	(27.7)	24	(18.9)	50	(22.6)
> 182	8	(8.5)	6	(4.7)	14	(6.3)
Overall Mean	117.7		98.8		106.9	
Range	2 to 194		2 to 197		2 to 197	
Age Group: Children	**(N= 49)**		**(N=70)**		**(N= 119)**	
≥ 1	49	(100.0)	70	(100.0)	119	(100.0)
> 7	48	(98.0)	69	(98.6)	117	(98.3)
> 14	47	(95.9)	67	(95.7)	114	(95.8)
> 21	46	(93.9)	64	(91.4)	110	(92.4)
> 28	46	(93.9)	62	(88.6)	108	(90.8)
> 42	43	(87.8)	56	(80.0)	99	(83.2)
> 56	41	(83.7)	46	(65.7)	87	(73.1)
> 70	31	(63.3)	40	(57.1)	71	(59.7)
> 84	29	(59.2)	36	(51.4)	65	(54.6)
> 112	24	(49.0)	29	(41.4)	53	(44.5)
> 140	23	(46.9)	21	(30.0)	44	(37.0)
> 168	15	(30.6)	13	(18.6)	28	(23.5)
> 182	5	(10.2)	6	(8.6)	11	(9.2)
Overall Mean	114.2		97.4		104.3	
Range	2 to 194		2 to 197		2 to 197	

Source Tables 13.10.5.1b, Section 10; Listing 13.10.1, Appendix B.

Table 23 Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group					
Paroxetine Exposure	**Paroxetine**		**Placebo**		**Total**	
(Days)	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Adolescents	**(N=45)**		**(N=57)**		**(N=102)**	
≥ 1	45	(100.0)	57	(100.0)	102	(100.0)
> 7	44	(97.8)	56	(98.2)	100	(98.0)
> 14	44	(97.8)	53	(93.0)	97	(95.1)
> 21	43	(95.6)	52	(91.2)	95	(93.1)
> 28	43	(95.6)	51	(89.5)	94	(92.2)
> 42	40	(88.9)	44	(77.2)	84	(82.4)
> 56	37	(82.2)	38	(66.7)	75	(73.5)
> 70	35	(77.8)	33	(57.9)	68	(66.7)
> 84	35	(77.8)	33	(57.9)	68	(66.7)
> 112	27	(60.0)	27	(47.4)	54	(52.9)
> 140	20	(44.4)	18	(31.6)	38	(37.3)
> 168	11	(24.4)	11	(19.3)	22	(21.6)
> 182	3	(6.7)	0	(0.0)	3	(2.9)
Overall Mean	121.6		100.6		109.9	
Range	2 to 184		2 to 182		2 to 184	

Source Tables 13.10.5.1b, Section 10; Listing 13.10.1, Appendix B.

5.2 Adverse Events

All adverse events were coded from the verbatim term according to the WHO ART dictionary and then mapped by body system and preferred term according to the COSTART-based ADECS. All adverse events were summarized according to the phase of the study in which they initially occurred, that is, pre-acute study treatment phase, acute study treatment phase if ongoing into 716, open-label treatment phase, taper phase, or follow-up phase (Section 3.14.6.1). Adverse events occurring in pre-acute study treatment phase and acute study treatment phase if ongoing into 716 are discussed in Section 4.5.

For completeness, the sponsor also prepared tables that summarized all adverse events that occurred during either the open-label treatment phase or taper phase, i.e., while the patient was actively taking open-label study medication. These summaries combine data from the two phases. Tables were also prepared that combined taper phase and follow-up phase; and open-label treatment phase, taper phase and follow-up phase.

All adverse events that occurred after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the week 24 or early withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the follow-up phase if the patient did not enter the taper phase, and as occurring during the taper phase if the patient did enter the taper phase.

Summaries of all adverse events during the open-label treatment phase, taper phase, and follow-up phase may be found in Section 12: Tables 15.1.1.1 and 15.1.1.1x for open-label treatment phase-emergent adverse events, 15.1.1.2 and 15.1.1.2x for taper phase-emergent adverse events, 15.1.1.3 and 15.1.1.3x for combined open-label treatment phase-emergent and taper phase-emergent adverse events, 15.1.1.4 and 15.1.1.4x for follow-up phase-emergent adverse events, 15.1.1.5 and 15.1.1.5x for combined taper phase-emergent and follow-up phase-emergent adverse events, and Tables 15.1.1.6 and 15.1.1.6x for combined open-label treatment phase-emergent, taper phase-emergent and follow-up phase-emergent adverse events. Individual patient listings of adverse events may be found in Listings 15.1.1 and 15.1.2, Appendix D.

The incidence of adverse events was determined for serious and non-serious combined, regardless of investigator-deemed relationship to study medication.

5.2.1 Open Label Treatment Phase-Emergent Adverse Events

Table 24 presents a summary of the most frequently reported (≥ 5% either acute study treatment group within either age group) open-label treatment phase-emergent gender-non-specific adverse events, regardless of treatment attribution, for both age groups combined and separately. Open-label treatment phase-emergent adverse events are summarized in Tables 15.1.1.1, Section 12, (by body system and preferred term), and 15.1.1.1x, Section 12, (by preferred term occurring in 1% or more of the population in descending order).

Overall, 72.9% (161/221) of patients reported a gender-non-specific emergent adverse event during the open-label treatment phase. The proportion of patients reporting at least one gender-non-specific adverse event during the open-label treatment phase was similar between the two acute study treatment groups: 75.5% (71/94) of patients in the acute study paroxetine group and 70.9% (90/127) of patients in the acute study placebo group. Overall, the most common (>10%) gender-non-specific adverse events for patients in the acute study paroxetine group were headache (25.5%, 24/94), respiratory disorder (16.0%, 15/94), infection (13.8%, 13/75), trauma (12.8%, 12/94), and nausea (10.6% 10/94), while

the most common adverse events for patients in the acute study placebo group were respiratory disorder (19.7%, 25/127), headache (18.9%, 24/127), infection (11.8%, 15/127), and nervousness (10.2%, 13/127).

Three adverse events occurred with an incidence of ≥ 5% in the acute study paroxetine group and with an incidence of at least twice that in the acute study placebo group: vomiting [6.4% (6/94) compared to 3.1% (4/127)], sinusitis [7.4% (7/94) compared to 1.6% (2/127)], and diarrhea [6.4% (6/94) compared to 2.4% (3/127)]. Only one adverse event occurred with an incidence of ≥ 5% in the acute study placebo group and with an incidence of at least twice that in the acute study paroxetine group: decreased appetite [5.5% (7/127) compared to 2.1% (2/94)].

The overall frequency of gender-non-specific adverse events was slightly higher among children compared to adolescents. A total of 77.3% (92/119) of children reported gender-non-specific adverse events during the open-label treatment phase; 79.6% (39/49) of patients in the acute study paroxetine group and 75.7% (53/70) of patients in the acute study placebo group. A total of 67.6% (69/102) of adolescents reported gender-non-specific adverse events during the open-label treatment phase; 71.1% (32/45) of patients in the acute study paroxetine group and 64.9% (37/57) of patients in the acute study placebo group. The nature of the adverse events were similar among children and adolescents.

Adverse events that occurred in children with an incidence of ≥ 5% and with an incidence of at least twice that in adolescents were rhinitis [9.2% (11/119) compared to 3.9% (4/102)], pharyngitis [10.9% (13/119) compared to 2.0% (2/102)], hyperkinesia [9.2% (11/119) compared to 2.0% (2/102)], fever [8.4% (10/119) compared to 2.0% (2/102)], vomiting [6.7% (8/119) compared to 2.0% (2/102)], and otitis media [5.0% (6/119) compared to 2.0% (2/102)].

Adverse events that occurred in adolescents with an incidence of ≥ 5% and with an incidence of at least twice that in children were asthenia [8.8% (9/102) compared to 1.7% (2/119)], somnolence [5.9% (6/102) compared to 2.5% (3/119)], emotional lability [6.9% (7/102) compared to 0.8% (1/119)], and asthma [5.9% (6/102) compared to 1.7% (2/119)].

Table 24 Most Frequent (≥5% in Either Acute Study Treatment Group Within Either Age Group) Open-Label Treatment Phase-Emergent Gender-Non-Specific Adverse Events by Age Group and Acute Study Treatment Group (ITT Population) Continued…

	Age Group: Total						Age Group: Children						Age Group: Adolescents					
AE Preferred Term*	**Paroxetine (N=94)**		**Placebo (N=127)**		**Total (N=221)**		**Paroxetine (N=49)**		**Placebo (N=70)**		**Total (N=119)**		**Paroxetine (N=45)**		**Placebo (N=57)**		**Total (N=102)**	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at least 1 AE	71	(75.5)	90	(70.9)	161	(72.9)	39	(79.6)	53	(75.7)	92	(77.3)	32	(71.1)	37	(64.9)	69	(67.6)
Headache	24	(25.5)	24	(18.9)	48	(21.7)	13	(26.5)	10	(14.3)	23	(19.3)	11	(24.4)	14	(24.6)	25	(24.5)
Respiratory disorder	15	(16.0)	25	(19.7)	40	(18.1)	9	(18.4)	13	(18.6)	22	(18.5)	6	(13.3)	12	(21.1)	18	(17.6)
Infection	13	(13.8)	15	(11.8)	28	(12.7)	7	(14.3)	10	(14.3)	17	(14.3)	6	(13.3)	5	(8.8)	11	(10.8)
Trauma	12	(12.8)	10	(7.9)	22	(10.0)	8	(16.3)	7	(10.0)	15	(12.6)	4	(8.9)	3	(5.3)	7	(6.9)
Nausea	10	(10.6)	10	(7.9)	20	(9.0)	5	(10.2)	3	(4.3)	8	(6.7)	5	(11.1)	7	(12.3)	12	(11.8)
Nervousness	7	(7.4)	13	(10.2)	20	(9.0)	4	(8.2)	9	(12.9)	13	(10.9)	3	(6.7)	4	(7.0)	7	(6.9)
Abdominal pain	7	(7.4)	12	(9.4)	19	(8.6)	5	(10.2)	8	(11.4)	13	(10.9)	2	(4.4)	4	(7.0)	6	(5.9)
Rhinitis	7	(7.4)	8	(6.3)	15	(6.8)	5	(10.2)	6	(8.6)	11	(9.2)	2	(4.4)	2	(3.5)	4	(3.9)
Pharyngitis	6	(6.4)	9	(7.1)	15	(6.8)	6	(12.2)	7	(10.0)	13	(10.9)	0	-	2	(3.5)	2	(2.0)
Insomnia	5	(5.3)	10	(7.9)	15	(6.8)	2	(4.1)	5	(7.1)	7	(5.9)	3	(6.7)	5	(8.8)	8	(7.8)
Dyspepsia	7	(7.4)	7	(5.5)	14	(6.3)	5	(10.2)	4	(5.7)	9	(7.6)	2	(4.4)	3	(5.3)	5	(4.9)
Hostility	5	(5.3)	9	(7.1)	14	(6.3)	4	(8.2)	5	(7.1)	9	(7.6)	1	(2.2)	4	(7.0)	5	(4.9)
Allergic reaction	7	(7.4)	6	(4.7)	13	(5.9)	2	(4.1)	3	(4.3)	5	(4.2)	5	(11.1)	3	(5.3)	8	(7.8)
Hyperkinesia	7	(7.4)	6	(4.7)	13	(5.9)	6	(12.2)	5	(7.1)	11	(9.2)	1	(2.2)	1	(1.8)	2	(2.0)

Source Table 15.1.1.1 and 15.1.1.1x,Section 12, Listing 15.1.1, Appendix D

* sorted by decreasing frequency in the total group

Table 24 Most Frequent (≥5% in Either Acute Study Treatment Group Within Either Age Group) Open-Label Treatment Phase-Emergent Gender-Non-Specific Adverse Events by Age Group and Acute Study Treatment Group (ITT Population)

	Age Group: Total						Age Group: Children						Age Group: Adolescents					
AE Preferred Term*	**Paroxetine (N=94)**		**Placebo (N=127)**		**Total (N=221)**		**Paroxetine (N=49)**		**Placebo (N=70)**		**Total (N=119)**		**Paroxetine (N=45)**		**Placebo (N=57)**		**Total (N=102)**	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Weight gain	6	(6.4)	7	(5.5)	13	(5.9)	4	(8.2)	4	(5.7)	8	(6.7)	2	(4.4)	3	(5.3)	5	(4.9)
Fever	7	(7.4)	5	(3.9)	12	(5.4)	7	(14.3)	3	(4.3)	10	(8.4)	0	-	2	(3.5)	2	(2.0)
Asthenia	3	(3.2)	8	(6.3)	11	(5.0)	0	-	2	(2.9)	2	(1.7)	3	(6.7)	6	(10.5)	9	(8.8)
Vomiting	6	(6.4)	4	(3.1)	10	(4.5)	4	(8.2)	4	(5.7)	8	(6.7)	2	(4.4)	0	-	2	(2.0)
Sinusitis	7	(7.4)	2	(1.6)	9	(4.1)	4	(8.2)	2	(2.9)	6	(5.0)	3	(6.7)	0	-	3	(2.9)
Diarrhea	6	(6.4)	3	(2.4)	9	(4.1)	4	(8.2)	1	(1.4)	5	(4.2)	2	(4.4)	2	(3.5)	4	(3.9)
Somnolence	5	(5.3)	4	(3.1)	9	(4.1)	1	(2.0)	2	(2.9)	3	(2.5)	4	(8.9)	2	(3.5)	6	(5.9)
Decreased appetite	2	(2.1)	7	(5.5)	9	(4.1)	2	(4.1)	3	(4.3)	5	(4.2)	0	-	4	(7.0)	4	(3.9)
Emotional lability	4	(4.3)	4	(3.1)	8	(3.6)	1	(2.0)	0	-	1	(0.8)	3	(6.7)	4	(7.0)	7	(6.9)
Otitis media	4	(4.3)	4	(3.1)	8	(3.6)	3	(6.1)	3	(4.3)	6	(5.0)	1	(2.2)	1	(1.8)	2	(2.0)
Asthma	3	(3.2)	5	(3.9)	8	(3.6)	1	(2.0)	1	(1.4)	2	(1.7)	2	(4.4)	4	(7.0)	6	(5.9)
Agitation	2	(2.1)	6	(4.7)	8	(3.6)	0	-	1	(2.9)	1	(1.7)	1	(2.2)	3	(5.3)	4	(3.9)
Cough increased	3	(3.2)	3	(2.4)	6	(2.7)	3	(6.1)	2	(2.9)	5	(4.2)	0	-	1	(1.8)	1	(1.0)
Rash	1	(1.1)	5	(3.9)	6	(2.7)	1	(2.0)	4	(5.7)	5	(4.2)	0	-	1	(1.8)	1	(1.0)
Acne	3	(3.2)	3	(2.4)	6	(2.7)	0	-	0	-	0	-	1	(2.2)	3	(5.3)	4	(3.9)
Albuminuria	3	(3.2)	2	(1.6)	5	(2.3)	0	-	1	(1.4)	0	(0.8)	3	(6.7)	1	(1.8)	4	(3.9)
Neurosis	4	(4.3)	0	-	4	(1.8)	1	(2.0)	0	-	1	(0.8)	3	(6.7)	0	-	3	(2.9)

Source Table 15.1.1.1 and 15.1.1.1x, Section 12, Listing 15.1.1, Appendix D

* sorted by decreasing frequency in the total group

Table 25 presents a summary of the most frequently reported (≥ 5% in either acute study treatment group within either primary diagnosis) open-label treatment phase-emergent gender-non-specific adverse events, regardless of treatment attribution, by primary diagnosis. Treatment phase-emergent adverse events are summarized in Tables 15.1.1.1, Section 12, (by body system and preferred term), and 15.1.1.1x, Section 12, (by preferred term occurring in 1% or more of the population in descending order).

The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 70.7% (82/116). A total of 76.0% (38/50) of patients in the acute study paroxetine group and 66.7% (44/66) of patients in the acute study placebo group reported at least one gender-non-specific adverse event during the open label treatment phase. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD was 75.2% (79/105). A total of 75.0% (33/44) of patients in the acute study paroxetine group and 75.4% (46/61) of patients in the acute study placebo group reported at least one gender-non-specific adverse event during the open label treatment phase.

Adverse events that occurred in patients with a primary diagnosis of MDD with an incidence of ≥ 5% and with an incidence of at least twice that in patients with a primary diagnosis of OCD were weight gain [9.5% (11/116) compared to 1.9% (2/105)], vomiting [8.6% (10/116) compared to 0.0% (0/105)], and emotional lability [5.2% (6/116) compared to 1.9% (2/105)].

Adverse events that occurred in patients with a primary diagnosis of OCD with an incidence of ≥ 5% and with an incidence of at least twice that in patients with a primary diagnosis of MDD were nervousness [13.3% (14/105) compared to 5.2% (6/116)], hostility [8.6% (9/105) compared to 4.3% (5/116)], and hyperkinesia [10.5% (11/105) compared to 1.7% (2/116)].

Table 25 Most Frequent (≥5% in Either Acute Study Treatment Group Within Either Primary Diagnosis) Open-Label Treatment Phase-Emergent Gender-Non-Specific Adverse Events by Primary Diagnosis and Acute Study Treatment Group (ITT Population) Continued…

	Primary Diagnosis: Total						Primary Diagnosis: MDD						Primary Diagnosis: OCD					
AE Preferred Term*	**Paroxetine (N=94)**		**Placebo (N=127)**		**Total (N=221)**		**Paroxetine (N=50)**		**Placebo (N=66)**		**Total (N=116)**		**Paroxetine (N=44)**		**Placebo (N=61)**		**Total (N=105)**	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at least 1 AE	71	(75.5)	90	(70.9)	161	(72.9)	38	(76.0)	44	(66.7)	82	(70.7)	33	(75.0)	46	(75.4)	79	(75.2)
Headache	24	(25.5)	24	(18.9)	48	(21.7)	9	(18.0)	10	(15.2)	19	(16.4)	15	(34.1)	14	(23.0)	29	(27.6)
Respiratory disorder	15	(16.0)	25	(19.7)	40	(18.1)	12	(24.0)	13	(19.7)	25	(21.6)	3	(6.8)	12	(19.7)	15	(14.3)
Infection	13	(13.8)	15	(11.8)	28	(12.7)	6	(12.0)	11	(16.7)	17	(14.7)	7	(15.9)	4	(6.6)	11	(10.5)
Trauma	12	(12.8)	10	(7.9)	22	(10.0)	8	(16.0)	6	(9.1)	14	(12.1)	4	(9.1)	4	(6.6)	8	(7.6)
Nausea	10	(10.6)	10	(7.9)	20	(9.0)	6	(12.0)	4	(6.1)	10	(8.6)	4	(9.1)	6	(9.8)	10	(9.5)
Nervousness	7	(7.4)	13	(10.2)	20	(9.0)	5	(10.0)	1	(1.5)	6	(5.2)	2	(4.5)	12	(19.7)	14	(13.3)
Abdominal pain	7	(7.4)	12	(9.4)	19	(8.6)	5	(10.0)	4	(6.1)	9	(7.8)	2	(4.5)	8	(13.1)	10	(9.5)
Rhinitis	7	(7.4)	8	(6.3)	15	(6.8)	3	(6.0)	4	(6.1)	7	(6.0)	4	(9.1)	4	(6.6)	8	(7.6)
Pharyngitis	6	(6.4)	9	(7.1)	15	(6.8)	4	(8.0)	5	(7.6)	9	(7.8)	2	(4.5)	4	(6.6)	6	(5.7)
Insomnia	5	(5.3)	10	(7.9)	15	(6.8)	1	(2.0)	5	(7.6)	6	(5.2)	4	(9.1)	5	(8.2)	9	(8.6)
Dyspepsia	5	(7.4)	7	(5.5)	14	(6.3)	5	(10.0)	4	(6.1)	9	(7.8)	2	(4.5)	3	(4.9)	5	(4.8)
Hostility	5	(5.3)	9	(7.1)	14	(6.3)	3	(6.0)	2	(3.0)	5	(4.3)	2	(4.5)	7	(11.5)	9	(8.6)
Allergic reaction	7	(7.4)	6	(4.7)	13	(5.9)	4	(8.0)	2	(3.0)	6	(5.2)	3	(6.8)	4	(6.6)	7	(6.7)
Hyperkinesia	7	(7.4)	6	(4.7)	13	(5.9)	1	(2.0)	1	(1.5)	2	(1.7)	6	(13.6)	5	(8.2)	11	(10.5)

Source Table 15.1.1.1 and 15.1.1.1x, Section 12, Listing 15.1.1, Appendix D

* sorted by decreasing frequency in the total group

Table 25 Most Frequent (≥5% in Either Acute Study Treatment Group Within Either Primary Diagnosis) Open-Label Treatment Phase-Emergent Gender-Non-Specific Adverse Events by Primary Diagnosis and Acute Study Treatment Group (ITT Population)

	Primary Diagnosis: Total						Primary Diagnosis: MDD						Primary Diagnosis: OCD					
AE Preferred Term*	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)		Paroxetine (N=49)		Placebo (N=70)		Total (N=116)		Paroxetine (N=45)		Placebo (N=57)		Total (N=102)	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Weight gain	6	(6.4)	7	(5.5)	13	(5.9)	5	(10.0)	6	(9.1)	11	(9.5)	1	(2.3)	1	(1.6)	2	(1.9)
Fever	7	(7.4)	5	(3.9)	12	(5.4)	4	(8.0)	3	(4.5)	7	(6.0)	3	(6.8)	2	(3.3)	5	(4.8)
Asthenia	3	(3.2)	8	(6.3)	11	(5.0)	0	-	5	(7.6)	5	(4.3)	3	(6.8)	3	(4.9)	6	(5.7)
Vomiting	6	(6.4)	4	(3.1)	10	(4.5)	6	(12.0)	4	(6.1)	10	(8.6)	0	-	0	-	0	-
Sinusitis	7	(7.4)	2	(1.6)	9	(4.1)	3	(6.0)	1	(1.5)	4	(3.4)	4	(9.1)	1	(1.6)	5	(4.8)
Diarrhea	6	(6.4)	3	(2.4)	9	(4.1)	3	(6.0)	2	(3.0)	5	(4.3)	3	(6.8)	1	(1.6)	4	(3.8)
Somnolence	5	(5.3)	4	(3.1)	9	(4.1)	3	(6.0)	3	(4.5)	6	(5.2)	2	(4.5)	1	(1.6)	3	(2.9)
Decreased appetite	2	(2.1)	7	(5.5)	9	(4.1)	0	-	3	(4.5)	3	(2.6)	2	(4.5)	4	(6.6)	6	(5.7)
Emotional lability	4	(4.3)	4	(3.1)	8	(3.6)	3	(6.0)	3	(4.5)	6	(5.2)	1	(2.3)	1	(1.6)	2	(1.9)
Depression	3	(3.2)	2	(1.6)	5	(2.3)	3	(6.0)	1	(1.5)	4	(3.4)	0	-	1	(1.6)	1	(1.0)
Dry Mouth	3	(3.2)	2	(1.6)	5	(2.3)	3	(6.0)	0	-	3	(2.6)	0	-	2	(3.3)	2	(1.9)
Neurosis	4	(4.3)	0	-	4	(1.8)	0	-	0	-	0	-	4	(9.1)	0	-	4	(3.8)

Source Table 15.1.1.1 and 15.1.1.1x, Section 12, Listing 15.1.1, Appendix D

* sorted by decreasing frequency in the total group

Adverse events that occurred in children with a primary diagnosis of MDD with an incidence of ≥ 5% and with an incidence of at least twice that in adolescents with a primary diagnosis of MDD were infection [21.3% (13/61) compared to 7.3% (4/55)], pharyngitis [13.1% (8/61) compared to 1.8% (1/55)], vomiting [13.1% (8/61) compared to 3.6% (2/55)], abdominal pain [11.5% (7/61) compared to 3.6% (2/55)], fever [9.8 % (6/61) compared to 1.8% (1/55)], rhinitis [8.2 % (5/61) compared to 3.6% (2/55)], and hostility [6.6 % (4/61) compared to 1.8% (1/55)] (Table 15.1.1.1, Section 12).

Adverse events that occurred in adolescents with a primary diagnosis of MDD with an incidence of ≥ 5% and with an incidence of at least twice that in children with a primary diagnosis of MDD were nausea [12.7% (7/55) compared to 4.9% (3/61)], somnolence [9.1% (5/55) compared to 1.6% (1/61)], emotional lability [9.1% (5/55) compared to 1.6% (1/61)], asthma [5.5% (3/55) compared to 1.6% (1/61)], and bronchitis [5.5% (3/55) compared to 1.6% (1/61)] (Table 15.1.1.1, Section 12).

Adverse events that occurred in children with a primary diagnosis of OCD with an incidence of ≥ 5% and with an incidence of at least twice that in adolescents with a primary diagnosis of OCD were nervousness [17.2% (10/58) compared to 8.5% (4/47)], hyperkinesia [15.5% (9/58) compared to 4.3% 92/47)], trauma [12.1% (7/58) compared to 2.1% (1/47)], rhinitis [10.3% (6/58) compared to 4.3% (2/47)], pharyngitis [8.6% (5/58) compared to 2.1% (1/47)], fever [6.9% (4/58) compared to 2.1% (1/47)], otitis media [6.9% (4/58) compared to 2.1% 91/47)], cough increased [5.2% (3/58) compared to 0% (0/47)], otitis externa [5.2% (3/58) compared to 0% (0/47)], and vasodilation [5.2% (3/58) compare to 0% (0/47)] (Table 15.1.1.1, Section 12).

Adverse events that occurred in adolescents with a primary diagnosis of OCD with an incidence of ≥ 5% and with an incidence of at least twice that in children with a primary diagnosis of OCD were infection [14.9% (7/47) compared to 6.9% (4/58)], allergic reaction [12.8% (6/47) compared to 1.7% (1/58)], asthenia [12.8% (6/47) compared to 0.0% (0/58)], insomnia [10.6% (5/47) compared to 6.9% (4/58)], neurosis [6.4% (3/47) compared to 1.7% (1/58)], arthralgia[6.4% (3/47) compared to 0.0% (0/58)], acne [6.4% (3/47) compared to 0.0% (0/58)], and asthma [6.4% (3/47) compared to 1.7% (1/58)] (Table 15.1.1.1, Section 12).

No patients reported a male-specific emergent adverse event during the open-label treatment phase. Six patients reported a female-specific emergent adverse event during the open label treatment phase: dysmenorrhea [6.7% (3/45) of females in the acute study paroxetine group; 2.0% (1/50) of females in the acute study

placebo group], female genital disorders [2.0% (1/50) of females in the acute study placebo group], and menstrual disorder [2.0% (1/50) of females in the acute study placebo group] (Table 15.1.1.1, Section 12).

5.2.1.1 Open-Label Treatment Phase-Emergent Adverse Events by Investigator-Assessed Intensity

Open-label treatment phase-emergent adverse events are summarized by intensity in Tables 15.1.3.1, Section 12, (by body system and preferred term), and 15.1.3.1x, Section 12, (by preferred term occurring in 1% or more of the population in descending order). In addition, open-label treatment phase-emergent adverse events are summarized by maximum intensity, by body system and preferred term in Table 15.1.7.1, Section 12. The majority of open-label treatment phase-emergent adverse events were mild or moderate in intensity.

A summary of the most frequent severe gender-non-specific open-label treatment phase-emergent adverse events by acute study treatment group is presented in Table 26. Overall, 11.3% (25/221) of patients reported a severe gender-non-specific adverse event during the open-label treatment phase. The proportion of patients reporting at least one severe gender-non-specific adverse event during the open-label treatment phase was 9.6% (9/94) of patients in the acute study paroxetine group and 12.6% (16/127) of patients in the acute study placebo group. The only severe adverse events occurring in more than one patient in either acute study treatment group were hostility, emotional lability and infection. There were no severe gender-specific adverse events.

Table 26 Summary of Number (%) of Patients with Open-Label Treatment Phase-Emergent Severe Adverse Events by Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group					
	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 Severe AE	9	(9.6)	16	(12.6)	25	(11.3)
Hostility	1	(1.1)	3	(2.4)	4	(1.8)
Emotional lability	2	(2.1)	1	(0.8)	3	(1.4)
Infection	2	(2.1)	1	(0.8)	3	(1.4)
Agitation	1	(1.1)	1	(0.8)	2	(0.9)
Trauma	1	(1.1)	1	(0.8)	2	(0.9)
Abscess	1	(1.1)	0	-	1	(0.5)
Depression	1	(1.1)	0	-	1	(0.5)
Lack of emotion	1	(1.1)	0	-	1	(0.5)
Neurosis	1	(1.1)	0	-	1	(0.5)
Pharyngitis	1	(1.1)	0	-	1	(0.5)
Somnolence	1	(1.1)	0	-	1	(0.5)
Abdominal pain	0	-	1	(0.8)	1	(0.5)
Anxiety	0	-	1	(0.8)	1	(0.5)
Asthma	0	-	1	(0.8)	1	(0.5)
Hallucinations	0	-	1	(0.8)	1	(0.5)
Hyperkinesia	0	-	1	(0.8)	1	(0.5)
Nausea	0	-	1	(0.8)	1	(0.5)
Nervousness	0	-	1	(0.8)	1	(0.5)
Otitis media	0	-	1	(0.8)	1	(0.5)
Rash	0	-	1	(0.8)	1	(0.5)
Syncope	0	-	1	(0.8)	1	(0.5)
Tooth caries	0	-	1	(0.8)	1	(0.5)
Urinary incontinence	0	-	1	(0.8)	1	(0.5)
Migraine	0	-	1	(0.8)	1	(0.5)
Euphoria	0	-	1	(0.8)	1	(0.5)
Paralysis	0	-	1	(0.8)	1	(0.5)

Source Table 15.1.3.1 Section 12; Listing 15.1.1, Appendix D
* Sorted by decreasing frequency in the total group

The proportion of patients reporting severe gender-non-specific open-label treatment phase-emergent adverse events was similar in children and adolescents

(Table 15.1.3.1, Section 12). Among children, 8.2% (4/49) of patients in the acute study paroxetine group and 14.3% (10/70) of patients in the acute study placebo group reported severe gender-non-specific open-label treatment phase-emergent adverse events. Among adolescents, 11.1% (5/45) of patients in the acute study paroxetine group and 10.5% (6/57) of patients in the acute study placebo group reported severe gender-non-specific open-label treatment phase-emergent adverse events.

The proportion of patients reporting severe gender-non-specific open-label treatment phase-emergent adverse events was slightly slightly higher in patients with a primary diagnosis of MDD compared to patients with a primary diagnosis of OCD (Table 15.1.3.1, Section 12). Among patients with a primary diagnosis of MDD, 10.0% (5/50) of patients in the acute study paroxetine group and 16.7% (11/66) of patients in the acute study placebo group reported severe gender-non-specific open-label treatment phase-emergent adverse events. Among patients with a primary diagnosis of OCD, 9.1% (4/44) of patients in the acute study paroxetine group and 8.2% (5/61) of patients in the acute study placebo group reported severe gender-non-specific open-label treatment phase-emergent adverse events.

The majority of open-label severe treatment phase-emergent adverse events were considered unrelated to study medication. One patient in the acute study paroxetine group and 6 patients in the acute study placebo group had severe adverse events during the open-label treatment phase that were considered by the investigator to be related or possibly related to open-label study medication (Section 5.2.1.2).

5.2.1.2 Open-Label Treatment Phase-Emergent Adverse Events by Relationship to Study Medication

Patients with adverse events judged by the investigator to be related or possibly related to open-label study medication are summarized in Tables 15.1.4.1, Section 12, (by body system and preferred term), and 15.1.4.1x, Section 12, (by preferred term occurring in 1% or more of the population in descending order).

A summary of the most frequent (incidence ≥ 5% in either acute study treatment group) gender-non-specific open-label treatment phase-emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication are presented in Table 27 by acute study treatment group.

Overall, 47.1% (104/221) of patients reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the open-label treatment phase: 47.9% (45/94) of patients in the acute study paroxetine group and 46.5% (59/127) of patients in the acute study placebo group.

Table 27 Summary of Number (%) of Patients with Open-Label Treatment Phase-Emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥ 5% of Patients in Either Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group					
	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 Related or Possibly Related AE	45	(47.9)	59	(46.5)	104	(47.1)
Headache	12	(12.8)	11	(8.7)	23	(10.4)
Nervousness	5	(5.3)	12	(9.4)	17	(7.7)
Hyperkinesia	7	(7.4)	6	(4.7)	13	(5.9)
Weight gain	6	(6.4)	6	(4.7)	12	(5.4)
Nausea	7	(7.4)	4	(3.1)	11	(5.0)
Insomnia	4	(4.3)	7	(5.5)	11	(5.0)
Decreased appetite	2	(2.1)	7	(5.5)	9	(4.1)

Source Table 15.1.4.1 and 15.1.4.1x, Section 12; Listing 15.1.1, Appendix D
* Sorted by decreasing frequency in the total group

The proportion of patients reporting gender-non-specific open-label treatment phase-emergent adverse events judged as related or possibly related to study medication was similar in children and adolescents in the acute study placebo group (Table 15.1.4.1, Section 12). A total of 47.1% (33/70) of children in the acute study placebo group and 45.6% (26/57) of adolescents in the acute study placebo group reported adverse events judged related or possibly related to study medication. In contrast, a higher proportion of children in the acute study paroxetine group (57.1%, 28/49) reported adverse events judged as related or possibly related to study medication compared to adolescents (37.8%, 17/45).

The proportion of patients reporting gender-non-specific open-label treatment phase-emergent adverse events judged as related or possibly related to study

medication was slightly higher in patients with a primary diagnosis of OCD compared to patients with a primary diagnosis of MDD (Tables 15.1.4.1, Section 12) . Among patients with a primary diagnosis of MDD, 46.0% (23/50) of patients in the acute study paroxetine group and 40.9% (27/66) of patients in the acute study placebo group reported adverse events judged as related or possibly related to study medication. Among patients with a primary diagnosis of OCD, 50.0% (22/44) of patients in the acute study paroxetine group and 52.5% (32/61) of patients in the acute study placebo group reported adverse events judged as related or possibly related to study medication.

The only gender-specific adverse event judged to be related or possibly related to open-label study medication was female genital disorders, which occurred in 1 patient in the acute study placebo group.

As shown in Table 28, 1 patient in the acute study paroxetine group and 6 patients in the acute study placebo group had severe adverse events during the open-label treatment phase that were considered by the investigator to be related or possibly related to open-label study medication. As a result of a severe adverse event, 4 of the acute study placebo patients were withdrawn from the study. None of these severe adverse events were reported as a serious adverse event.

Table 28 Open-Label Treatment Phase-Emergent Severe Adverse Events Considered Related or Possibly Related to Study Medication (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Preferred Term (Verbatim Term)	Relationship	Study Medication Action	Day of Onset *	Duration (days)
Acute Study Paroxetine Group								
716.168.27077	F	15	30	Neurosis (impulsivity)	Possibly related	Continued	13(-41)	Ongoing
Acute Study Placebo Group								
716.010.25840	F	11	30	Urinary incontinence (bed wetting)	Possibly related	Continued	78 (-6)	13
716.016.25447	M	7	20	Hostility (aggression)	Possibly related	Stopped	47 (-2)	8
716.016.25450	F	11	20	Nervousness (irritability)	Possibly related	Stopped	45 (-2)	6
716.016.27021	M	8	20	Hyperkinesia (hyperactivity)	Related	Stopped	27 (-3)	8
716.016.27017	M	12	30	Hostility (oppositional behavior)	Related	Stopped	52 (-7)	10
716.168.27075	F	12	40	Abdominal pain (stomach discomfort)	Possibly related	Continued	23 (-96)	37

Source Tables 15.1.3.1 and 15.1.4.1, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication (relative to the last dose of open-label study medication, excluding taper). The patient had not necessarily withdrawn from study medication at that time.

5.2.1.3 Open-Label Treatment Phase-Emergent Adverse Events by Time of First Occurrence

A summary of all open-label treatment phase emergent adverse events by the time of first occurrence by preferred term is presented in Table 15.1.6.1.X, Section 12. Table 29 and Table 30 summarize the most frequently occurring open-label treatment phase-emergent adverse events (i.e., those occurring in ≥ 5% of patients in either acute study treatment group) by the time of first occurrence for the acute study paroxetine and placebo groups, respectively.

In the acute study paroxetine group the time to first occurrence for the most frequent adverse events was spread across the course of the open-label treatment phase. One exception was headache where the time to first occurrence was generally within the first 3 weeks of open-label study medication. In the acute study placebo group the time to first occurrence for the most frequent adverse events was spread across the course of the open-label treatment phase.

Table 29 Number (%) of Acute Study Paroxetine Patients with the Most Frequent (≥ 5%) Open-Label Treatment Phase-Emergent Adverse Events by Time of First Occurrence (ITT Population) Continued…

	Time of First Occurrence (Week)																					
	1		2		3		4		6		8		12		16		20		24		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Paroxetine N=94																						
Headache	9	(9.6)	3	(3.2)	4	(4.3)	0	-	1	(1.1)	3	(3.2)		-	1	(1.1)	2	(2.1)	1	(1.1)	24	(25.5)
Respiratory disorder	3	(3.2)	0	-	1	(1.1)	1	(1.1)	3	(3.2)	1	(1.1)	2	(2.1)	1	(1.1)	2	(2.1)	1	(1.1)	15	(16.0)
Infection	0	-	0	-	0	-	2	(2.1)	3	(3.2)	3	(3.2)	2	(2.1)	1	(1.1)	0	(0.0)	2	(2.1)	13	(13.8)
Trauma	0	-	3	(3.2)	2	(2.1)	1	(1.1)	1	(1.1)	0	-	4	(4.3)	1	(1.1)	0	-	0	-	12	(12.8)
Nausea	1	(1.1)	1	(1.1)	2	(2.1)	1	(1.1)	0	-	1	(1.1)	3	(3.2)	0	-	1	(1.1)	0	-	10	(10.6)
Abdominal pain	1	(1.1)	1	(1.1)	2	(2.1)	0	-	2	(2.1)	1	(1.1)	0	-	0	-	0	-	0	-	7	(7.4)
Allergic reaction	0	-	2	(2.1)	0	-	1	(1.1)	2	(2.1)	0	-	1	(1.1)	1	(1.1)	0	-	0	-	7	(7.4)
Dyspepsia	0	-	1	(1.1)	0	-	3	(3.2)	0	-	1	(1.1)	0	-	0	-	2	(2.1)	0	-	7	(7.4)
Fever	0	-	0	-	1	(1.1)	1	(1.1)	3	(3.2)	1	(1.1)	0	-	0	-	0	-	1	(1.1)	7	(7.4)
Hyperkinesia	1	(1.1)	0	-	1	(1.1)	1	(1.1)	2	(2.1)	0	-	2	(2.1)	0	-	0	-	0	-	7	(7.4)
Nervousness	2	(2.1)	2	(2.1)	1	(1.1)	0	-	1	(1.1)	1	(1.1)	0	-	0	-	0	-	0	-	7	(7.4)
Rhinitis	1	(1.1)	0	-	1	(1.1)	0	-	1	(1.1)	2	(2.1)	0	-	1	(1.1)	1	(1.1)	0	-	7	(7.4)
Sinusitis	1	(1.1)	3	(3.2)	1	(1.1)	0	-	0	-	1	(1.1)	1	(1.1)	0	-	0	-	0	-	7	(7.4)
Diarrhea	1	(1.1)	0	-	1	(1.1)	0	-	0	-	2	(2.1)	0	-	1	(1.1)	0	-	1	(1.1)	6	(6.4)
Pharyngitis	0	-	0	-	1	(1.1)	0	-	1	(1.1)	2	(2.1)	1	(1.1)	1	(1.1)	0	-	0	-	6	(6.4)
Vomiting	1	(1.1)	0	-	0	-	0	-	0	-	1	(1.1)	2	(2.1)	0	-	0	-	2	(2.1)	6	(6.4)
Weight gain	1	(1.1)	0	-	0	-	0	-	0	-	0	-	4	(4.3)	0	-	0	-	1	(1.1)	6	(6.4)
Hostility	0	-	0	-	0	-	1	(1.1)	2	(2.1)	0	-	2	(2.1)	0	-	0	-	0	-	5	(5.3)
Somnolence	2	(2.1)	1	(1.1)	0	-	0	-	0	-	0	-	2	(2.1)	0	-	0	-	0	-	5	(5.3)

Data Source Table 15.1.6.1x, Section 12; Listing 15.1.1, Appendix D

No adverse events fell in the post week 24 time interval

Table 30 Number (%) of Acute Study Placebo Patients with the Most Frequent (≥ 5%) Open-Label Treatment Phase-Emergent Adverse Events by Time of First Occurrence (ITT Population)

	Time of First Occurrence (Week)																					
	1		2		3		4		6		8		12		16		20		24		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Placebo N=127																						
Respiratory disorder	5	(3.9)	2	(1.6)	3	(2.4)	2	(1.6)	6	(4.7)	3	(2.4)	1	(0.8)	0	-	3	2.4	0	(0.0)	25	(19.7)
Headache	6	(4.7)	4	(3.1)	3	(2.4)	2	(1.6)	2	(1.6)	4	(3.1)	1	(0.8)	1	(0.8)	0	-	1	(0.8)	24	(18.9)
Infection	1	(0.8)	4	(3.1)	2	(1.6)	0	-	2	(1.6)	2	(1.6)	3	(2.4)	1	(0.8)	0	-	0	-	15	(11.8)
Nervousness	3	(2.4)	0	-	4	(3.1)	1	(0.8)	3	(2.4)	1	(0.8)	1	(0.8)	0	-	0	-	0	-	13	(10.2)
Abdominal pain	2	(1.6)	3	(2.4)	3	(2.4)	0	-	0	-	1	(0.8)	0	-	3	(2.4)	0	-	0	-	12	(9.4)
Insomnia	3	(2.4)	3	(2.4)	0	-	1	(0.8)	1	(0.8)	0	-	0	-	2	(1.6)	0	-	0	-	10	(7.9)
Nausea	3	(2.4)	1	(0.8)	1	(0.8)	0	-	2	(1.6)	1	(0.8)	2	(1.6)	0	-	0	-	0	-	10	(7.9)
Trauma	2	(1.6)	1	(0.8)	1	(0.8)	1	(0.8)	3	(2.4)	0	-	1	(0.8)	0	-	0	-	1	(0.8)	10	(7.9)
Hostility	0	-	0	-	3	(2.4)	3	(2.4)	2	(1.6)	0	-	0	-	0	-	1	(0.8)	0	-	9	(7.1)
Pharyngitis	3	(2.4)	3	(2.4)	0	-	1	(0.8)	1	(0.8)	0		0	-	0	-	1	(0.8)	0	-	9	(7.1)
Asthenia	2	(1.6)	2	(1.6)	0	-	1	(0.8)	0	-	0	-	1	(0.8)	0	-	1	(0.8)	1	(0.8)	8	(6.3)
Rhinitis	1	(0.8)	2	(1.6)	0	-	1	(0.8)	2	(1.6)	2	(1.6)	0	-	0	-	0	-	0	-	8	(6.3)
Decreased appetite	4	(3.1)	1	(0.8)	0	-	0	-	1	(0.8)	1	(0.8)	0	-	0	-	0	-	0	-	7	(5.5)
Dyspepsia	2	(1.6)	1	(0.8)	2	(1.6)	0	-	0	-	1	(0.8)	1	(0.8)	0	-	0	-	0	-	7	(5.5)
Weight gain	1	(0.8)	0	-	0	-	0	-	1	(0.8)	0	-	3	(2.4)	1	(0.8)	1	(0.8)	0	-	7	(5.5)

Source Table 15.1.6.1x, section 12; Listing 15.1.1, Appendix D
No adverse events fell in the post week 24 time interval

5.2.1.4 Dose Reductions for Open-Label Treatment-Phase Emergent Adverse Events

Dose reductions of 10 mg/day at weekly intervals were permitted at the discretion of the investigator. It was recommended that dose reductions were to be initiated at clinic visits. If the dose reduction was due to an adverse event, the patient could return to the previous dose level upon resolution of the adverse event. A summary of the number and percentage of patients with a decrease in open-label medication dose due to an open-label treatment phase emergent adverse event by body system and preferred term is presented in Table 15.1.8, Section 12. Adverse events leading to dose reduction occurred with the greatest frequency in the nervous system body system.

The number and proportion of patients whose dose of open-label study medication was decreased during the open-label treatment phase because of an adverse event is summarized in Table 31. Overall, 15.8% (35/221) of patients had dose reductions because of a gender-non-specific adverse event during the open-label treatment phase [14.9% (14/94) of patients in the acute study paroxetine group and 16.5% (21/127) of patients in the acute study placebo group]. The adverse events that most frequently resulted in a dose reduction in the acute study paroxetine group were nervousness (4.3%, 4/94), hostility (3.2%, 3/94), and hyperkinesia (4.3%, 4/94). In the acute study placebo group, the adverse events that most frequently resulted in a dose reduction were nervousness (3.9%, 5/127) and hostility (3.1%, 4/127).

The proportion of patients reporting gender-non-specific open-label treatment phase-emergent adverse events that required dose reduction was higher in children (20.2%, 24/119) compared to adolescents (10.8%, 11/102) (Table 15.1.8, Section 12). Among children, 16.3% (8/49) of patients in the acute study paroxetine group and 22.9% (16/70) of patients in the acute study placebo group had at least one adverse event that resulted in dose reduction. Among adolescents, 13.3% (6/45) of patients in the acute study paroxetine group and 8.8% (5/57) of patients in the acute study placebo group had at least one adverse event that resulted in dose reduction.

The proportion of patients reporting gender-non-specific open-label treatment phase-emergent adverse events that required dose reduction was higher in patients with a primary diagnosis of OCD compared to patients with a primary diagnosis of MDD. Among patients with a primary diagnosis of MDD, 14.0% (7/50) of patients in the acute study paroxetine group and 12.1% (8/66) of patients in the acute study placebo group had at least one adverse event that resulted in dose

reduction. Among patients with a primary diagnosis of OCD, 15.9% (7/44) of patients in the acute study paroxetine group and 21.3% (13/61) of patients in the acute study placebo group had at least one adverse event that resulted in dose reduction.

There were no gender-specific adverse events that resulted in a dose reduction.

Table 32 presents a listing of patients who had an adverse event identified as leading to a dose reduction. One patient in the acute study placebo group reported a serious adverse event (psychosis) that resulted in a dose reduction.

Table 31 Open-Label Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Body System and Acute Study Treatment Group (ITT Population) Continued…

		Acute Study Treatment Group					
		Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
		n	(%)	n	(%)	n	(%)
Total Patients with Dose Reduction Due to an Adverse Event*		14	(14.9)	21	16.5	35	(15.8)
Nervous System	Total	13	(13.8)	17	(13.4)	30	(13.6)
	Nervousness	4	(4.3)	5	(3.9)	9	(4.1)
	Hostility	3	(3.2)	4	(3.1)	7	(3.2)
	Hyperkinesia	4	(4.3)	2	(1.6)	6	(2.7)
	Agitation	1	(1.1)	2	(1.6)	3	(1.4)
	Insomnia	1	(1.1)	2	(1.6)	3	(1.4)
	Somnolence	2	(2.1)	0	-	2	(0.9)
	Anxiety	1	(1.1)	1	(0.8)	2	(0.9)
	Tremor	0	-	2	(1.6)	2	(0.9)
	Manic reaction	1	(1.1)	0	-	1	(0.5)
	Dyskinesia	0	-	1	(0.8)	1	(0.5)
	Emotional lability	0	-	1	(0.8)	1	(0.5)
	Lack of emotion	0	-	1	(0.8)	1	(0.5)
	Psychosis	0	-	1	(0.8)	1	(0.5)

Source Table 15.1.8., Section 12; Listing 15.1.1, Appendix D

*A patient may have more than 1 AE that led to dose reduction.

Table 31 Open-Label Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Body System and Acute Study Treatment Group (ITT Population)

		Acute Study Treatment Group					
		Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
		n	(%)	n	(%)	n	(%)
Body as a Whole	Total	2	(2.1)	3	(2.4)	5	(2.3)
	Headache	1	(1.1)	2	(1.6)	3	(1.4)
	Abdominal pain	0	-	2	(1.6)	2	(0.9)
	Asthenia	1	(1.1)	0	-	1	(0.5)
Digestive System	Total	2	(2.1)	3	(2.4)	5	(2.3)
	Dyspepsia	1	(1.1)	1	(0.8)	2	(0.9)
	Nausea	1	(1.1)	1	(0.8)	2	(0.9)
	Vomiting	1	(1.1)	1	(0.8)	2	(0.9)
	Decreased appetite	0	-	1	(0.8)	1	(0.5)
Urogenital System	Total	1	(1.1)	1	(0.8)	1	(0.9)
	Urinary incontinence	1	(1.1)	1	(0.8)	1	(0.9)
Metabolic and Nutritional Disorders	Total	0	-	1	(0.8)	1	(0.5)
	Weight gain	0	-	1	(0.8)	1	(0.5)

Source Table 15.1.8., Section 12; Listing 15.1.1, Appendix D

*A patient may have more than 1 AE that led to dose reduction.

Table 32 Open-Label Treatment-Phase Emergent Adverse Events That Led to Dose Reductions (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (Yrs)	Date of Onset	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Paroxetine							
716.005.25414	F	10	21 (-25)	20	Headache (headache)	Mild	Possibly related
716.006.27177	F	9	28 (-30)	30	Hyperkinesia (hyperactivity)	Moderate	Possibly related
716.016.25448	F	11	81 (-105)	30	Hyperkinesia (hyperactive)	Moderate	Possibly related
716.043.27694	M	9	76 (-94)	30	Hostility (anger)	Moderate	Possibly related
716.148.27658	F	10	22 (-28)	30	Nervousness (restlessness)	Moderate	Possibly related
716.159.25799	M	10	36 (-57)	40	Hostility (aggression)	Moderate	Possibly related
			36 (-57)	40	Nervousness (irritability)	Moderate	Possibly related
716.168.27072	F	10	43 (-88)	50	Hyperkinesia (hyperactivity)	Moderate	Possible related
716.172.25619	M	10	130 (-45)	40	Dyspepsia (gastrointestinal upset)	Mild	Possibly related
			130 (-45)	40	Agitation (psychomotor agitation, hyper)	Moderate	Possibly related
			130 (-45)	40	Urinary incontinence (enuresis daily)	Moderate	Possibly related
716.006.25420	F	14	19 (-147)	20	Asthenia (day time tiredness)	Moderate	Probably unrelated
			19 (-147)	20	Anxiety (increased anxiety)	Moderate	Probably unrelated
			19 (-147)	20	Insomnia (restless sleep)	Mild	Probably unrelated
			-	-	Insomnia (restless sleep)	Mild	Probably unrelated
			17 (-149)	20	Nervousness (increased irritability)	Moderate	Probably unrelated

Source Table 15.1.8, Section 12; Listing 13.5.1 and 13.10.1, Appendix B; Listings 15.1.1, Appendix D

** This event was a serious adverse event

Table 32 Open-Label Treatment-Phase Emergent Adverse Events That Led to Dose Reductions (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (Yrs)	Date of Onset	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Paroxetine							
716.016.27016	F	14	89 (-94)	40	Hostility (hyperactive defiant)	Moderate	Related
			89 (-94)	40	Hyperkinesia (hyperactive defiant)	Moderate	Related
716.028.25962	F	15	83 (-6)	40	Nausea (nausea)	Mild	Possibly related
			83 (-6)	40	Vomiting (vomiting)	Mild	Possibly related
			81 (-8)	40	Somnolence (sedation)	Mild	Possibly related
716.168.27077	F	15	23 (-31)	50	Manic reaction (mood cycling)	Moderate	Possibly related
716.180.25641	F	14	57 (-49)	30	Somnolence (sedation)	Moderate	Possibly related
716.186.25992	F	15	17 (-162)	10	Nervousness (restlessness)	Mild	Possibly related
Placebo							
716.002.25443	M	11	84 (-48)	50	Weight gain (weight gain)	Moderate	Possibly related
716.005.25412	M	11	20 (-62)	30	Dyskinesia (shoulder shrug)	Mild	Possible related
			20 (-62)	30	Tremor (tremor)	Mild	Possibly related
			20 (-62	30	Nervousness (restless)	Moderate	Possibly related
716.015.27042	M	7	31 (-40)	0	Abdominal pain (stomach ache)	Moderate	Related
			31 (-40)	20	Hostility (disruptive behavior)	Mild	Related
716.016.25447	M	7	9 (-40)	20	Headache (headache)	Moderate	Possibly related
			20 (-29)	30	Hostility (aggression)	Moderate	Possibly related

Source Table 15.1.8, Section 12; Listing 13.5.1 and 13.10.1, Appendix B; Listings 15.1.1, Appendix D

** This event was a serious adverse event

Table 32 Open-Label Treatment-Phase Emergent Adverse Events That Led to Dose Reductions (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (Yrs)	Date of Onset	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Placebo							
716.016.25450	F	11	29 (-18)	30	Hyperkinesia (hyperactivity)	Moderate	Possibly related
716.016.27019	M	11	48 (-45)	30	Lack of emotion (apathy)	Moderate	Related
716.020.25458	F	11	67 (0)	50	Psychosis (psychosis nos)**	Moderate	Probably Unrelated
716.020.25461	F	11	65 (-120)	50	Nervousness (irritable)	Mild	Possibly related
716.028.27683	F	11	36 (-30)	20	Nausea (nausea)	Moderate	Probably unrelated
			36 (-30)	20	Vomiting (vomiting)	Mild	Possibly related
716.040.27112	F	8	19 (-37)	20	Hostility (disruptive behavior)	Moderate	Unrelated
716.165.25664	M	9	109 (-18)	50	Agitation (increased agitation)	Moderate	Unrelated
716.167.25696	M	8	95 (-73)	30	Urinary incontinence (enuresis)	Mild	Possibly related
716.168.27071	M	10	53 (-11)	20	Anxiety (anxiety)	Moderate	Possibly related
			53 (-11)	20	Nervousness (irritability)	Moderate	Possibly related
716.170.25634	F	10	45(-99)	30	Tremor (hand shaking)	Moderate	Related
			45 (-99)	30	Tremor (hand tremors)	Moderate	Possibly related
716.176.27174	M	7	39 (-50)	40	Nervousness (restless)	Moderate	Possibly related

Source Table 15.1.8, Section 12; Listing 13.5.1 and 13.10.1, Appendix B; Listings 15.1.1, Appendix D

** This event was a serious adverse event

Table 32 Open-Label Treatment-Phase Emergent Adverse Events That Led to Dose Reductions (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Date of Onset	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Placebo							
716.179.25922	M	10	24 (-144)	30	Dyspepsia (upset stomach)	Mild	Probably unrelated
			11 (-157)	20	Insomnia (insomnia)	Mild	Probably unrelated
716.010.25741	F	17	5 (-163)	10	Agitation (restlessness and agitation)	Moderate	Related
			19 (-149)	30	Agitation (restlessness and agitation)	Moderate	Related
			5 (-163)	10	Nervousness (restlessness and agitation)	Moderate	Related
			19 (–149)	30	Nervousness (restlessness and agitation)	Moderate	Related
716.016.27017	M	12	39 (-20)	30	Hostility (defiant)	Moderate	Related
			39 (-20)	30	Hyperkinesia (hyperactivity)	Moderate	Related
716.049.28152	M	14	48 (-61)	50	Decreased appetite (decreased appetite)	Mild	Possibly related
716.159.25798	F	13	106 (-69)	20	Abdominal pain (stomach aches)	Moderate	Possibly related
			106 (-69)	20	Headache (headaches)	Moderate	Possibly related
			106 (-69)	20	Insomnia (insomnia)	Mild	Possibly related
716.192.25874	M	14	30 (-139)	40	Emotional lability	Moderate	Possibly related

Source Table 15.1.8, Section 12; Listing 13.5.1 and 13.10.1, Appendix B; Listings 15.1.1, Appendix D

** This event was a serious adverse event

5.2.2 Taper and/or Follow-up Phase Emergent Adverse Events

During the taper phase, open-label study medication was reduced by 10 mg/day every week for a period of up to 4 weeks for patients who completed the open-label treatment phase or were prematurely withdrawn at a dosage of ≥ 20 mg/day. Patients completing or withdrawing at 10 mg/day did not enter the taper phase. Patients completing or withdrawing at ≥ 20 mg/day commenced taper phase dosing at a dosage of 10 mg/day below the dose of their final open-label treatment phase dose (see Section 3.5.3). All patients, whether or not they completed the open-label study and whether or not they required down-titration, were scheduled to return for a follow-up visit 14 days after the last dose of open-label study medication.

The number and percentage of patients with emergent adverse events during the taper phase or follow up phase are summarized in Tables 15.1.1.5, Section 12, (by body system and preferred term), and 15.1.1.5x, Section 12, (by preferred term occurring in 1% or more of the population in descending order). Of the 94 acute study paroxetine patients in the open-label treatment phase, 50 (53.2%) entered the taper phase and/or the follow-up phase. Of the 127 placebo patients in the open-label treatment phase, 69 (54.3%) entered the taper and/or follow-up phase.

A summary of the most frequent (incidence ≥ 2% in either acute study treatment group) gender-non-specific taper phase or follow-up phase-emergent adverse events regardless of treatment attribution by acute study treatment group are presented in Table 33. Overall, 32.8% (39/119) of patients reported a gender-non-specific adverse event during the taper phase or follow-up phase. The proportion of patients reporting at least one gender-non-specific adverse event during the taper phase or follow-up phase was higher in the acute study paroxetine group (40.0%, 20/50) compared to the acute study placebo group (27.5%, 19/69). The most common (≥5%) gender-non-specific adverse events for patients in the acute study paroxetine group were headache, abdominal pain, respiratory disorder and sinusitis. No adverse events were reported during the taper phase or follow-up phase in the acute study placebo group at a frequency of ≥ 5%.

No gender specific adverse events were reported in either acute study treatment group during the taper phase and/or follow-up phase.

Table 33 Number (%) of Patients with the Most Frequent (≥ 2%) Taper or Follow-up Phase-Emergent Adverse Events by Acute Study Treatment Group (ITT Population Entering the Taper or Follow-up Phase)

	Acute Study Treatment Group					
	Paroxetine (N=50)		Placebo (N=69)		Total (N=119)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 AE	20	(40.0)	19	(27.5)	39	(32.8)
Respiratory disorder	3	(6.0)	3	(4.3)	6	(5.0)
Headache	4	(8.0)	1	(1.4)	5	(4.2)
Abdominal pain	4	(8.0)	0	-	4	(3.4)
Nausea	1	(2.0)	3	(4.3)	4	(3.4)
Sinusitis	3	(6.0)	0	-	3	(2.5)
Depression	2	(4.0)	1	(1.4)	3	(2.5)
Diarrhea	1	(2.0)	2	(2.9)	3	(2.5)
Infection	0	-	3	(4.3)	3	(2.5)
Fever	2	(4.0)	0	-	2	(1.7)
Hostility	1	(2.0)	1	(1.4)	2	(1.7)
Insomnia	1	(2.0)	1	(1.4)	2	(1.7)
Myalgia	1	(2.0)	1	(1.4)	2	(1.7)
Weight gain	1	(2.0)	1	(1.4)	2	(1.7)
Withdrawal syndrome	1	(2.0)	1	(1.4)	2	(1.7)
Anxiety	1	(2.0)	0	-	1	(0.8)
Asthma	1	(2.0)	0	-	1	(0.8)
Bradycardia	1	(2.0)	0	-	1	(0.8)
Ear pain	1	(2.0)	0	-	1	(0.8)
Increased appetite	1	(2.0)	0	-	1	(0.8)
Leukopenia	1	(2.0)	0	-	1	(0.8)
Nervousness	1	(2.0)	0	-	1	(0.8)
Pain	1	(2.0)	0	-	1	(0.8)
Paresthesia	1	(2.0)	0	-	1	(0.8)
Pharyngitis	1	(2.0)	0	-	1	(0.8)
Abnormal thinking	1	(2.0)	0	-	1	(0.8)

Source Table 15.1.1.5x, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the taper phase or follow-up phase
* Sorted by decreasing frequency in the total group

5.2.2.1 Taper Phase-Emergent Adverse Events

The number and percentage of patients with emergent adverse events during the taper phase are summarized in Tables 15.1.1.2, Section 12, (by body system and preferred term), and 15.1.1.2x, Section 12, (by preferred term occurring in 1% or more of the population in descending order).

A summary of gender-non-specific taper phase-emergent adverse events regardless of treatment attribution by acute study treatment group is presented in Table 34. Overall, 34.6% (18/52) of patients who entered the taper phase reported a gender-non-specific adverse event during the taper phase. The proportion of patients reporting at least one gender-non-specific adverse event during the taper phase was slightly higher in the acute study paroxetine group (40.9%, 9/22) compared to the acute study placebo group (30.0%, 9/30). The only adverse events reported by more than one patient in either acute study treatment group were depression and weight gain. Depression was reported by two patients in the acute study paroxetine group with a primary diagnosis of MDD and one patient in the acute study placebo group with a primary diagnosis of MDD. Weight gain was reported by one patient in the acute study paroxetine group with a primary diagnosis of MDD and one patient in the acute study placebo group with a primary diagnosis of OCD.

No gender-specific adverse events were reported during the taper phase.

Four adverse events emerged during the taper phase that had not occurred in either treatment group during the open-label treatment phase (Tables 15.1.1.1, 15.1.1.1x, 15.1.1.2 and 15.1.1.2x, Section 12; Listing 15.1.2, Appendix D):

- Patient 716.006.25420, a 14 year old female in the acute study paroxetine group, had bradycardia 1 day after the last dose of open-label study medication in the open-label treatment phase. This event, which lasted 29 days, was considered by the investigator to be moderate in intensity and possibly related to study medication. The duration of open-label treatment (including taper) was 168 days.

- Patient 716.179.25922, a 10 year old male in the acute study placebo group, had hysteria 7 days after the last dose of open-label study medication in the open-label treatment phase. This event, which lasted 5 days, was considered by the investigator to be moderate in intensity and probably unrelated to study medication. The duration of open-label treatment (including taper) was 182 days.

- Patient 716.028.27080, a 13 year old female in the acute study placebo group, reported abnormal dreams 3 days after the last dose of open-label study medication in the open-label treatment phase. This event, which lasted 5 days, was considered by the investigator to be mild in intensity and unrelated to study medication. The duration of open-label treatment (including taper) was 176 days.

- Patient 716.159.25629, a 12 year old female in the acute study placebo group, experienced withdrawal syndrome 1 day after the last dose of open-label study medication in the open-label treatment phase. This event, which lasted 4 days was considered by the investigator to be mild in intensity and related to study medication. Taper phase medication was stopped as a result of this event. The duration of open-label treatment (including taper) was 184 days.

Table 34 Number (%) of Patients with Taper Phase-Emergent Adverse Events by Acute Study Treatment Group (ITT Population Entering the Taper Phase)

	Acute Study Treatment Group					
	Paroxetine (N=22)		Placebo (N=30)		Total (N=52)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 AE	9	(40.9)	9	(30.0)	18	(34.6)
Depression	2	(9.1)	1	(3.3)	3	(5.8)
Weight gain	1	(4.5)	1	(3.3)	2	(3.8)
Abdominal pain	1	(4.5)	0	-	1	(1.9)
Bradycardia	1	(4.5)	0	-	1	(1.9)
Fever	1	(4.5)	0	-	1	(1.9)
Headache	1	(4.5)	0	-	1	(1.9)
Hostility	1	(4.5)	0	-	1	(1.9)
Leukopenia	1	(4.5)	0	-	1	(1.9)
Respiratory disorder	1	(4.5)	0	-	1	(1.9)
Sinusitis	1	(4.5)	0	-	1	(1.9)
Abnormal dreams	0	-	1	(3.3)	1	(1.9)
Hysteria	0	-	1	(3.3)	1	(1.9)
Infection	0	-	1	(3.3)	1	(1.9)
Insomnia	0	-	1	(3.3)	1	(1.9)
Myalgia	0	-	1	(3.3)	1	(1.9)
Nausea	0	-	1	(3.3)	1	(1.9)
Puncture site pain	0	-	1	(3.3)	1	(1.9)
Somnolence	0	-	1	(3.3)	1	(1.9)
Syncope	0	-	1	(3.3)	1	(1.9)
Withdrawal syndrome	0	-	1	(3.3)	1	(1.9)

Source Table 15.1.1.2x, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the taper phase
* Sorted by decreasing frequency in the total group

The number and percentage of patients with related or possibly related taper phase-emergent adverse events are summarized by body system and preferred term in Table 15.1.4.2, Section 12.

A summary of gender-non-specific taper phase-emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication by acute study treatment group is presented in Table 35. Overall, 19.2% (10/52) of patients who entered the taper phase reported a gender-non-specific adverse event judged by the investigator to be related or possibly

related to open-label study medication during the taper phase. The proportion of patients reporting at least one related or possibly related gender-non-specific adverse event during the taper phase was 22.7% (5/22) of patients in the acute study paroxetine group and 16.7% (5/30) of patients in the acute study placebo group. Weight gain was the only related or possibly related adverse events reported during the taper phase by more than one patient in either acute study treatment group.

Table 35 Number (%) of Patients with Related or Possibly Related Taper Phase-Emergent Adverse Events by Acute Study Treatment Group (ITT Population Entering the Taper Phase)

	Acute Study Treatment Group					
	Paroxetine (N=22)		Placebo (N=30)		Total (N=52)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 Related or Possibly Related AE	5	(22.7)	5	(16.7)	10	(19.2)
Weight gain	1	(4.5)	1	(3.3)	2	(3.8)
Depression	1	(4.5)	0	-	1	(1.9)
Hostility	1	(4.5)	0	-	1	(1.9)
Bradycardia	1	(4.5)	0	-	1	(1.9)
Leukopenia	1	(4.5)	0	-	1	(1.9)
Somnolence	0	-	1	(3.3)	1	(1.9)
Withdrawal syndrome	0	-	1	(3.3)	1	(1.9)
Syncope	0	-	1	(3.3)	1	(1.9)
Nausea	0	-	1	(3.3)	1	(1.9)
Myalgia	0	-	1	(3.3)	1	(1.9)

Source Table 15.1.4.2, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the taper phase
* Sorted by decreasing frequency in the total group

The number and percentage of patients with emergent adverse events during the taper phase by intensity are summarized in Tables 15.1.3.2, Section 12, (by body system and preferred term), and 15.1.3.2x, Section 12, (by preferred term occurring in 1% or more of the population in descending order). In addition, taper phase-emergent adverse events are summarized by maximum intensity, by body system and preferred term in Table 15.1.7.2, Section 12. One patient in each acute study treatment group had a taper phase-emergent adverse event that was considered severe by the investigator (Tables 15.1.3.2 and 15.1.3.2x, Section 12; Listing 15.1.2, Appendix D):

- Patient 716.172.25619, a 10 year old male in the acute study paroxetine group, had fever 1 day after the last dose of open-label study medication in the open-label treatment phase. This event, which lasted 1 day, was considered by the investigator to be severe in intensity and unrelated to study medication.

- Patient 716.002.25443, an 11 year old male in the acute study placebo group, reported a throat infection on day 1 and day 20 after the last dose of open-label study medication in the open-label treatment phase. These events, which lasted 10 and 11 days, respectively, were considered by the investigator to be severe in intensity and unrelated to study medication.

The number and percentage of patients with emergent adverse events during the open-label treatment phase or taper phase are summarized in Tables 15.1.1.3, Section 12, (by body system and preferred term), and 15.1.1.3x, Section 12, (by preferred term occurring in 1% or more of the population in descending order). The number and percentage of patients with related or possibly related open-label treatment phase or taper phase-emergent adverse events are summarized by body system and preferred term in Table 15.1.4.3, Section 12. The number and percentage of patients with emergent adverse events during the open-label treatment phase or taper phase by intensity are summarized in Table 15.1.3.3, Section 12.

5.2.2.2 Follow-up Phase-emergent Adverse Events

The number and percentage of patients with emergent adverse events during the follow-up phase are summarized in Tables 15.1.1.4, Section 12, (by body system and preferred term), and 15.1.1.4x, Section 12, (by preferred term occurring in 1% or more of the population in descending order).

A summary of gender-non-specific follow-up phase-emergent adverse events regardless of treatment attribution by acute study treatment group is presented in Table 36. Overall, 26.9% (28/104) of patients who entered the follow-up phase reported a gender-non-specific adverse event during the follow-up phase. The proportion of patients reporting at least one gender-non-specific adverse event during the follow-up phase was 33.3% (15/45) of patients in the acute study paroxetine group compared to 22.0% (13/59) of patients in the acute study placebo group. Adverse events reported by more than one patient in the acute study paroxetine group were headache, abdominal pain, respiratory disorders, and sinusitis. Adverse events reported by more than one patient in the acute study placebo group were respiratory disorders, infection, diarrhea, and nausea.

No gender-specific adverse events were reported during the follow-up phase.

Three patients reported five adverse events during the follow-up phase that had not occurred in either treatment group during the open-label treatment phase or taper phase (Tables 15.1.1.3x and 15.1.1.4x, Section 12; Listing 15.1.2, Appendix D):

- Patient 716.014.25355, a 13 year old male in the acute study paroxetine group, had paresthesia and abnormal thinking 1 day after the last dose of open-label study medication. These events, which lasted 11 days, were considered by the investigator to be moderate in intensity and possibly related to study medication.

- Patient 716.028.27685, a 10 year old female in the acute study placebo group, reported fecal incontinence 8 days after the last dose of open-label study medication. This event, which lasted 12 days, was considered by the investigator to be mild in intensity and unrelated to study medication. In addition, this patient also had increased SGOT levels 8 days after the last dose of open-label study medication, which was considered by the investigator to be moderate in intensity and possibly related to study medication. This event was ongoing at the time of this report.

- Patient 716.167.25696, an 8 year old male in the acute study paroxetine group, had lymphocytosis 14 days after the last dose of open-label study medication. This event, which lasted 6 days, was considered by the investigator to be moderate in intensity and possibly related to study medication.

Table 36 Number (%) of Patients with Follow-up Phase-Emergent Adverse Events by Acute Study Treatment Group (ITT Population Entering the Follow-up Phase) Continued…

	Acute Study Treatment Group					
	Paroxetine (N=45)		Placebo (N=59)		Total (N=104)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 AE	15	(33.3)	13	(22.0)	28	(26.9)
Respiratory disorder	2	(4.4)	3	(5.1)	5	(4.8)
Headache	3	(6.7)	1	(1.7)	4	(3.8)
Abdominal pain	3	(6.7)	0	-	3	(2.9)
Diarrhea	1	(2.2)	2	(3.4)	3	(2.9)
Nausea	1	(2.2)	2	(3.4)	3	(2.9)
Sinusitis	2	(4.4)	0	-	2	(1.9)
Infection	0	-	2	(3.4)	2	(1.9)
Anxiety	1	(2.2)	0	-	1	(1.0)
Asthma	1	(2.2)	0	-	1	(1.0)
Depression	1	(2.2)	0	-	1	(1.0)
Ear pain	1	(2.2)	0	-	1	(1.0)
Fever	1	(2.2)	0	-	1	(1.0)
Increased appetite	1	(2.2)	0	-	1	(1.0)
Insomnia	1	(2.2)	0	-	1	(1.0)
Myalgia	1	(2.2)	0	-	1	(1.0)
Nervousness	1	(2.2)	0	-	1	(1.0)
Pain	1	(2.2)	0	-	1	(1.0)
Paresthesia	1	(2.2)	0	-	1	(1.0)
Pharyngitis	1	(2.2)	0	-	1	(1.0)
Thinking abnormal	1	(2.2)	0	-	1	(1.0)
Withdrawal syndrome	1	(2.2)	0	-	1	(1.0)
Allergic reaction	0	-	1	(1.7)	1	(1.0)
Concentration impaired	0	-	1	(1.7)	1	(1.0)
Cough increased	0	-	1	(1.7)	1	(1.0)
Fecal incontinence	0	-	1	(1.7)	1	(1.0)

Source Table 15.1.1.4x, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the follow-up phase
* Sorted by decreasing frequency in the total group

Table 36 Number (%) of Patients with Follow-up Phase-Emergent Adverse Events by Acute Study Treatment Group (ITT Population Entering the Follow-up Phase)

	Acute Study Treatment Group					
	Paroxetine (N=45)		Placebo (N=59)		Total (N=104)	
AE Preferred Term*	n	(%)	n	(%)	n	(%)
Fungal dermatitis	0	-	1	(1.7)	1	(1.0)
Hostility	0	-	1	(1.7)	1	(1.0)
Liver function tests abnormal	0	-	1	(1.7)	1	(1.0)
Lymphocytosis	0	-	1	(1.7)	1	(1.0)
SGOT increased	0	-	1	(1.7)	1	(1.0)
Trauma	0	-	1	(1.7)	1	(1.0)
Urinary incontinence	0	-	1	(1.7)	1	(1.0)
Vomiting	0	-	1	(1.7)	1	(1.0)

Source Table 15.1.1.4x, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the follow-up phase
* Sorted by decreasing frequency in the total group

The number and percentage of patients with related or possibly related follow-up phase emergent adverse events are summarized by body system and preferred term in Table 15.1.4.4, Section 12.

A summary of gender-non-specific follow-up phase emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication by acute study treatment group is presented in Table 37. Overall, 8.7% (9/104) of patients who entered the follow-up phase reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the follow-up phase: 11.1% (5/45) of patients in the acute study paroxetine group and 6.8% (4/59) of patients in the acute study placebo group. The only related or possibly related adverse event reported during the follow-up phase by more than one patient in either acute study treatment group was headache.

Table 37 Number (%) of Patients with Related or Possibly Related Follow-up Phase-Emergent Adverse Events by Acute Study treatment Group (ITT Population Entering the Follow-up Phase)

	Acute Study Treatment Group					
	Paroxetine (N=45)		Placebo (N=59)		Total (N=104)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least 1 AE	5	(11.1)	4	(6.8)	9	(8.7)
Headache	1	(2.2)	1	(1.7)	2	(1.9)
Anxiety	1	(2.2)	0	-	1	(1.0)
Insomnia	1	(2.2)	0	-	1	(1.0)
Nervousness	1	(2.2)	0	-	1	(1.0)
Paresthesia	1	(2.2)	0	-	1	(1.0)
Thinking abnormal	1	(2.2)	0	-	1	(1.0)
Withdrawal syndrome	1	(2.2)	0	-	1	(1.0)
Increased appetite	1	(2.2)	0	-	1	(1.0)
Myalgia	1	(2.2)	0	-	1	(1.0)
Respiratory disorder	1	(2.2)	0	-	1	(1.0)
Liver function tests abnormal	0	-	1	(1.7)	1	(1.0)
Lymphocytosis	0	-	1	(1.7)	1	(1.0)
SGOT increased	0	-	1	(1.7)	1	(1.0)

Source Table 15.1.4.4, Section 12; Listing 15.1.2, Appendix D
N is the number of patients entering the follow-up phase
* Sorted by decreasing frequency in the total group

The number and percentage of patients with emergent adverse events during the follow-up phase by intensity are summarized in Tables 15.1.3.4, Section 12, (by body system and preferred term), and 15.1.3.4x, Section 12, (by preferred term occurring in 1% or more of the population in descending order). In addition, follow-up phase-emergent adverse events are summarized by maximum intensity, by body system and preferred term in Table 15.1.7.4, Section 12. One patient in the acute study placebo group had a follow-up phase-emergent adverse event that was considered severe by the investigator (Tables 15.1.3.4 and 15.1.3.4x, Section 12; Listing 15.1.2, Appendix D). Patient 716.026.27047, a 10 year old male, had an infection 1 day after the last dose of open-label study medication. This event, which lasted 7 days, was considered by the investigator to be severe in intensity and unrelated to study medication.

5.3 Deaths

No deaths were reported prior to the clinical cut-off for this interim report (October 1, 2001).

5.4 Serious Adverse Events

A serious adverse event was defined as any event which is fatal, life threatening, disabling/incapacitating or resulted in hospitalization,[4] prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any event which the investigator regarded as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug was documented as a serious event. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug event when, based upon appropriate medical judgement, they may jeopardize the patient or patients and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Pregnancy was captured as a serious adverse event for the purpose of tracking the status of pregnancies to term.

The number of patients with serious emergent adverse events during the open-label treatment phase, taper phase or follow-up phase by body system and preferred term by primary diagnosis and acute study treatment group is presented in table 15.1.2.1, Section 12. Listings of patients with serious emergent adverse events during the open-label treatment phase, taper phase, follow-up phase or post follow-up phase are provided in Listings 15.1.3.2 and 15.1.3.3, Appendix D.

The number and percentage of patients with non-fatal serious emergent adverse events during the open-label treatment, taper, or follow-up phase is presented by acute study treatment group in Table 38. Overall, 5.4% (12/223) of patients reported at least one serious adverse event during the open-label treatment phase, taper phase, or within 30 days of the last dose of open-label study medication. The proportion of patients reporting at least one serious adverse event was similar between the two acute study treatment groups: 5.2% (5/96) of patients in the acute

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[4] Elective surgery or routine clinical procedures which required hospitalization but were not the result of an adverse event, and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the CRF.

study paroxetine group and 5.5% (7/127) of patients in the acute study placebo group. (Note: the total number of patients includes two patients who had no post-716 baseline assessments and thus are not included in the ITT population). Of the 14 serious adverse events reported, 12 were reported during the open-label treatment phase. The majority of serious adverse events were judged as moderate or severe in intensity and unrelated to open-label study medication (Listing 15.1.3.2 and 15.1.3.3, Appendix D). No gender-specific serious adverse events were reported for either acute study treatment group. The number of serious adverse events reported during the open-label treatment phase was greater in children (9/119) compared to adolescents (3/104).

Table 39 presents a listing of all patients with serious adverse events occurring during the open-label treatment phase, taper phase, or within 30 days of the last dose of open-label study medication. One patient with a serious adverse event had a psychiatric condition (psychosis) reported in addition to the primary diagnosis of OCD.

Table 38 Number (%) of Patients with Non-Fatal Serious Emergent Adverse Events (Open-Label Treatment Phase, Taper Phase, or Within 30 Days of the Last Dose of Open-Label Study Medication) by Acute Study Treatment Group (All Patients)

	Acute Study Treatment Group					
	Paroxetine (N=96)		Placebo (N=127)		Total (N=223)	
Serious Adverse Event Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at least 1 SAE *	5	(5.2)	7	(5.5)	12	(5.4)
Emotional Lability	2	(2.1)	1	(0.8)	3	(1.3)
Depression	1	(1.0)	1	(0.8)	2	(0.9)
Hostility	1	(1.0)	1	(0.8)	2	(0.9)
Hallucinations	0	-	1	(0.8)	1	(0.4)
Paralysis	0	-	1	(0.8)	1	(0.4)
Psychosis	0	-	1	(0.8)	1	(0.4)
Abnormal Laboratory Value	1	(1.0)	0	-	1	(0.4)
Abscess	1	(1.0)	0	-	1	(0.4)
Trauma	0	-	1	(0.8)	1	(0.4)
Asthma	0	-	1	(0.8)	1	(0.4)

Source Table 15.1.2.1, Section 12; Listings 15.1.3.2 and 15.1.3.3, Appendix D

* Serious adverse events up to 30 days after the last dose of open-label medication are included in this summary.

N is the total number of patients and includes two patients in the acute study paroxetine group that did not have any post study 716 baseline assessments

Complete narratives for these patients may be found in Table 15.1.9, Section 13. There may be minor discrepancies in the details of the serious adverse events included in the clinical narratives compared with the safety tabulations, because the data come from two different databases and have been collected at different points in time. However, it is considered that these differences, if any, are minor in nature and do not change the overall clinical significance or understanding of the serious adverse events. In the safety tabulations, serious adverse events were coded by the WHO ART dictionary and mapped by ADECS for preferred term. In the separate database used for preparing the clinical narratives, serious adverse events were coded by the WHO ART dictionary.

Table 39 Patients with Non-Fatal Serious Adverse Events (Open-Label Treatment Phase, Taper Phase, or Within 30 Days of the Last Dose of Open-Label Study Medication) (All Patients) Continued…

Patient Number	Gender (M/F)	Age (yrs)	SAE (Preferred Term)	SAE (Verbatim Term)	Intensity	Relationship	Day of Onset*	Duration (days)
Acute Study Paroxetine Patients								
716.004.25405	F	7	Abscess	Left retropharyngeal abscess	Severe	Unrelated	158 (-23)	8
716.014.25652	F	9	Depression**	Increased depression, suicidal ideation, held knife to chest	Severe	Unrelated	108 (-2)	3
			Emotional lability**	Increased depression, suicidal ideation, held knife to chest	Severe	Unrelated	108 (-2)	3
716.025.25802	M	11	Hostility**	Homicidal ideation	Severe	Unrelated	42 (0)	6
716.044.27656	M	12	Emotional lability**	Suicidal	Severe	Unrelated	39 (-4)	7
716.049.28149	M	14	Abnormal Laboratory Value	Unintentional overdose	Mild	Unrelated	87 (-29)	1

Source Table 15.1.2.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.3.2 and 15.1.3.3, Appendix D

*Relative to the first day of open-label study medication (relative to the last day of open-label medication (excluding taper))

**Patient was withdrawn from study 716 because of the serious adverse event

† Serious adverse event occurred during the taper phase or follow-up phase

Table 39 Patients with Non-Fatal Serious Adverse Events (Open-Label Treatment Phase, Taper Phase, or Within 30 Days of the Last Dose of Open-Label Study Medication) (All Patients)

Patient Number	Gender (M/F)	Age (yrs)	SAE (Preferred Term)	SAE (Verbatim Term)	Intensity	Relationship	Day of Onset*	Duration (days)
Acute Study Placebo Patients								
716.019.25751	M	9	Trauma	Fractured left ulna and radius (compound fracture of left arm)	Severe	Unrelated	45 (–133)	43
716.019.25752	M	11	Hallucinations**	Auditory hallucinations	Moderate	Probably Unrelated	68 (0)	Ongoing
			Paralysis	Temporary paralysis of right leg	Severe	Unrelated	31 (-37)	1
716.020.25458	F	11	Psychosis**	Psychosis nos	Moderate	Probably Unrelated	67 (0)	Ongoing
716.028.27683	F	11	Depression†	Acute exacerbation of MDD	Moderate	Unrelated	77 (11)	5
716.028.27685	F	10	Hostility†	Aggression	Moderate	Unrelated	36 (1)	6
716.151.25607	F	16	Emotional lability	Hospitalization for suicide attempt	Severe	Unrelated	95 (0)	3
716.176.27678	M	9	Asthma	Worsening of Asthma	Severe	Unrelated	105 (-63)	3

Source Table 15.1.2.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.3.2 and 15.1.3.3, Appendix D

*Relative to the first day of open-label study medication (relative to the last day of open-label medication (excluding taper))

**Patient was withdrawn from study 716 because of the serious adverse event

† Serious adverse event occurred during the taper phase or follow-up phase

5.5 Withdrawals Due to Adverse Events

The number of patients with emergent adverse events leading to withdrawal during the open-label treatment phase (including taper) by body system and preferred term by primary diagnosis, age group, and acute study treatment group is presented in Table 15.1.5.1, Section 12 (by body system and preferred term) and Table 15.1.5.1x, Section 12 (by preferred term occurring in 1% or more of the population in descending order). Listing 15.1.4, Appendix D, provides additional details regarding the events, including intensity, time of occurrence relative to the start of study medication, duration and investigator assessment of relationship to study drug.

Overall, 14.9% (33/221) of patients were withdrawn from the study during the open-label treatment phase because of an adverse event (31 patients during the open-label treatment phase and 2 patients during the taper phase). The proportion of patients withdrawn because of an adverse event was lower in the acute study paroxetine group (9.6%, 9/94) compared to the acute study placebo group (18.9%, 24/127).

Table 40 presents a summary of the number of patients who were withdrawn for an adverse event during the open-label treatment phase (excluding taper). The most frequently reported reason for withdrawal during the open-label treatment phase (excluding taper) was emotional lability in the acute study paroxetine group (3.2%, 3/94) and hostility in the acute study placebo group (4.7%, 6/127).

Adverse events leading to withdrawal during the open-label treatment phase (excluding taper) occurring in more than 1% of the population were hostility (3.6%, 8/221), emotional lability (1.8%, 4/221), hyperkinesia (1.8%, 4/221) and nervousness (1.4%, 3/221). Two patients in the acute study placebo group reported a gender specific adverse events leading to withdrawal (libido decreased and abnormal ejaculation).

Table 40 Number (%) of Patients Withdrawn During the Open-Label Treatment Phase (Excluding Taper) by Acute Study Treatment Group (ITT Population)

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Adverse Event	(N=94)		(N=127)		(N=221)	
Preferred Term	n	(%)	n	(%)	n	(%)
Total Patients with an AE Leading to Withdrawal	8	(8.5)	19	(15.0)	27	(12.2)
Hostility	2	(2.1)	6	(4.7)	8	(3.6)
Emotional Lability	3	(3.2)	1	(0.8)	4	(1.8)
Hyperkinesia	1	(1.1)	3	(2.4)	4	(1.8)
Nervousness	0	-	3	(2.4)	3	(1.4)
Agitation	0	-	2	(1.6)	2	(0.9)
Anxiety	0	-	2	(1.6)	2	(0.9)
Hallucinations	0	-	2	(1.6)	2	(0.9)
Concentration Impaired	1	(1.1)	0	-	1	(0.5)
Convulsions	1	(1.1)	0	-	1	(0.5)
Depression	1	(1.1)	0	-	1	(0.5)
Libido Decreased	0	-	1	(0.8)	1	(0.5)
Manic Reaction	0	-	1	(0.8)	1	(0.5)
Nausea	1	(1.1)	0	-	1	(0.5)
Vomiting	1	(1.1)	0	-	1	(0.5)
Asthenia	0	-	1	(0.8)	1	(0.5)
ECG Abnormal	0	-	1	(0.8)	1	(0.5)

Source Table 15.1.5.1, Section 12; Listings 15.1.4, Appendix D
A patient may have more than one adverse event leading to withdrawal
Patient 716.019.25753, in the acute study paroxetine group, has the reason for withdrawal listed as 'other', however, the patient had an adverse event of vomiting for which study medication was stopped and is therefore included in this summary table.
Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but are not included in this summary table because they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.
Patient 716.008.25644 in the acute study paroxetine group and patients 716.015.25464 and 716.010.25371 in the acute study placebo group withdrew due to an adverse event during the open-label treatment phase, but are not included in this summary as the corresponding adverse event started prior to the open-label treatment phase.

Table 41 presents a listing of patients withdrawn from the study during the open-label treatment or taper phase because of an adverse event. Of the 33 patients withdrawn from the study because of an adverse event 15.1% (18/119)

were children, 14.7% (15/102) were adolescents, 14.7 % (17/116) had a primary diagnosis of MDD and 15.2% (16/105) had a primary diagnosis of OCD. The majority of the adverse events leading to withdrawal were judged moderate or severe in intensity by the investigator.

Three patients in the acute study paroxetine group and 1 patient in the acute study placebo group experienced a serious adverse event that resulted in withdrawal. Narratives for these patients may be found in Table 15.1.9, Section 12. Detailed narratives for patients with non-serious adverse events that resulted in withdrawal may be found in Table 15.1.10, Section 12.

Table 41 Patients Withdrawn from Study During the Open-Label Treatment Phase Because of an Adverse Event (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute Study Paroxetine Patients								
716.014.25652	F	9	30 mg	Depression (increased depression, suicidal ideation, held knife to chest)**	Severe	Unrelated	108 (-2)	3
			30 mg	Emotional lability (increased depression, suicidal ideation, held knife to chest)**	Severe	Unrelated	108 (-2)	3
716.015.25469	M	8	30 mg	Concentration impaired (exacerbation of attention deficit hyperactivity disorder)	Mild	Related	34 (-29)	Ongoing
			30 mg	Hostility (exacerbation of attention deficit hyperactivity disorder)	Mild	Related	34 (-29)	Ongoing
			30 mg	Hyperkinesia (exacerbation of attention deficit hyperactivity disorder)	Mild	Related	34 (-29)	Ongoing
716.025.25802	M	11	30 mg	Hostility (homicidal ideation)**	Severe	Unrelated	42 (0)	6

Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

* Relative to the first day of open-label study medication (relative to the last dose of open-label study medication (excluding taper)).

** AE leading to withdrawal was considered to be a serious, non-fatal AE.

Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.

Patient 716.019.25753, in the acute study paroxetine group, had an adverse event of vomiting for which study medication was stopped, however, the reason for withdrawal is listed as 'other' and the patient is therefore not included in this table.

Table 41 Patients Withdrawn from Study During the Open-Label Treatment Phase Because of an Adverse Event (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute Study Paroxetine Patients								
716.180.25776	M	7	10 mg	Convulsions (possible seizure activity)	Moderate	Possibly related	6 (-15)	26
716.008.25644	M	16	-	Somnolence (sedation)	Moderate	Possible related	-40 (-58)	62
716.010.25606	F	13	30 mg	Hostility (aggression)	Moderate	Possibly related	150 (25)	3
716.015.27043	F	16	30 mg	Emotional lability (suicidal ideation)	Moderate	Possibly related	41 (-24)	2
716.044.27656	M	12	50 mg	Emotional lability (suicidal)**	Severe	Unrelated	39(-4)	7
716.164.25721	M	14	20 mg	Nausea (nausea)	Moderate	Possibly related	85 (-14)	21
Acute Study Placebo Patients								
716.004.25403	M	10	20 mg	Hyperkinesia (hyperactivity)	Moderate	Possibly related	16 (-5)	Ongoing
			20 mg	Manic reaction (hypomanic symptoms)	Moderate	Possibly related	16 (-5)	Ongoing
716.015.25464	M	7	-	Manic reation (manic activation)	Related	Moderate	-18 (-53)	Ongoing
716.016.25447	M	7	20 mg	Hostility (aggression)	Severe	Possibly related	47 (-2)	Ongoing
716.016.25450	F	11	20 mg	Nervousness (irritability)	Severe	Possibly related	45 (-2)	6
716.016.27019	M	11	20 mg	Hyperkinesia (hyperactivity)	Moderate	Related	90 (-3)	5

Source Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

* Relative to the first day of open-label study medication (relative to the last dose of open-label study medication (excluding taper)).

** AE leading to withdrawal was considered to be a serious, non-fatal AE.

Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.

Patient 716.019.25753, in the acute study paroxetine group, had an adverse event of vomiting for which study medication was stopped, however, the reason for withdrawal is listed as 'other' and the patient is therefore not included in this table.

Table 41 Patients Withdrawn from Study During the Open-Label Treatment Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute Study Placebo Patients								
716.016.27021	M	8	20 mg	Hyperkinesia (hyperactivity)	Severe	Related	27 (-3)	8
716.019.25752	M	11	30 mg	Hallucinations (auditory hallucinations)**	Moderate	Probably unrelated	68 (0)	Ongoing
716.020.25458	F	11	50 mg	Psychosis (psychosis nos)**	Moderate	Probably unrelated	67 (0)	Ongoing
716.025.25822	M	7	30 mg	Agitation (increased agitation)	Moderate	Possibly related	20 (0)	18
716.025.27060	M	8	20 mg	Hostility (oppositional defiant)	Moderate	Unrelated	127(-14)	Ongoing
716.028.27685	F	10	-	-	-	-	-	-
716.043.27696	M	8	10 mg	Hostility (defiant behavior)	Severe	Unrelated	27 (-11)	24
716.165.25664	M	9	50 mg	ECG abnormal (abnormal ECG)	Mild	Unrelated	127 (0)	15
716.176.25794	M	11	30 mg	Syncope (syncope)	Moderate	Possibly related	62 (6)	1

Source Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

* Relative to the first day of open-label study medication (relative to the last dose of open-label study medication (excluding taper)).

** AE leading to withdrawal was considered to be a serious, non-fatal AE.

Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.

Patient 716.019.25753, in the acute study paroxetine group, had an adverse event of vomiting for which study medication was stopped, however, the reason for withdrawal is listed as 'other' and the patient is therefore not included in this table.

Table 41 Patients Withdrawn from Study During the Open-Label Treatment Phase Because of an Adverse Event (ITT Population) Continued…

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute Study Placebo Patients								
716.006.25418	M	13	30 mg	Agitation (increased agitation)	Moderate	Possibly related	30 (-7)	Ongoing
			30 mg	Emotional lability (mood swing)	Moderate	Probably unrelated	30 (-7)	Ongoing
			30 mg	Hostility (aggression)	Moderate	Probably unrelated	30 (-7)	Ongoing
			30 mg	Hostility (temper outburst)	Moderate	Probably unrelated	30 (-7)	Ongoing
			30 mg	Nervousness (irritability)	Moderate	Probably unrelated	30 (-7)	Ongoing
716.010.25371	M	15	-	Abnormal ejaculation (delayed ejaculation)	Moderate	Related	-16 (-30)	32
716.014.25651	F	17	50 mg	Hostility (aggression anger)	Moderate	Possibly related	37 (-2)	1
716.015.25466	M	13	50 mg	Nervousness (irritability)	Moderate	Related	44 (-12)	Ongoing
716.016.27017	M	12	20 mg	Hostility (oppositional behavior)	Severe	Related	52 (-7)	10
716.025.27059	M	14	20 mg	Anxiety (anxiety increase)	Moderate	Unrelated	129(-14)	Ongoing
716.044.27655	F	12	20 mg	Anxiety (post traumatic syndrome)	Severe	Unrelated	24 (-5)	Ongoing

Source Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

* Relative to the first day of open-label study medication [relative to the last dose of open-label study medication (excluding taper)].

** AE leading to withdrawal was considered to be a serious, non-fatal AE.

Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.

Patient 716.019.25753, in the acute study paroxetine group, had an adverse event of vomiting for which study medication was stopped, however, the reason for withdrawal is listed as 'other' and the patient is therefore not included in this table.

Table 41 Patients Withdrawn from Study During the Open-Label Treatment Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute Study Placebo Patients								
716.047.27156	F	12	10 mg	Asthenia (fatigue)	Moderate	Possibly related	1 (-7)	10
716.183.25901	F	17	30 mg	Libido decreased (decreased libido inorgasmia)	Mild	Related	98 (0)	15
716.192.25870	M	17	40 mg	Hallucination (auditory hallucinations)	Severe	Unrelated	127(-11)	Ongoing
			40 mg	Hallucinations (visual hallucinations)	Severe	Unrelated	127(-11)	Ongoing

Source Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

* Relative to the first day of open-label study medication [relative to the last dose of open-label study medication (excluding taper)].

** AE leading to withdrawal was considered to be a serious, non-fatal AE.

Patients 716.020.25458 and 716.028.27685 in the acute study placebo group withdrew due to an adverse event, but they did not have a corresponding adverse event with an action of study medication stopped. Patients 716.020.25458 was withdrawn for the adverse event psychosis, which is listed as resulting in dose reduction.

Patient 716.019.25753, in the acute study paroxetine group, had an adverse event of vomiting for which study medication was stopped, however, the reason for withdrawal is listed as 'other' and the patient is therefore not included in this table.

5.6 Medical Procedures

Elective therapeutic, diagnostic or surgical procedures that required hospitalization but were not the result of an adverse event, and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the CRF. A listing of non-medication therapeutic, diagnostic or surgical procedures performed during this study may be found in Listing 15.5.1, Appendix D.

Overall, 16 acute study paroxetine patients and 23 acute study placebo patients recorded at least one medical procedure. The majority of medical procedures in both treatment groups were either non-routine dental work, treatment for injury or diagnostic procedures for concurrent adverse events.

5.7 Pregnancy

None of the female patients in study 716 had a positive serum HCG pregnancy test at baseline, and none of the patients had a positive serum HCG pregnancy test or became pregnant prior to the clinical cut-off date for this interim report (October 1, 2001).

5.8 Vital Signs

5.8.1 Vital Signs of Potential Clinical Concern

Vital signs data were listed by acute study treatment group, age group and patient number. The number and percentage of patients with a significant increase or decrease in any vital sign from acute study baseline, which was of potential clinical concern, during the study was tabulated by parameter by acute study treatment group. Table 4, Section 3.14.6.2, shows these pre-determined levels of potential clinical concern for vital signs.

All vital signs that were assessed after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the week 24 or early withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the follow-up phase if the patient did not enter the taper phase, and as occurring during the taper phase if the patient did enter the taper phase. Patient listings of vital signs data are provided in Listing 15.2.1, Appendix E.

Summaries of the number of patients with vital signs of potential clinical concern during the open-label treatment phase (including taper) and open label treatment phase, taper phase or follow up phase, by variable and acute study treatment group, are provided in Table 15.2.2.1 and Table 15.2.2.2, Section 12, respectively.

A summary of the number and percentage of patients with vital sign measurements meeting the predefined clinical concern criteria [i.e., both an absolute value of concern and a significant increase or decrease in the same direction during the open-label treatment phase (including taper) from acute study baseline] is presented in Table 42. There were no important differences between the acute study treatment groups or age groups in the number or the type of vital signs meeting this combination of clinical concern criteria.

Overall 14.4% (21/147) patients had an increase in weight that met the predefined clinical concern criteria during the open-label treatment phase (including taper): 19.4% (12/62) of patients who received paroxetine in their acute study and 10.7% (9/85) of patients who received placebo in their acute study (Table 42). Four of these patients had an increase in weight that was considered clinically significant by the investigator and recorded as an adverse event; narratives for these patients are provided in Table 15.2.3, Section 12.

Table 42 Number (%) of Patients with Vital Sign Values Meeting Predefined Clinical Concern Criteria During the Open-Label Treatment Phase (Including Taper) by Acute Study Treatment Group (ITT Population)

Vital Sign Sponsor Defined Clinical Concern Criteria	Acute Study Treatment Group								
	Paroxetine			Placebo			Total		
	N	n	(%)	N	n	(%)	N	n	(%)
Total patients with a vital sign of clinical concern		20			20			40	
Systolic Blood Pressure (mmHg)									
> 145 and increase of ≥ 40	91	0	(0.0)	123	2	(1.6)	214	2	(0.9)
< 95 and decrease of ≥ 30	91	3	(3.3)	123	3	(2.4)	214	6	(2.8)
Diastolic Blood Pressure (mmHg)									
> 85 and increase ≥ 30	91	1	(1.1)	123	1	(0.8)	214	2	(0.9)
< 50 and decrease ≥ 20	91	1	(1.1)	123	3	(2.4)	214	4	(1.9)
Heart Rate (bpm)									
Ages 7 to 12 > 115, ages 13 to 17 > 110, plus increase ≥ 30	91	2	(2.2)	123	1	(0.8)	214	3	(1.4)
Ages 7 to 12 < 65, ages 13 to 17 < 55, plus decrease ≥ 30	91	1	(1.1)	123	3	(2.4)	214	4	(1.9)
Weight (kg)									
Above normal range, * and increase ≥ 7%	62	12	(19.4)	85	9	(10.7)	147	21	(14.4)
Below normal range, * and decrease ≥ 7%	62	1	(1.6)	85	0	(0.0)	147	1	(0.7)

Source Table 15.2.2.1, Section 12; Listing 15.2.1, Appendix E

N is the number of patients who had a measurement for this vital sign at acute study baseline and at any time during the open-label treatment phase (including taper)

n is the number of patients meeting the predefined clinical concern criteria

* normal ranges for weight may be found in Table 4

A list of patients with vital sign values meeting pre-defined clinical concern criteria during the open-label treatment or taper phase is provided in Table 43. As shown in Table 43 and Table 42, 20 patients in the acute study paroxetine group and 20 patients in the acute study placebo group were identified as having a change and absolute value in one or more of the vital signs that met the criteria for clinical concern during the open-label treatment phase (including taper). A small number of patients had more than one vital sign flagged as meeting the criteria for clinical concern (1 patient in the acute study paroxetine group and 2 patients in the acute study placebo group). In addition, 3 patients had a vital sign change and absolute value meeting the concern criteria during the follow-up phase (Listing 15.2.1, Appendix E):

- Patient 716.014.25652, a 9 year old female, in the acute study paroxetine group had a decrease from acute study baseline of 70 mmHg in diastolic blood pressure to 42 mmHg , 6 days after stopping paroxetine. This patient also had an increase in weight from acute study screening of 48.6 kg to 52.7 kg, 6 days after stopping paroxetine.

- Patient 716.014.25651, a 17 year old female, in the acute study placebo group had an increase in weight from acute study screening of 93.6 kg to 105.3 kg, 4 days after stopping paroxetine.

- Patient 716.167.25903, a 12 year old female, in the acute study placebo group had an increase in weight from acute study screening of 60.4 kg to 66.4 kg, 1 day after stopping paroxetine.

Table 43 Patients with Vital Sign Values Meeting Predefined Clinical Concern Criteria (Open-Label Treatment or Taper Phase) (ITT Population) Continued…

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute Study Baseline Value*	Value of Concern	Visit
Paroxetine							
716.019.25943	F	MDD	7	Pulse rate low/decrease	97 bpm	60 bpm	Week 12
716.025.25802	M	MDD	11	Pulse rate high/increase	96 bpm	128 bpm	Week 2
				Pulse rate high/increase	96 bpm	128 bpm	Week 4
716.159.25797	F	MDD	9	Pulse rate high/increase	72 bpm	120 bpm	Week 16
716.025.25801	M	MDD	8	Diastolic blood pressure low/decrease	76 mmHg	45 mmHg	Week 2
				Diastolic blood pressure low/decrease	76 mmHg	45 mmHg	Week 8
716.016.25448	F	OCD	11	Diastolic blood pressure high/increase	60 mmHg	90 mmHg	Week 3
716.176.25668	F	MDD	10	Systolic blood pressure low/decrease	122 mmHg	92 mmHg	Week 24
716.055.28133	F	OCD	13	Systolic blood pressure low/decrease	125 mmHg	94 mmHg	Week 8
716.055.28137	F	OCD	10	Systolic blood pressure low/decrease	117 mmHg	87 mmHg	Week 2
716.028.25962	M	MDD	15	Weight low/decrease	40.9 kg (BMI 19.9)	36.8 kg (BMI 18.0)	Week 12
716.010.25603	M	MDD	13	Weight high/increase	56.8 kg (BMI 18.5)	69.5 kg (BMI 22.6)	Week 24
716.043.27694	M	MDD	9	Weight high/increase	39.5 kg (BMI 15.1)	44.0 kg (BMI 21.5)	Week 24
716.044.27654	M	MDD	14	Weight high/increase	65.0 kg (BMI 26.2)	78.0 kg (BMI 29.6)	Week 24
716.176.25668	F	MDD	10	Weight high/increase	67.0 kg (BMI 27.4)	77.5 kg (BMI 29.9)	Week 12
				Weight high/increase	67.0 kg (BMI 27.4)	81.8 kg (BMI 31.0)	Week 24

Source Table 15.2.2.1, Section 12; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline.

Table 43 Patients with Vital Sign Values Meeting Predefined Clinical Concern Criteria (Open-Label Treatment or Taper Phase) (ITT Population) Continued…

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute Study Baseline Value*	Value of Concern	Visit
Paroxetine							
716.159.25626	M	MDD	13	Weight high/increase	74.5 kg (BMI 27.3)	81.1 kg (BMI 30.5)	Week 12
				Weight high/increase	74.5 kg (BMI 27.3)	82.0 kg (BMI 30.1)	Week 24
716.176.25795	F	MDD	11	Weight high/increase	60.0 kg (BMI 27.4)	69.0 kg (BMI 29.9)	Week 12
				Weight high/increase	60.0 kg (BMI 27.4)	72.5 kg (BMI 31.0)	Week 24
716.168.25809	M	MDD	12	Weight high/increase	105.0 kg (BMI 41.5)	113.0 kg (BMI 41.5)	Week 12
				Weight high/increase	105.0 kg (BMI 41.5)	113.0 kg (BMI 41.5)	Week 24
716.014.25652	F	MDD	9	Weight high/increase	48.6 kg (BMI 27.9)	54.9 kg (BMI 28.7)	Week 12
716.012.25480	M	OCD	9	Weight high/increase	69.9 kg (BMI 32.8)	77.1 kg (BMI 35.4)	Week 12
				Weight high/increase	69.9 kg (BMI 32.8)	77.5 kg (BMI 34.5)	Week 24
716.016.27018	F	OCD	6	Weight high/increase	30.3 kg (BMI 19.4)	37.9 kg (BMI 23.5)	Week 24
716.026.27045	M	OCD	9	Weight high/increase	40.9 kg (BMI 18.5)	45.0 kg (BMI 20.0)	Week 12
716.192.25872	M	MDD	13	Weight high/increase	68.0 kg (BMI 20.9)	79.0 kg (BMI 24.3)	Week 24

Source Table 15.2.2.1, Section 12; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline.

Table 43 Patients with Vital Sign Values Meeting Predefined Clinical Concern Criteria (Open-Label Treatment or Taper Phase) (ITT Population) Continued…

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute Study Baseline Value*	Value of Concern	Visit
Placebo							
716.025.25806	M	MDD	13	Pulse rate low/decrease	88 bpm	48 bpm	Week 24
716.009.25505	M	OCD	10	Pulse rate low/decrease	97 bpm	58 bpm	Week 8
716.025.27060	M	OCD	8	Pulse rate low/decrease	96 bpm	64 bpm	Week 1
				Pulse rate low/decrease	96 bpm	63 bpm	Week 2
716.015.25466	M	OCD	13	Pulse rate high/increase	88 bpm	120 bpm	Week 2
716.010.25604	M	MDD	9	Systolic blood pressure low/decrease	110 mmHg	80 mmHg	Week 6
716.016.27021	M	OCD	8	Systolic blood pressure low/decrease	122 mmHg	90 mmHg	Week 3
716.040.27112	F	OCD	8	Systolic blood pressure low/decrease	111 mmHg	75 mmHg	Week 3
716.159.25628	M	MDD	12	Systolic blood pressure high/increase	100 mmHg	150 mmHg	Week 4
716.002.25439	M	OCD	14	Systolic blood pressure high/increase	126 mmHg	168 mmHg	Week 1
716.151.25609	M	MDD	7	Diastolic blood pressure low/decrease	64 mmHg	40 mmHg	Week 3
				Diastolic blood pressure low/decrease	64 mmHg	44 mmHg	Week 4
				Diastolic blood pressure low/decrease	64 mmHg	34 mmHg	Week 20
716.015.25464	M	OCD	7	Diastolic blood pressure low/decrease	70 mmHg	40 mmHg	Week 2
				Diastolic blood pressure low/decrease	70 mmHg	48 mmHg	Week 4
716.055.28136	M	OCD	13	Diastolic blood pressure low/decrease	66 mmHg	46 mmHg	Week 4
716.025.25995	M	MDD	10	Diastolic blood pressure high/increase	65 mmHg	98 mmHg	Week 8

Source Table 15.2.2.1, Section 12; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline.

Table 43 Patients with Vital Sign Values Meeting Predefined Clinical Concern Criteria (Open-Label Treatment or Taper Phase) (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute Study Baseline Value*	Value of Concern	Visit
Placebo							
716.014.25913	F	MDD	8	Weight high/increase	62.6 kg (BMI 33.3)	68.1 kg (BMI 31.9)	Week 24
716.019.25751	M	MDD	9	Weight high/increase	52.3 kg (BMI 28.3)	57.2 kg (BMI 27.8)	Week 24
716.159.25628	M	MDD	14	Weight high/increase	95.0 kg (BMI 29.2)	102.3 kg (BMI 29.8)	Week 12
				Weight high/increase	95.0 kg (BMI 29.2)	109.1 kg (BMI 33.0)	Week 24
716.159.25629	M	MDD	12	Weight high/increase	71.8 kg (BMI 26.3)	79.5 kg (BMI 26.6)	Week 24
716.171.25673	F	MDD	10	Weight high/increase	68.3 kg (BMI 30.4)	75.2 kg (BMI 33.0)	Week 20
716.028.27683	F	MDD	11	Weight high/increase	58.6 kg (BMI 25.2)	64.5 kg (BMI 26.5)	Week 1
716.016.25447	M	OCD	7	Weight high/increase	50.0 kg (BMI 25.1)	55.0 kg (BMI 26.2)	Week 8
716.025.27059	M	OCD	14	Weight high/increase	69.5 kg (BMI 23.0)	80.8 kg (BMI 26.1)	Week 12
				Weight high/increase	69.5 kg (BMI 23.0)	77.3 kg (BMI 24.4)	Week 20
716.028.27079	F	OCD	10	Weight high/increase	39.0 kg (BMI 19.6)	50.0 kg (BMI 25.1)	Week 24

Source Table 15.2.2.1, Section 12; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline.

If any vital signs or vital sign changes were considered clinically significant by the investigator, whether or not they met the sponsor-defined potential clinical concern criteria, they were to be recorded as adverse events in the patient's CRF. A total of 8 patients in the acute study paroxetine group recorded vital sign changes during study 716 that were considered clinically significant by the investigator and recorded as an adverse event:

- Patient 716.005.25409, an 8 year old female, was reported as having a moderate gain in weight, judged possibly study related by the investigator, at 716 baseline. The patient's weight measured at screening (26.4 kg) and at 716 baseline (26.6 kg) was within the normal range (17.3 kg to 36.8 kg).

- Patient 716.025.25921, a 7 year old female, was reported as having an increase in weight, judged mild in intensity and possibly study related by the investigator, on day 93 of open-label treatment. The patient's weight, measured at acute screening (24.9 kg) and week 12 (29.9 kg) was within the normal range (17.3 kg to 36.8 kg).

- Patient 716.028.25962, a 15 year old female, reported weight loss, judged moderate in intensity and unrelated to study medication by the investigator, on day 14 of open-label treatment. The patient's weight, measured at week 12 (36.8 kg) was outside the normal range (38.6 kg to 79.9 kg). The patient's weight at acute screening was 40.9 kg. This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the absolute value). A narrative for this patient is provided in Table 15.2.3, Section 12.

- Patient 716.167.25691, a 10 year old female, was reported as having an increase in weight, judged mild in intensity and possibly study related by the investigator, on day 166 of open-label treatment. The patient's weight, measured at acute screening (28.6 kg) and week 24 (34.1 kg) was within the normal range (21.8 kg to 49.5 kg).

- Patient 716.176.25668, a 10 year old female, was reported as having a moderate increase in weight, judged as possibly study related by the investigator, on day 1 of open-label treatment. The patient's weight, measured at acute screening (67.0 kg), 716 baseline (73.0 kg), week 12 (77.5 kg) and week 24 (81.8 kg) was outside the normal range (21.8 kg to 49.5 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same

direction as the absolute value). A narrative for this patient is provided in Table 15.2.3, Section 12.

- Patient 716.176.25795, an 11 year old female, was reported as having a moderate increase in weight, judged as possibly study related by the investigator, on day 85 of open-label treatment. The patient's weight, measured at acute screening (60.0 kg), at week 12 (69.0 kg) and week 24 (72.5 kg) was outside the normal range (25.0 kg to 56.3 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the absolute value). A narrative for this patient is provided in Table 15.2.3, Section 12.

- Patient 716.020.25456, a 16 year old female, was reported as having a moderate increase in weight, judged as possibly study related by the investigator, on day 75 of open-label treatment. The patient's weight, measured at acute screening (62.7 kg), at week 12 (64.5 kg) and week 24 (71.8 kg) was within the normal range (40.9 kg to 83.1 kg).

- Patient 716.192.25872, a 13 year old male, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, on day 169 of open-label treatment. The patient's weight, measured at acute screening (68.0 kg) and at week 24 (79.0 kg) was outside the normal range (31.43 kg to 67.2 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the absolute value). A narrative for this patient is provided in Table 15.2.3, Section 12.

A total of 9 patients in the acute study placebo group recorded vital sign changes during study 716 that were considered clinically significant by the investigator and recorded as an adverse event:

- Patient 716.002.25443, an 11 year old male, was reported as having a moderate increase in weight, judged as possibly study related by the investigator, on day 84 and 133 of open-label treatment. The patient's weight, measured at acute screening (34.9 kg), at week 12 (39.3 kg), and at week 24 (44.5 kg), was within the normal range (24.5 kg to 53.6 kg). The patient's paroxetine doseage on day 84 was 50 mg/day. The dosage of paroxetine was reduced as a result of this adverse event.

- Patient 716.165.25664, a 9 year old male, was reported as having an increase in weight, judged as mild in intensity and probably unrelated to open label medication by the investigator, on day 127 of open-label treatment. The patient's weight, measured at acute screening (32.7 kg) and at week 20 (38.2 kg), was within the normal range (20.0 kg to 41.8 kg).

- Patient 716.179.25922, a 10 year old male, was reported as having a moderate increase in weight, judged as possibly study related by the investigator, on day 45 of open-label treatment. The patient's weight, measured at acute screening (38.5 kg), at week 12 (39.9 kg) and week 20 (42.5 kg), was within the normal range (21.8 kg to 47.2 kg).

- Patient 716.183.27647, an 11 year old female, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, on day 84 of open-label treatment. The patient's weight, measured at acute screening (39.0 kg) and at week 12 (42.9 kg), was within the normal range (25.0 kg to 56.3 kg).

- Patient 716.049.28152, a 14 year old male, was reported as having weight loss, judged moderate in intensity and possibly study related by the investigator, on day 24 and 44 of open-label treatment. The patient's weight, measured at acute screening (69.1 kg) and at week 16 (52.2 kg), was within the normal range (35.9 kg to 74.5 kg).

- Patient 716.159.25628, a 14 year old male, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, at the study 716 baseline. The patient's weight, measured at acute screening (95.0 kg), at study 716 baseline (102.3 kg) and week 12 (109.1 kg) was outside the normal range (35.9 kg to 74.5 kg). At week 24 the patients weight had increased to 109.1 kg. This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the absolute value). A narrative for this patient is provided in Table 15.2.3, Section 12.

- Patient 716.167.25903, a 12 year old female, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, on day 111 of open-label treatment. The patient's weight, measured at acute screening (60.4 kg), at week 12 (63.6 kg) and week 24 (66.4 kg), was outside the normal range (28.1 kg to 63.1 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the

absolute value) during the follow-up phase. A narrative for this patient is provided in Table 15.2.3, Section 12.

- Patient 716.176.25672, a 12 year old male, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, on day 7 of open-label treatment. The patient's weight, measured at acute screening (40.0 kg) and at week 8 (40.5 kg) was within the normal range (27.2 kg to 60.4 kg).

- Patient 716.192.25870, a 17 year old male, was reported as having an increase in weight, judged as mild in intensity and possibly study related by the investigator, on day 95 of open-label treatment. The patient's weight, measured at acute screening (67.2 kg) and at week 12 (71.0 kg) was within the normal range (49.0 kg to 93.5 kg).

Detailed patient narratives have been prepared for patients with any vital sign value that met the criteria both for absolute value of clinical concern and an increase or decrease from acute study baseline (in the same direction as the absolute value), and that was reported as an adverse event by the investigator. Six patients met this combination of criteria. Narratives for these patients are provided in Table 15.2.3, Section 12.

5.8.2 Changes in Vital Signs

Summary statistics for acute study baseline and change from acute study baseline for vital signs at each visit by acute study treatment group (pre open-label treatment phase and open-label treatment phase) are presented in Table 15.2.1.1, Section 12. Table 44 presents a summary of blood pressure, pulse rate, height, weight and BMI at acute study baseline and change from acute study baseline at week 24. Data are included in the summary for those patients who had a value both at acute study baseline and at week 24.

Overall, all changes in vital sign parameters were small. Baseline values were comparable between acute study treatment groups, and mean changes in all vital sign parameters were small and generally comparable between acute study treatment groups.

Summary statistics for acute study baseline and change from acute study baseline for vital signs at each visit by acute study treatment group (pre open-label treatment phase, taper phase and follow-up phase) are presented in Table 15.2.1.2, Section 12.

Table 44 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 in Vital Signs by Acute Study Treatment Group (Pre Open-Label treatment Phase and Open-Label Treatment Phase) (ITT Population)

	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Systolic Blood Pressure (mmHg)												
Acute Study Baseline	94	106.7	(10.94)	88 to 132	127	107.4	(11.54)	74 to 142	221	107.1	(11.27)	74 to 142
Change at Week 24	33	4.5	(11.60)	-30 to 22	30	5.0	(13.33)	-22 to 34	63	4.7	(12.35)	-30 to 34
Diastolic Blood Pressure (mmHg)												
Acute Study Baseline	94	66.9	(9.14)	40 to 85	127	67.6	(9.29)	40 to 86	221	67.3	(9.21)	40 to 86
Change at Week 24	33	1.6	(9.95)	-18 to 22	30	0.6	(10.04)	-30 to 13	63	0.6	(9.97)	-30 to 22
Heart Rate (bpm)												
Acute Study Baseline	94	81.5	(10.77)	60 to 104	127	78.5	(11.04)	52 to 110	221	79.8	(11.00)	52 to 110
Change at Week 24	33	-2.8	(12.69)	-36 to 28	30	-1.4	(14.89)	-40 to 25	63	-2.1	(13.68)	-40 to 28
Weight (kg)												
Acute Study Baseline	94	55.2	(22.96)	20.4 to132.6	126	51.5	(22.24)	20.5 to131.4	220	53.09	(22.57)	20.4 to132.6
Change at Week 24	31	5.80	(3.50)	-0.5 to 14.8	28	4.96	(4.47)	-0.8 to 16.8	59	5.40	(3.97)	-0.8 to 16.8
Height (cm)												
Acute Study Baseline	94	152.43	(17.57)	115 to 188	126	150.80	(16.46)	116 to180	220	151.50	(16.92)	115 to188
Change at Week 24	31	3.04	(8.19)	-19 to 40	28	2.73	(3.11)	-3 to 9	59	2.89	(6.26)	-19 to 40
BMI (kg/m^2)												
Acute Study Baseline	94	22.84	(6.51)	13.9 to 45.9	126	21.80	(6.22)	13.6 to 45.4	220	22.25	(6.35)	13.6 to 45.9
Change at Week 24	31	1.73	(2.24)	-5.8 to 6.4	28	1.26	(1.67)	-1.4 to 5.5	59	1.51	(1.99)	-5.8 to 6.4

Source Table 15.2.1.1, Section 12; Listing 15.2.1, Appendix E

For height, weight, and BMI the last pre-acute study treatment assessment is taken to be acute study baseline

5.9 Laboratory Data

5.9.1 Laboratory Values of Potential Clinical Concern

The number and percentage of patients with a significant increase or decrease in any laboratory parameter from acute study baseline, which was of potential clinical concern, during the study was tabulated. Table 5, Section 3.14.6.4, shows these pre-determined levels of potential clinical concern for laboratory parameters.

All laboratory parameters that were assessed after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the week 24 or early withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the follow-up phase if the patient did not enter the taper phase, and as occurring during the taper phase if the patient did enter the taper phase.

Summaries of the number and percentage of patients with laboratory values flagged as of potential clinical concern by acute study treatment group may be found in Table 15.3.1.1 (acute study baseline), Table 15.3.1.2 (open-label treatment phase including taper phase), Table 15.3.1.3 (follow-up phase), and Table 15.3.1.4 (open-label treatment phase, taper phase or follow-up phase), Section 12. Individual values of potential clinical concern are provided in Listing 15.3.3, Appendix F.

Table 45 presents a summary of the number and percentage of patients with open-label treatment (including taper) laboratory values meeting sponsor-defined criteria for potential clinical concern during the course of study 716. A total of 27 patients in the acute study paroxetine group and 26 patients in the acute study placebo group were identified as having an absolute value in one or more of the laboratory parameters that met the criteria for clinical concern during the open-label treatment phase (including taper). A small number of patients had more than one laboratory parameter flagged as meeting the criteria for clinical concern (1 patient in the acute study paroxetine group and 3 patients in the acute study placebo group).

Hematocrit was the laboratory parameter most frequently associated with values of potential clinical concern: 17.2% (15/87) of patients in the acute study paroxetine group and 18.9% (20/106) of patients in the acute study placebo group

had low hematocrit values of potential clinical concern during the open-label treatment phase and taper phase. Low hematocrit values of potential clinical concern were comparable between age groups: 18.4% (19/103) of children and 17.8% (16/90) during the open-label treatment phase and taper phase.

High lymphocyte values of potential clinical concern were reported in more patients in the acute study paroxetine group (5.7%, 5/87) than in the acute study placebo group (0.9%, 1/106); of these, 2 acute study paroxetine patients and 1 acute study placebo patient had high lymphocyte values at acute study screening. Similarly, more children (4.9%, 5/103) reported high lymphocyte values of potential clinical concern than adolescents (1.1%, 1/90); of these, 2 of the children had high lymphocyte values at acute study screening. Other laboratory values of potential clinical concern occurred with comparable frequency in the both acute study treatment groups and age groups.

During the follow-up phase 1 patient in the acute study paroxetine group and 3 patients in the acute study placebo group had low neutrophils of potential clinical concern. In addition, 2 patients in the acute study placebo group had a low hematocrit of potential clinical concern (Table 15.3.1.3, Section 12).

Laboratory values by patient and parameter may be found in Listing 15.3.1 and Listing 15.3.2, Appendix F, respectively.

Table 45 Number (%) of Patients with Laboratory Values Meeting Predefined Clinical Concern Criteria* During the Open-Label Treatment Phase (Including Taper) by Acute Study Treatment Group (ITT Population)

Laboratory Parameter		Acute Study Treatment Group								
		Paroxetine			Placebo			Total		
Sponsor Defined Clinical Concern Criteria*	High/Low	N	n	(%)	N	n	(%)	N	n	(%)
Total patients with a laboratory parameter of clinical concern			27			26			53	
Hematocrit	Low	87	15	(17.2)	106	20	(18.9)	193	35	(18.1)
Eosinophils, absolute	High	87	2	(2.3)	106	3	(2.8)	193	5	(2.6)
Lymphocytes, absolute	High	87	5	(5.7)	106	1	(0.9)	193	6	(3.1)
Monocytes, absolute	High	87	0	-	106	1	(0.9)	193	1	(0.5)
Neutrophils, absolute	Low	87	3	(3.4)	106	3	(2.8)	193	6	(3.1)
Neutrophils, absolute	High	87	3	(3.4)	106	1	(0.9)	193	4	(2.1)

Source Table 15.3.1.2, Section 12; Listing 15.3.3, Appendix F

N is the number of patients who had a measurement for this laboratory parameter at any time during the open-label treatment phase (including taper)

n is the number of patients meeting the predefined clinical concern criteria

* Laboratory values of potential clinical concern may be found in Table 5

If any laboratory parameters or laboratory parameter changes were considered clinically significant by the investigator, whether or not they met the sponsor-defined potential clinical concern criteria, they were to be recorded as adverse events in the patient's CRF. A total of 4 patients in the acute study paroxetine group recorded laboratory values during study 716 that were considered clinically significant by the investigator and recorded as an adverse event:

- Patient 716.176.27164, an 11 year old male, had mild anemia (verbatim: low hematocrit and low hemoglobin), which was considered unrelated to open-label study medication, on day 84 of open-label treatment. This patient's hematocrit value met the criteria for clinical concern at acute study screening (33.7%, normal range low is 35.0%), week 4 (33.9%), week 12 (33.2%) and week 24 (31.8%). The patients hematocrit value was within the normal range at the final assessment in their acute study, therefore it was not necessary to do a repeat assessment at study 716 baseline. The patients hemoglobin was low, but not of clinical concern at week 12 (112 g/L, normal range low is 115 g/L). A narrative for this patient is provided in Table 15.3.3, Section 12.

- Patient 716.192.25946, an 11 year old female, had mild leukopenia (verbatim: abnormal monocyte count), which was considered possibly related to open-label study medication, on day 29 of open-label treatment. The patient's monocyte count decreased from normal at acute study screening ($0.43x10^9$/L) to below the normal range at week 4 ($0.14x10^9$/L, normal range low is 0.2 $x10^9$/L).

- Patient 716.192.25868, a 15 year old male, had mild leukopenia (verbatim: low absolute neutrophils and low white blood cell count), which was considered possibly related to open-label study medication, on day 70 of open-label treatment. The patient's neutrophil count decreased from normal at acute study screening ($2.18x10^9$/L) to below the normal range at week 8 ($1.02x10^9$/L, normal range low is 1.8 $x10^9$/L). The patient's neutrophil value at week 8 met the criteria for clinical concern. In addition, the patients white blood cell count decreased from normal at acute study screening ($5.1x10^9$/L) to below the normal range at week 8 ($3.0x10^9$/L, normal range low is 4.5 $x10^9$/L). A narrative for this patient is provided in Table 15.3.3, Section 12.

- Patient 716.176.25671, a 13 year old male had mild leukopenia (verbatim: leukopenia and neutropenia), which was considered possibly related to open-label study medication, during the taper phase, 1 day after the last dose of open-label treatment phase medication.

A total of 7 patients in the acute study placebo group recorded laboratory values during study 716 that were considered clinically significant by the investigator and recorded as an adverse event:

- Patient 716.165.25664, a 9 year old male, had abnormal liver function test (verbatim: increase in liver enzymes), which was considered to be mild in intensity and unrelated to open-label study medication, on day 85 of open-label treatment. The patient's AST levels increased from normal at acute study screening (42 IU/L) to above the normal range at week 12 (54 IU/L, normal range high is 42 IU/L). In addition, the patients ALT levels were above the normal range (normal high is 45 IU/L) at acute study screening (46 IU/L) and week 12 (84 IU/L).

- Patient 716.167.25696, an 8 year old male, had albuminuria (verbatim: urine dipstick positive for protein), which was considered to be moderate in intensity and unrelated to study medication, on day 26 of open-label treatment. On day 168 (week 24) of open-label treatment the patient had leukopenia (verbatim: low eosinophils absolute, low netrophils absolute and low white cell count), which was considered to be mild in intensity and possibly related to study medication. The patient's white blood cell count decreased from normal ($6.3x10^9$/L) at screening and was below the normal range (normal range low $4.5x10^9$/L) at week 24 ($3.0x10^9$/L) and the follow up visit ($2.0x10^9$/L). The patient's absolute eosinophil count decreased from normal ($0.10x10^9$/L) at screening and was below the normal range (normal range low $0.05x10^9$/L) at week 24 ($0.00x10^9$/L) and the follow-up visit ($0.02x10^9$/L). The patient's absolute neutrophil count decreased from normal ($4.06x10^9$/L) at screening and was below the normal range (normal range low $1.80x10^9$/L) at week 24 ($1.44x10^9$/L) and the follow-up visit ($0.9x10^9$/L). The patient's neutrophil levels met the criteria for clinical concern. A narrative for this patient is provided in Table 15.3.3, Section 12.

- Patient 716.169.25781, a 10 year old female, had anemia and leukopenia (verbatim: abnormal laboratory results), which was considered to be mild in intensity and unrelated to open-label study medication, on day 85 of open-label treatment. This patient's hematocrit value met the criteria for clinical concern at acute study screening (33.1%, normal range low is 35.0%), week 4 (34.6%), week 12 (32.7%) and week 24 (34.8%). In addition, the patient's hemoglobin level and white blood cell count were low, but not of clinical concern, at week 12 (hemoglobin, 108 g/L, normal range low is 115 g/L; white blood cell count $4.1x10^9$/L, normal range low is 4.5 $x10^9$/L). A narrative for this patient is provided in Table 15.3.3, Section 12.

- Patient 716.031.25533, a 16 year old male, had mild leukocytosis (verbatim: increased white cell count), which was considered unrelated to open-label study medication on day 165 of open-label treatment. Laboratory results at week 24 show the patient's white blood cell count to be below the normal range ($4.3x10^9$/L, normal range low is $4.5x10^9$/L).

- Patient 716.176.27172, a 15 year old male, had eosinophilia (verbatim: elevated eosinophils) and monocytosis (elevated monocytes), which were moderate in intensity and considered unrelated to open-label study medication, on day 12 of open-label treatment. The patient's monocyte and eosinophil levels increased from acute study baseline (eosinophils, $0.4x10^9$/L; monocytes, $0.56x10^9$/L) to above the normal range at week 2 (eosinophils, $1.12\ x10^9$/L, normal range high is $0.55x10^9$/L; monocytes, $1.61x10^9$/L, normal range high is $1.10x10^9$/L). The patient's eosinophil and monocyte levels at week 8 met the criteria for clinical concern. A narrative for this patient is provided in Table 15.3.3, Section 12.

- Patient 716.028.27685, a 10 year old female, had increased SGOT (verbatim: increased liver enzymes), which was moderate in intensity and considered possibly related to open-label study medication, 8 days after the last dose of open-label treatment. The patients SGOT levels increased from acute study baseline (47 IU/L) to above the normal range 7 days after the last dose of open-label medication (82 IU/L, normal range high 42 IU/L).

- Patient 716.006.25418, a 13 year old male, had abnormal liver function tests (verbatim: elevated liver enzymes), which was mild in intensity and considered possibly related to open-label study medication. The patient's liver enzyme levels increased from normal at acute study screening (AST, 27 IU/L; ALT, 18 IU/L) to above the normal range at week 6 (AST, 104 IU/L, normal range high is 42 IU/L; ALT, 169 IU/L, normal high is 45 IU/L). The patient had stopped open-label study medication 6 days prior to the onset of this adverse event.

Detailed patient narratives have been prepared for patients with any laboratory value meeting the potential clinical concern criteria, and that was reported as an adverse event by the investigator. Five patients met this combination of criteria. Narratives for these patients are provided in Table 15.3.3, Section 12.

5.9.2 Changes in Laboratory Values

Summary statistics for acute study baseline and change from acute study baseline to endpoint for laboratory parameters by acute study treatment group are presented in Table 46. Summary statistics for thyroid tests are not presented here because they were not required to be performed at endpoint (summary Table 15.3.6, Section 12 includes acute study baseline values). Overall, changes in laboratory parameters from acute study baseline to week 24 or endpoint were small. The acute study treatment groups were comparable at acute study baseline with respect to laboratory parameters, and there were no substantial differences between the acute study paroxetine and acute study placebo groups at week 24, at endpoint, or in change from acute study baseline to week 24 or endpoint.

Table 46 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute Study Treatment Group (ITT Population) Continued…

Laboratory Test (units)	Acute Study Treatment Group: Paroxetine N	Mean	(SD)	Range	Placebo N	Mean	(SD)	Range	Total N	Mean	(SD)	Range
Hemoglobin g/L												
Acute Study Baseline	94	134.19	(10.17)	106.0 to164.0	127	132.17	(11.33)	104.0 to 163.0	220	133.03	(10.88)	104.0 to 164.0
Change to Week 24	37	-2.18	(7.21)	-16.0 to 14.0	30	-1.73	(10.00)	-20.0 to 20.0	67	-1.99	(8.50)	-20.0 to 20.0
Change to Endpoint	86	-2.49	(7.42)	-17.0 to 18.0	106	-1.30	(7.89)	-24.0 to 20.0	192	-1.83	(7.68)	-24.0 to 20.0
Hematocrit (%)												
Acute Study Baseline	93	39.71	(3.21)	32.5 to 52.5	127	39.22	(3.40)	31.8 to 48.8	220	39.43	(3.32)	31.8 to 52.5
Change to Week 24	37	-0.65	(2.52)	-5.0 to 6.1	30	-0.78	(2.66)	-6.1 to 4.7	67	-0.71	(2.56)	-6.1 to 6.1
Change to Endpoint	86	-0.77	(2.61)	-8.1 to 6.2	106	-0.37	(2.48)	-7.1 to 6.2	192	-0.55	(2.54)	-8.1 to 6.2
RBC Count (10^{12}/L)												
Acute Study Baseline	93	4.64	(0.33)	4.0 to 5.6	127	4.57	(0.38)	3.7 to 5.4	220	4.60	(0.36)	3.7 to 5.6
Change to Week 24	37	-0.04	(0.26)	-0.5 to 0.7	30	-0.06	(0.29)	-0.6 to 0.5	67	-0.05	(0.27)	-0.6 to 0.7
Change to Endpoint	86	-0.08	(0.27)	-0.7 to 0.7	106	-0.03	(0.26)	-0.8 to 0.5	192	-0.06	(0.26)	-0.8 to 0.7
WBC Count (10^{9}/L)												
Acute Study Baseline	93	7.16	(2.01)	3.9 to 14.9	127	6.82	(1.76)	3.8 to 13.2	220	6.96	(1.88)	3.8 to 14.9
Change to Week 24	37	-0.42	(1.77)	-3.5 to 5.2	30	0.01	(1.83)	-3.7 to 3.4	67	-0.23	(1.80)	-3.7 to 5.2
Change to Endpoint	86	-0.28	(1.91)	-6.5 to 5.2	106	0.01	(1.77)	-4.2 to 5.8	192	-0.12	(1.84)	-6.5 to 5.8

Data Source Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table 46 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute Study Treatment Group (ITT Population) Continued…

Laboratory Test (units)	Acute Study Treatment Group: Paroxetine N	Mean	(SD)	Range	Placebo N	Mean	(SD)	Range	Total N	Mean	(SD)	Range
Platelets (10^9/L)												
Acute Study Baseline	93	286.08	(58.49)	154.0 to 425.0	127	294.68	(63.21)	115.0 to 468.0	220	291.04	(61.27)	115.0 to 468.0
Change to Week 24	37	-8.22	(49.77)	-107.0 to 171.0	30	12.47	(44.55)	-43.0 to 130.0	67	1.04	(48.28)	-107.0 to 171.0
Change to Endpoint	86	-12.34	(45.96)	-145.0 to 171.0	106	-1.58	(45.99)	-154.0 to 130.0	192	-6.39	(46.17)	-154.0 to 171.0
Basophils (10^9/L)												
Acute Study Baseline	93	0.021	(0.0162)	0.00 to 0.11	127	0.020	(0.013)	0.00 to 0.07	220	0.021	(0.014)	0.00 to 0.11
Change to Week 24	37	0.007	(0.0231)	-0.09 to 0.02	30	-0.004	(0.015)	-0.03 to 0.03	67	-0.006	(0.020)	-0.09 to 0.03
Change to Endpoint	86	0.005	(0.0185)	-0.09 to 0.03	106	-0.0048	(0.024)	-0.03 to 0.17	192	-0.002	(0.021)	-0.09 to 0.17
Eosinophils (10^9/L)												
Acute Study Baseline	93	0.273	(0.210)	0.00 to 0.96	127	0.245	(0.202)	0.00 to 1.33	220	0.257	(0.205)	0.00 to 1.33
Change to Week 24	37	-0.094	(0.217)	-0.62 to 0.28	30	-0.042	(0.173)	-0.54 to 0.29	67	-0.070	(0.199)	-0.62 to 0.29
Change to Endpoint	86	-0.036	(0.188)	-0.60 to 0.43	106	0.004	(0.178)	-0.54 to 0.56	192	-0.138	(0.183)	-0.60 to 0.56
Lymphocytes (10^9/L)												
Acute Study Baseline	93	2.588	(0.797)	1.39 to 5.80	127	2.362	(0.661)	0.80 to 4.87	220	2.458	(0.729)	0.80 to 5.80
Change to Week 24	37	-0.219	(0.704)	-1.35 to 1.61	30	-0.005	(0.516)	-1.03 to 1.05	67	-0.123	(0.631)	-1.35 to 1.61
Change to Endpoint	86	-0.202	(0.712)	-2.44 to 1.61	106	-0.042	(0.603)	-2.46 to 2.42	192	-0.113	(0.657)	-2.46 to 2.42

Data Source Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table 46 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute Study Treatment Group (ITT Population) Continued…

Laboratory Test (units)	Acute Study Treatment Group: Paroxetine N	Mean	(SD)	Range	Placebo N	Mean	(SD)	Range	Total N	Mean	(SD)	Range
Monocytes (10^9/L)												
Acute Study Baseline	93	0.422	(0.192)	0.06 to 0.92	127	0.356	(0.188)	0.00 to 1.40	220	0.384	(0.192)	0.00 to 1.40
Change to Week 24	37	-0.094	(0.194)	-0.73 to 0.43	30	0.011	(0.194)	-0.41 to 0.52	67	-0.047	(0.200)	-0.73 to 0.52
Change to Endpoint	86	-0.065	(0.195)	-0.73 to 0.44	106	-0.013	(0.195)	-0.97 to 0.54	192	-0.036	(0.196)	-0.97 to 0.54
Neutrophils (10^9/L)												
Acute Study Baseline	93	3.862	(1.445)	0.89 to 8.61	127	3.833	(1.392)	1.46 to 8.65	220	3.845	(1.411)	0.89 to 8.65
Change to Week 24	87	-0.018	(1.463)	-3.39 to 3.89	30	0.029	(1.546)	-2.62 to 2.91	67	0.003	(1.490)	-3.39 to 3.89
Change to Endpoint	86	0.026	(1.486)	-3.46 to 3.89	106	0.061	(1.573)	-4.11 to 4.80	192	0.045	(1.531)	-4.11 to 4.80
Sodium (mmol/L)												
Acute Study Baseline	94	141.76	(2.11)	137.0 to 149.0	127	141.76	(2.21)	137.0 to 149.0	221	141.76	(2.17)	137.0 to 149.0
Change to Week 24	37	-0.35	(3.22)	-7.0 to 8.0	29	-0.76	(3.30)	-8.0 to 5.0	66	-0.53	(3.24)	-8.0 to 8.0
Change to Endpoint	87	-0.05	(3.14)	-7.0 to 9.0	107	-0.49	(2.96)	-8.0 to 7.0	194	-0.29	(3.04)	-8.0 to 9.0
Potassium (mmol/L)												
Acute Study Baseline	94	4.31	(0.35)	3.6 to 5.6	127	4.40	(0.38)	3.3 to 6.1	221	4.36	(0.37)	3.3 to 6.1
Change to Week 24	36	0.28	(0.52)	-1.8 to 1.2	29	-0.11	(0.37)	-0.9 to 0.8	65	-0.03	(0.46)	-1.8 to 1.2
Change to Endpoint	87	0.22	(0.53)	3.6 to 6.9	107	-0.80	(0.42)	3.9 to 5.9	194	4.33	(0.42)	3.6 to 6.9

Data Source Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table 46 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute Study Treatment Group (ITT Population) Continued…

Laboratory Test (units)	Acute Study Treatment Group: Paroxetine N	Mean	(SD)	Range	Placebo N	Mean	(SD)	Range	Total N	Mean	(SD)	Range
BUN (mmol/L)												
Acute Study Baseline	94	4.58	(1.17)	2.9 to 7.9	127	4.37	(1.30)	1.4 to 8.9	221	4.46	(1.25)	1.4 to 8.9
Change to Week 24	37	0.96	(1.31)	-2.1 to 3.9	29	0.28	(1.26)	-2.9 to 2.5	66	0.18	(1.28)	-2.9 to 3.9
Change to Endpoint	87	0.11	(1.24)	-2.9 to 3.9	107	0.32	(1.29)	-2.9 to 4.3	194	0.23	(1.27)	-2.9 to 4.3
Creatinine (umol/L)												
Acute Study Baseline	94	51.82	(14.74)	26.5 to 88.4	127	51.7	(14.65)	26.5 to 132.6	221	51.76	(14.66)	26.5 to 132.6
Change to Week 24	37	2.39	(11.35)	-26.5 to 35.4	29	4.27	(9.34)	-17.7 to 26.5	66	3.21	(10.48)	-26.5 to 35.4
Change to Endpoint	87	3.45	(10.81)	-26.5 to 35.4	107	1.98	(12.58)	-79.6 to 44.2	194	2.64	(11.81)	-79.6 to 44.2
Alkaline Phosphatase (IU/L)												
Acute Study Baseline	94	227.57	(88.98)	64.0 to 452.0	127	235.94	(93.98)	49.0 to 512.0	221	232.38	(91.78)	49.0 to 512.0
Change to Week 24	37	-21.62	(38.13)	-158.0 to 72.0	29	-17.93	(33.90)	-112.0 to 64.0	66	-20.00	(36.11)	-158.0 to 72.0
Change to Endpoint	87	-20.46	(40.97)	-158.0 to 80.0	107	-22.50	(43.90)	-207.0 to 93.0	194	-21.59	(42.51)	-207.0 to 93.0

Data Source Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table 46 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute Study Treatment Group (ITT Population)

Laboratory Test (units)	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
AST (SGOT) (IU/L)												
Acute Study Baseline	94	23.06	(6.02)	12.0 to 38.0	127	24.40	(6.54)	12.0 to 47.0	221	23.83	(6.35)	12.0 to 47.0
Change to Week 24	37	2.86	(10.05)	-6.0 to 49.0	29	1.21	(7.20)	-16.0 to 28.0	66	2.14	(8.89)	-16.0 to 49.0
Change to Endpoint	87	2.05	(7.45)	-8.0 to 49.0	107	2.00	(5.83)	-16.0 to 28.0	194	2.02	(6.59)	-16.0 to 49.0
ALT (SGPT) (IU/L)												
Acute Study Baseline	94	16.33	(6.41)	6.0 to 47.0	127	16.72	(8.25)	7.0 to 59.0	221	16.55	(7.51)	6.0 to 59.0
Change to Week 24	37	4.89	(13.03)	-9.0 to 69.0	29	1.93	(6.76)	-12.0 to 27.0	66	3.59	(10.76)	-12.0 to 69.0
Change to Endpoint	87	2.36	(10.80)	-15.0 to 69.0	107	2.00	(7.06)	-19.0 to 33.0	194	2.16	(8.91)	-19.0 to 69.0
Total Bilirubin (umol/L)												
Acute Study Baseline	94	8.04	(4.07)	0.0 to 22.2	127	7.28	(3.96)	3.4 to 34.2	221	7.61	(4.01)	0.0 to 34.2
Change to Week 24	36	-0.71	(3.71)	-12.0 to 6.8	29	0.41	(2.53)	-3.4 to 5.3	65	-0.21	(3.26)	-12.0 to 6.8
Change to Endpoint	87	-0.43	(3.34)	-12.0 to 6.8	107	-0.18	(3.24)	-18.8 to 5.13	194	-0.29	(3.28)	-18.8 to 6.8

Data Source Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute study baseline.

Endpoint was the last on treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Acute study baseline values, endpoint values (including taper), and follow-up values were categorized as high and of clinical concern, above normal range, within range, below normal range, and low and of clinical concern. Table 15.3.4, Section 12, presents the number and percentage of patients with transitions in laboratory values per parameter (that is, whose laboratory value changed categories) from acute study baseline to endpoint and/or follow-up. The number of transitions was small and transitions were generally comparable between the acute study treatment groups.

5.9.3 Urinalysis Results

The number and percentage of patients with abnormal urine results during the open-label treatment phase (including taper phase) may be found in Table 15.3.5.2, Section 12. The number and percentage of patients with abnormal urine test results during the follow-up phase are provided in Table 15.3.5.3, Section 12. Urinalysis results for each patient are provided by patient and by parameter in Listing 15.3.1 and Listing 15.3.2, respectively, Appendix F.

Three patients in the acute study paroxetine group had urine abnormalities associated with an adverse event during the course of study 716:

- Patient 716.006.25420, a 14 year old female, had mild albuminuria (verbatim: proteinuria), judged probably unrelated to open-label medication by the investigator, on day 44 of open-label treatment, and mild hematuria (verbatim: hemataurial), judged unrelated to open-label medication by the investigator, on day 44 of open-label treatment.

- Patient 716.028.25962, a 15 year old female, had mild albuminuria (verbatim: urine dipstick positive for trace protein), judged unrelated to open-label medication by the investigator, on day 29 of open-label treatment. Other positive urinalysis results on day 29 of open-label treatment were amorphous sediment, bacteria, generic dipstick and white blood cells.

- Patient 716.049.28148, a 13 year old female, had recorded albuminuria (verbatim: week 4 positive dipstick protein) judged probably unrelated to open-label medication by the investigator, on day 36 of open-label treatment. A repeat test was positive for albuminuria on day 38 of open-label study medication. Other positive urinalysis results on day 36 of open-label treatment were amorphous sediment, blood dipstick, red blood cells, generic dipstick and squamous epithelial cells.

Five patients in the acute study placebo group had urine abnormalities associated with an adverse event during the course of study 716:

- Patient 716.028.25964, a 10 year old male, had mild hematauria (verbatim: trace blood urine dipstick), judged unrelated to open-label medication by the investigator, at the study 716 baseline visit. At the study 716 baseline visit the generic urine dipstick results were positive.

- Patient 716.031.25534, a 9 year old male, had mild hematauria (verbatim: occult urine), judged unrelated to open-label medication by the investigator, at the study 716 baseline visit. At the study 716 baseline visit the generic urine dipstick results were positive.

- Patient 716.167.25696, an 8 year old male, had mild albuminuria (verbatim: urine dipstick positive for protein), judged unrelated to study medication by the investigator, on day 26 of open-label treatment. Other positive urinalysis results on day 26 of open-label treatment were amorphous sediment, red blood cells, white blood cells, generic dipstick, protein dipstick, and squamous epithelial cells.

- Patient 716.170.25634, a 10 year old female, had mild hematauria (verbatim: blood in urine), judged unrelated to open-label medication by the investigator, on day 91 of open-label treatment. Other positive urinalysis results on day 91 of open-label treatment were white blood cells, bacteria, amorphous sediment, generic dipstick, mucous threads, and squamous epithelial cells.

- Patient 716.192.25874, a 14 year old male, had mild albuminuria (verbatim: urine dipstick positive protein) and mild hematuria (verbatim: urine dipstick positive for blood), both judged probably unrelated to open-label medication by the investigator, on day 169 of open-label treatment. Other positive urinalysis results on day 169 of open-label treatment were white blood cells, generic dipstick, protein dipstick, mucous threads, and squamous epithelial cells.

5.10 Electrocardiographic Data

A 12-lead ECG was conducted at the open-label study 716 baseline visit (the last assessment from paroxetine study 701 or 704 was acceptable if taken within 3 weeks of the open-label baseline assessment and not clinically significant). An additional ECG was performed at the week 24 or early withdrawal visit; a repeat ECG was performed at the taper phase end visit and 14 day follow-up visit if

clinically significant abnormalities were found at the previous visit. Table 15.4.1, Section 12, presents summary data for all patients with ECG assessments during the study.

No patients in the study had abnormal ECG assessments at the study 716 baseline visit or week 24/early withdrawal visit. One acute study paroxetine patient (716.006.25420) had an abnormal ECG assessment (as assessed by the investigator) at the taper end visit (Listing 15.4.1, Appendix E) (this patient does not apear in Table 15.4.1, Section 12 as they had a repeat ECG in the taper phase that was normal). One acute study placebo patient (716.186.25990) had an abnormal ECG assessments (as assessed by the investigator) at the follow-up visit (Listing 15.4.1, Appendix E). One acute study paroxetine patient (716.025.25805) had an abnormal ECG assessments (as assessed by the investigator) at the follow-up visit (this was associated with an adverse event see narrative below) (Listing 15.4.1, Appendix E).

Two patients had an ECG during the study that was associated with an adverse event:

- Patient 716.025.25805, a 12 year old female in the acute study paroxetine group, had an abnormal ECG, judged unrelated to open-label study medication by the investigator, 18 days after they stopped study medication (study day 59) (Listing 15.1.2, Appendix D).

- Patient 716.165.25664, a 9 year old male in the acute study placebo group, had an an adverse event of abnormal ECG, judged unrelated to open-label study medication by the investigator on day 127 of open-label study medication (Listing 15.1.1, Appendix D). This patient does not apear in Table 15.4.1, Section 12 or Listing 15.4.1, Appendix E as the ECG was recorded as normal on the ECG page of the CRF, see Errata, Section 13.

6 Efficacy Results

6.1 Efficacy Evaluations

This section presents summaries for all of the efficacy variables. Efficacy variables were summarized descriptively for the ITT and PPX populations (Section 3.14.3), except for the CGI-Global Improvement item which was summarized for the ITT population only. The ITT population comprised 94 patients in the acute studies paroxetine group and 127 patients in the acute studies placebo group. The PPX population comprised 94 patients in the acute studies paroxetine group.

Data are presented in the form of data listings and tables of counts, means and standard deviations. Listings and tables were obtained using the SAS statistical package, version 6.12.

6.1.1 Datasets Analyzed

Two datasets were used to summarize the efficacy results: an OC dataset and a LOCF dataset. For both the ITT population and PPX population, descriptive summaries are provided based on the OC data set at each visit and the LOCF data set, with primary inferences based on the protocol defined week 24 endpoint.

In the OC data set efficacy data were assessed at the time point at which they were collected; no data were carried forward to estimate missing data.

In the LOCF datasets for change in CY-BOCS total score and change in CDRS-R total score, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in CGI-Severity of Illness, and proportion of responders based on the CGI-Global Improvement item, the last non zero post-baseline score for each patient was carried forward to estimate missing data points. The LOCF dataset contains all data from the week 24 visit, plus the last on-treatment assessment for patients who withdrew before week 24.

6.2 Primary Efficacy Variable

There was no primary measure of efficacy in this study.

6.3 Secondary Efficacy Variables

6.3.1 Change from Baseline in Children's Depression Rating Scale-Revised (CDRS-R)

The predefined endpoint was the change from baseline in CDRS-R total score at the week 24 visit (OC and LOCF). As this efficacy variable was specific to MDD, only those patients entering from the acute study 701 were included in these summaries. Individual and total CDRS-R scores are listed by patient, by acute study treatment group, and age group in Listing 14.1.1, Appendix C.

The week 24 OC dataset based on the ITT population for the change from acute study baseline in CDRS-R total score contained 27 patients from the acute study paroxetine group and 22 patients from the acute study placebo group. The week 24 LOCF dataset based on the ITT population for change from baseline in CDRS-R total score contained 36 patients from the acute study paroxetine group and 46 patients from the acute study placebo group.

Table 47 presents summary statistics for the change from acute study baseline in CDRS-R total score for the week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined (ITT population). The overall mean change from acute study baseline was a decrease of 33.4 points for week 24 OC and a decrease of 26.8 points for week 24 LOCF. The mean CDRS-R total score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints for both acute study treatment groups. Although the change was similar for both acute study treatment groups, there were differences in response between children and adolescents in patients who had received paroxetine in their acute study. Children had a greater change in CDRS-R total score from acute study baseline to the week 24 OC and week 24 LOCF endpoints compared to adolescents if they had received paroxetine in their acute study.

Table 47 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CDRS-R Total Score by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total												
Acute Study Baseline	50	60.4	(9.63)	45 to 84	66	60.4	(7.97)	45 to 87	116	60.4	(8.68)	45 to 87
Change from Acute Study Baseline to:												
Week 24 OC	27	-33.4	(14.01)	-54 to 2	22	-33.4	(9.60)	-51 to –8	49	-33.4	(12.11)	-54 to 2
Week 24 LOCF	36	-28.9	(16.34)	-54 to 13	46	-25.2	(15.18)	-51 to 3	82	-26.8	(15.71)	-54 to 13
Age Group: Children												
Acute Study Baseline	25	58.5	(6.80)	47 to 78	36	59.7	(8.04)	45 to 82	61	59.2	(7.53)	45 to 82
Change from Acute Study Baseline to:												
Week 24 OC	13	-36.7	(8.19)	-52 to -24	9	-33.2	(9.59)	-51 to -22	22	-35.3	(8.74)	-52 to -22
Week 24 LOCF	15	-35.1	(8.83)	-52 to -20	26	-26.0	(14.65)	-51 to 1	41	-29.3	(13.46)	-52 to 1
Age Group: Adolescents												
Acute Study Baseline	25	62.2	(11.65)	45 to 84	30	61.3	(7.92)	46 to 87	55	61.7	(9.71)	45 to 87
Change from Acute Study Baseline to:												
Week 24 OC	14	-30.4	(17.61)	-54 to 2	13	-33.5	(10.01)	-46 to –8	27	-31.9	(14.27)	-54 to 2
Week 24 LOCF	21	-24.4	(19.03)	-54 to 13	20	-24.2	(16.81)	-46 to 3	41	-24.3	(17.48)	- 54 to 13

Source Table 14.1.1b, Section 11; Listing 14.1.1, Appendix C

The PPX population for the week 24 OC and week 24 LOCF datasets for the change from acute study treatment phase endpoint in CDRS-R total score contained 27 and 36 patients, respectively. All patients in the PPX population received paroxetine in their acute study. Table 48 presents summary statistics for the change from acute study treatment phase endpoint in CDRS-R total score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined (PPX population). The mean decrease in CDRS-R total score observed in the acute study was maintained during this open-label extension phase. Furthermore, the mean CDRS-R total score decreased slightly from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints. Children had a slightly greater change in CDRS-R total score from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints compared to adolescents.

Table 48 Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CDRS-R Total Score by Age Group (PPX Population with Primary Diagnosis of MDD)

	Paroxetine			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute Study Treatment Phase Endpoint	50	33.9	(12.23)	18 to 71
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	27	-6.8	(14.60)	-37 to 30
Week 24 LOCF	36	-3.1	(16.67)	-37 to 33
Age Group: Children				
Acute Study Treatment Phase Endpoint	25	33.2	(11.95)	18 to 63
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	13	-8.2	(13.87)	-37 to 3
Week 24 LOCF	15	-8.3	(12.89)	-37 to 3
Age Group: Adolescents				
Acute Study Treatment Phase Endpoint	25	34.5	(12.72)	19 to 71
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	14	-5.6	(15.66)	-30 to 30
Week 24 LOCF	21	0.7	(18.29)	-30 to 33

Source Table 14.1.1d, Section 11; Listing 14.1.1; Appendix C

Summary statistics for change from acute study treatment phase endpoint in CDRS-R total score for the week 24 OC and week 24 LOCF datasets for both age

groups separately and combined for patients in the acute study placebo group (ITT population) are provided in Table 14.1.1e, Section 11.

6.3.2 Change from Baseline in Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS)

The predefined endpoint was the change from baseline in CY-BOCS total score at the week 24 visit (OC and LOCF). As this efficacy variable was specific to OCD, only those patients entering from the acute study 704 were included in these summaries. Individual and total CY-BOCS scores are listed by patient, by acute study treatment group, and age group in Listing 14.2.1, Appendix C.

The week 24 OC dataset based on the ITT population for the change from acute study baseline in CY-BOCS total score contained 14 patients from the acute study paroxetine group and 9 patients from the acute study placebo group. The week 24 LOCF dataset based on the ITT population for change from baseline in CY-BOCS total score contained 20 patients from the acute study paroxetine group and 24 patients from the acute study placebo group.

Table 49 presents summary statistics for change from acute study baseline in CY-BOCS total score for the week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined (ITT population). The overall mean change from acute study baseline was a decrease of 15.8 points for week 24 OC and a decrease of 12.0 points for week 24 LOCF. Although the mean CY-BOCS total score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints for both acute study treatment groups the overall mean change from acute study baseline was greater in patients who received paroxetine in their acute study. Adolescents had a slightly greater change in CY-BOCS total score from acute study baseline to the week 24 OC and week 24 LOCF endpoints.

Table 49 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CY-BOCS Total Score by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total												
Acute Study Baseline	44	25.1	(4.76)	18 to 36	61	24.8	(4.91)	16 to 37	105	24.9	(4.83)	16 to 37
Change from Acute Study Baseline to:												
Week 24 OC	14	-17.2	(7.07)	-29 to –8	9	-13.7	(7.16)	-23 to –6	23	-15.8	(7.16)	-29 to –6
Week 24 LOCF	20	-17.8	(7.43)	-29 to -2	24	-7.1	(7.52)	-23 to 3	44	-12.0	(9.15)	-29 to 3
Age Group: Children												
Acute Study Baseline	24	23.9	(4.62)	18 to 34	34	25.1	(5.23)	16 to 37	58	24.6	(4.98)	16 to 37
Change from Acute Study Baseline to:												
Week 24 OC	8	-15.3	(6.50)	-25 to –8	5	-12.6	(6.91)	-20 to –6	13	-14.2	(6.51)	-25 to –6
Week 24 LOCF	11	-17.3	(6.66)	-27 to –8	13	-6.5	(7.38)	-20 to –2	24	-11.4	(8.83)	-27 to 2
Age Group: Adolescents												
Acute Study Baseline	20	26.6	(4.63)	20 to 36	27	24.4	(4.54)	16 to 37	47	25.3	(4.65)	16 to 37
Change from Acute Study Baseline to:												
Week 24 OC	6	-19.8	(7.52)	-29 to-10	4	-15.0	(8.29)	-23 to –6	10	-17.9	(7.78)	-29 to –6
Week 24 LOCF	9	-18.4	(8.65)	-29 to –2	11	-7.8	(7.99)	-23 to 3	20	-12.6	(9.72)	-29 to 3

Source Table 14.2.1b, Section 11; Listing 14.2.1, Appendix C

The PPX population for the week 24 OC and week 24 LOCF datasets for change from acute study treatment phase endpoint in CY-BOCS total score contained 14 and 20 patients, respectively. All patients in the PPX population received paroxetine in their acute study. Table 50 presents summary statistics for change from acute study treatment phase endpoint in CY-BOCS total score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined (PPX population). The mean decrease in CY-BOCS total score observed in the acute study was maintained during this open-label extension phase. The mean CY-BOCS total score decreased slightly from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints. Adolescents had a greater change in CY-BOCS total score from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints compared to children.

Table 50 Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CY-BOCS Total Score by Age Group (PPX Population with Primary Diagnosis of OCD)

	Paroxetine			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute Study Treatment Phase Endpoint	44	14.3	(8.45)	0 to 34
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	14	-2.7	(4.61)	-10 to 4
Week 24 LOCF	20	-4.1	(5.97)	-20 to 4
Age Group: Children				
Acute Study Treatment Phase Endpoint	24	12.0	(8.56)	0 to 34
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	8	0.4	(2.45)	-2 to 4
Week 24 LOCF	11	-1.5	(6.46)	-20 to 4
Age Group: Adolescents				
Acute Study Treatment Phase Endpoint	20	17.0	(7.67)	3 to 34
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	6	-6.8	(3.37)	-10 to -1
Week 24 LOCF	9	-7.2	(3.56)	-12 to –1

Source Table 14.2.1d, Section 11; Listing 14.2.1; Appendix C

Summary statistics for change from acute study treatment phase endpoint in CY-BOCS total score for the week 24 OC and week 24 LOCF datasets for both

age groups separately and combined for patients in the acute study placebo group are provided in Table 14.2.1e, Section 11.

6.3.3 Proportion of Responders Based in the Clinical Global Impression (CGI)–Global Improvement Item

CGI-Global Improvement item scores are listed by patient by acute study treatment group and age group in Listing 14.3.1, Appendix C.

6.3.3.1 CGI- Global Improvement in Patients with a Primary Diagnosis of MDD

The number of patients in each category of the CGI-Global Improvement item for patients in the ITT population with a primary diagnosis of MDD is presented in Table 51. Results are presented for week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined. The majority of patients had a score of 1 (very much improved) or 2 (much improved) at the week 24 OC (46/50, 92.0%) and week 24 LOCF (76/113, 67.3%) endpoints. In the week 24 OC dataset for the combined age groups, 92.6% (25/27) of patients in the acute study paroxetine group and 91.3% (21/23) of patients in the acute study placebo group had a score of 1 (very much improved) or 2 (much improved). In the week 24 LOCF data set for the combined age groups, 69.4% (34/49) of patients in the acute study paroxetine group and 65.6% (42/64) patients in the acute study placebo group had a score of 1 (very much improved) or 2 (much improved).

A responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to acute study baseline. Table 52 shows the number and percentage of responders based on the CGI-Global Improvement item for patients in the ITT population with a primary diagnosis of MDD by visit week. Results are presented for each visit by acute study treatment group for both age groups separately and combined. There were no notable differences between acute study treatment groups with respect to the number and percentage of responders based on the CGI-Global Improvement item. However, slightly higher percentages of children were generally rated as much or very much improved compared with adolescents.

Table 51 Number (%) of Patients in each Category of CGI-Global Improvement Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Week 24 OC						Week 24 LOCF					
	Parox		Placebo		Total		Parox		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total												
	(N=27)		(N=23)		(N=50)		(N=49)		(N=64)		(N=113)	
Very much improved	15	(55.6)	9	(39.1)	24	(48.0)	18	(36.7)	15	(23.4)	33	(29.2)
Much improved	10	(37.0)	12	(52.2)	22	(44.0)	16	(32.7)	27	(42.2)	43	(38.1)
Minimally improved	1	(3.7)	1	(4.3)	2	(4.0)	8	(16.3)	9	(14.1)	17	(15.0)
No change	1	(3.7)	1	(4.3)	2	(4.0)	5	(10.2)	8	(12.5)	13	(11.5)
Minimally worse	0	-	0	-	0	-	0	-	3	(4.7)	3	(2.7)
Much worse	0	-	0	-	0	-	1	(2.0)	2	(3.1)	3	(2.7)
Very much worse	0	-	0	-	0	-	1	(2.0)	-	-	1	(0.9)
Total	27	(100)	23	(100)	50	(100)	49	(100)	64	(100)	113	(100)
Age Group: Children												
	(N=13)		(N=10)		(N=23)		(N=24)		(N=35)		(N=59)	
Very much improved	8	(61.5)	3	(30.0)	9	(47.8)	9	(37.5)	9	(25.7)	18	(30.5)
Much improved	5	(38.5)	6	(60.0)	11	(47.8)	10	(41.7)	16	(45.7)	26	(44.1)
Minimally improved	0	-	1	(10.0)	1	(4.3)	3	(12.5)	5	(14.3)	8	(13.6)
No change	0	-	0	-	0	-	2	(8.3)	4	(11.4)	6	(10.2)
Minimally worse	0	-	0	-	0	-	0	-	1	(2.9)	1	(1.7)
Much worse	0	-	0	-	0	-	0	-	0	-	0	-
Very much worse	0	-	0	-	0	-	0	-	0	-	0	-
Total	13	(100)	10	(100)	23	(100)	24	(100)	35	(100)	59	(100)
Age Group: Adolescents												
	(N=14)		(N=13)		(N=27)		(N-25)		(N=29)		(N=54)	
Very much improved	7	(50.0)	6	(46.2)	13	(48.1)	9	(36.0)	6	(20.7)	15	(27.8)
Much improved	5	(35.7)	6	(46.2)	11	(40.7)	6	(24.0)	11	(37.9)	17	(31.5)
Minimally improved	1	(7.1)	0	-	1	(3.7)	5	(20.0)	4	(13.8)	9	(16.7)
No change	1	(7.1)	1	(7.7)	2	(7.4)	3	(12.0)	4	(13.8)	7	(13.0)
Minimally worse	0	-	0	-	0	-	0	-	2	(6.9)	2	(3.7)
Much worse	0	-	0	-	0	-	1	(4.0)	2	(6.9)	3	(5.6)
Very much worse	0	-	0	-	0	-	1	(4.0)	0	-	1	(1.9)
Total	14	(100)	13	(100)	27	(100)	25	(100)	29	(100)	54	(100)

Source Table 14.3.1, Section 11; Listing 14.3.1, Appendix C

N is the number of patients with a week 24 OC or LOCF assessment; Parox: paroxetine

Table 52 Proportion of Responders Based on CGI-Global Improvement Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD)

Visit	Acute Study Treatment Group								
	Paroxetine			Placebo			Total		
	N*	n**	%	N*	n**	%	N*	n**	%
Age Group: Total									
Week 1	41	15	36.6	59	28	47.5	100	43	43.0
Week 2	43	21	48.8	57	35	61.4	100	56	56.0
Week 3	44	29	65.9	53	37	69.8	97	66	68.0
Week 4	45	32	71.1	55	36	65.5	100	68	68.0
Week 8	40	31	77.5	47	37	78.7	87	68	78.2
Week 12	36	30	83.3	40	32	80.0	76	62	81.6
Week 16	33	25	75.8	37	30	81.1	70	55	78.6
Week 20	27	25	92.6	30	25	83.3	57	50	87.7
Week 24 OC	27	25	92.6	23	21	91.3	50	46	92.0
Week 24 LOCF	49	34	69.4	64	42	65.6	113	76	67.3
Age Group: Children									
Week 1	21	10	47.6	33	19	57.6	54	29	53.7
Week 2	21	10	47.6	32	20	62.5	53	30	56.6
Week 3	20	14	70.0	31	23	74.2	51	37	72.5
Week 4	23	15	65.2	31	21	67.7	54	36	66.7
Week 8	20	15	75.0	27	22	81.5	47	37	78.7
Week 12	17	14	82.4	22	17	77.3	39	31	79.5
Week 16	15	13	86.7	21	18	85.7	36	31	86.1
Week 20	13	13	100.0	17	14	82.4	30	27	90.0
Week 24 OC	13	13	100.0	10	9	90.0	23	22	95.7
Week 24 LOCF	24	19	79.2	35	25	71.4	59	44	74.6
Age Group: Adolescents									
Week 1	20	5	25.0	26	9	34.6	46	14	30.4
Week 2	22	11	50.0	25	15	60.0	47	26	55.3
Week 3	24	15	62.5	22	14	63.6	46	29	63.0
Week 4	22	17	77.3	24	15	62.5	46	32	69.6
Week 8	20	16	80.0	20	15	75.0	40	31	77.5
Week 12	19	16	84.2	18	15	83.3	37	31	83.8
Week 16	18	12	66.7	16	12	75.0	34	24	70.6
Week 20	14	12	85.7	13	11	84.6	27	23	85.2
Week 24 OC	14	12	85.7	13	12	92.3	27	24	88.9
Week 24 LOCF	25	15	60.0	29	17	58.6	54	32	59.3

Source Table 14.3.2, Section 11; Listing 14.3.1, Appendix C

* N is the total number of patients at the visit

**Responders (n) are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at the visit or endpoint

6.3.3.2 CGI-Global Improvement in Patients with a Primary Diagnosis of OCD

The number of patients in each category of the CGI-Global Improvement item for patients in the ITT population with a primary diagnosis of OCD is presented in Table 53. Results are presented for week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined. The majority of patients had a score of 1 (very much improved) or 2 (much improved) at the week 24 OC (23/25, 92.0%) and week 24 LOCF (70/103, 68.0%) endpoints. In the week 24 OC dataset for the combined age groups, 86.7% (13/15) of patients in the acute study paroxetine group and 100% (10/10) of patients in the acute study placebo group had a score of 1 (very much improved) or 2 (much improved). In the week 24 LOCF data set for the combined age groups, 69.8% (30/43) of patients in the acute study paroxetine group and 66.7% (40/60) patients in the acute study placebo group had a score of 1 (very much improved) or 2 (much improved).

Table 54 shows the number and percentage of responders based on the CGI-Global Improvement item for patients in the ITT population with a primary diagnosis of OCD. Results are presented for each visit by acute study treatment group for both age groups separately and combined. There were no notable differences between acute study treatment groups or age groups with respect to the number and percentage of responders based on the CGI-Global Improvement item.

Table 53 Number (%) of Patients in each Category of CGI-Global Improvement Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Week 24 OC						Week 24 LOCF					
	Parox		Placebo		Total		Parox		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total												
	(N=15)		(N=10)		(N=25)		(N=43)		(N=60)		(N=103)	
Very much improved	8	(53.3)	9	(90.0)	17	(68.0)	16	(37.2)	21	(35.0)	37	(35.9)
Much improved	5	(33.3)	1	(10.0)	6	(24.0)	14	(32.6)	19	(31.7)	33	(32.0)
Minimally improved	2	(13.3)	0	-	2	(8.0)	10	(23.3)	9	(15.0)	19	(18.4)
No change	0	-	0	-	0	-	1	(2.3)	8	(13.3)	9	(8.7)
Minimally worse	0	-	0	-	0	-	2	(4.7)	1	(1.7)	3	(2.9)
Much worse	0	-	0	-	0	-	0	-	2	(3.3)	2	(1.9)
Very much worse	0	-	0	-	0	-	0	-	0	-	0	-
Total	15	(100)	10	(100)	25	(100)	43	(100)	60	(100)	103	(100)
Age Group: Children												
	(N=9)		(N=6)		(N=15)		(N=24)		(N=33)		(N=57)	
Very much improved	5	(55.6)	5	(83.3)	10	(66.7)	9	(37.5)	13	(39.4)	22	(38.6)
Much improved	3	(33.3)	1	(16.7)	4	(26.7)	7	(29.2)	9	(27.3)	16	(28.1)
minimally improved	1	(11.1)	0	-	1	(6.7)	5	(20.8)	6	(18.2)	11	(19.3)
No change	0	-	0	-	0	-	1	(4.2)	4	(12.1)	5	(8.8)
Minimally worse	0	-	0	-	0	-	2	(8.3)	1	(3.0)	3	(5.3)
Much worse	0	-	0	-	0	-	0	-	0	-	0	-
Very much worse	0	-	0	-	0	-	0	-	0	-	0	-
Total	9	(100)	6	(100)	15	(100)	24	(100)	33	(100)	57	(100)
Age Group: Adolescents												
	(N=6)		(N=4)		(N=10)		(N=19)		(N=27)		(N=46)	
Very much improved	3	(50.0)	4	(100)	7	(70.0)	7	(36.8)	8	(29.6)	15	(32.6)
Much improved	2	(33.3)	0	-	2	(20.0)	7	(36.8)	10	(37.0)	17	(37.0)
minimally improved	1	(16.7)	0	-	1	(10.0)	5	(26.3)	3	(11.1)	8	(17.4)
No change	0	-	0	-	0	-	0	-	4	(14.8)	4	(8.7)
Minimally worse	0	-	0	-	0	-	0	-	0	-	0	-
Much worse	0	-	0	-	0	-	0	-	2	(7.4)	2	(4.3)
Very much worse	0	-	0	-	0	-	0	-	0	-	0	-
Total	6	(100)	4	(100)	10	(100)	19	(100)	27	(100)	46	(100)

Source Table 14.3.1, Section 11; Listing 14.3.1, Appendix C

N is the number of patients with a week 24 OC or LOCF assessment; Parox: paroxetine

Table 54 Proportion of Responders Based on CGI-Global Improvement Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD)

Visit	Acute Study Treatment Group								
	Paroxetine			Placebo			Total		
	N*	n**	%	N*	n**	%	N*	n**	%
Age Group: Total									
Week 1	38	15	39.5	51	12	23.5	89	27	30.3
Week 2	33	15	45.5	53	21	39.6	86	36	41.9
Week 3	34	18	52.9	53	31	58.5	87	49	56.3
Week 4	42	26	61.9	52	32	61.5	94	58	61.7
Week 8	37	25	67.6	37	23	62.2	74	48	64.9
Week 12	22	18	81.8	27	20	74.1	49	38	77.6
Week 16	22	17	77.3	22	18	81.8	44	35	79.5
Week 20	10	8	80.0	12	10	83.3	22	18	81.8
Week 24 OC	15	13	86.7	10	10	100.0	25	23	92.0
Week 24 LOCF	43	30	69.8	60	40	66.7	103	70	68.0
Age Group: Children									
Week 1	19	9	47.4	28	11	39.3	47	20	42.6
Week 2	17	8	47.1	29	14	48.3	46	22	47.8
Week 3	19	11	57.9	32	18	56.3	51	29	56.9
Week 4	23	15	65.2	28	18	64.3	51	33	64.7
Week 8	20	13	65.0	21	14	66.7	41	27	65.9
Week 12	11	10	90.9	16	11	68.8	27	21	77.8
Week 16	10	8	80.0	9	6	66.7	19	14	73.7
Week 20	7	6	85.7	7	7	100.0	14	13	92.9
Week 24 OC	9	8	88.9	6	6	100.0	15	14	93.3
Week 24 LOCF	24	16	66.7	33	22	66.7	57	38	66.7
Age Group: Adolescents									
Week 1	19	6	31.6	23	1	4.3	42	7	16.7
Week 2	16	7	43.8	24	7	29.2	40	14	35.0
Week 3	15	7	46.7	21	13	61.9	36	20	55.6
Week 4	19	11	57.9	24	14	58.3	43	25	58.1
Week 8	17	12	70.6	16	9	56.3	33	21	63.6
Week 12	11	8	72.7	11	9	81.8	22	17	77.3
Week 16	12	9	75.0	13	12	92.3	25	21	84.0
Week 20	3	2	66.7	5	3	60.0	8	5	62.5
Week 24 OC	6	5	83.3	4	4	100.0	10	9	90.0
Week 24 LOCF	19	14	73.7	27	18	66.7	46	32	69.6

Source Table 14.3.2, Section 11; Listing 14.3.1, Appendix C

* N is the total number of patients at the visit

**Responders (n) are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at the visit or endpoint

6.3.4 Change from Baseline in the Clinical Global Impression (CGI)-Severity of Illness Score

CGI-Severity of Illness item scores are listed by patient by acute study treatment group and age group in Listing 14.4.1, Appendix C.

6.3.4.1 CGI-Severity of Illness in Patients with a Primary Diagnosis of MDD

The number and percentage of patients in each category of the CGI-Severity of Illness score at each visit by age group and acute study treatment group is presented for the ITT population in Table 14.4.1b, Section 11. The number and percentage of patients in each category of the CGI-Severity of Illness score at each visit by age group is presented for the PPX population and ITT population (acute study placebo patients only) in Tables 14.4.1d and 14.4.1e, respectively, Section 11.

The number of patients in each category of the CGI-Severity of Illness item for patients in the ITT population with a primary diagnosis of MDD is presented in Table 55. Results are presented for acute study baseline, week 24 OC and week 24 LOCF by acute study treatment group for both age groups separately and combined.

Overall, 74.0% (37/50) of patients in the week 24 OC dataset and 56.6% (64/113) of patients in the week 24 LOCF dataset were rated as normal or borderline mentally ill, compared with no patients at acute study baseline. In the week 24 OC dataset for the combined age groups, 81.5% (22/27) of patients in the acute study paroxetine group and 65.2% (15/23) of patients in the acute study placebo group were rated as normal or borderline mentally ill. At acute study baseline, 1.7% (2/116) of patients were rated as severely ill or amongst the most extremely ill compared to no patients at the week 24 OC endpoint. Similarly, in the week 24 LOCF dataset for the combined age groups, 61.2% (30/49) of patients in the acute study paroxetine group and 50.0% (32/64) of patients in the acute study placebo group were rated as normal or borderline mentally ill. At week 24 LOCF one patient in the acute study paroxetine group was rated as severely ill, and no patients were rated amongst the most extremely ill.

Overall 59.3% (35/59) of children and 50.0% (27/54) of adolescents were rated normal or borderline mentally ill at week 24 LOCF. Among children, at the week 24 LOCF endpoint, 66.7% (16/24) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 54.3% (19/35) of acute study placebo patients. Among adolescents, at week 24 LOCF endpoint, 56.0% (14/25)

of acute study paroxetine patients were rated normal or borderline mentally ill compared with 44.8% (13/29) of acute study placebo patients. Among children, at the week 24 OC endpoint, 92.3% (12/13) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 60.0% (6/10) of acute study placebo patients. Among adolescents, at the week 24 OC endpoint, 71.4% (10/14) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 69.2% (9/13) of acute study placebo patients.

The number and percentage of patients by change in CGI-Severity of Illness from acute study baseline is presented for the ITT population in Table 14.4.2b, Section 11. The number and percentage of patients by change in CGI-Severity of Illness from acute study treatment phase endpoint is presented for the PPX population and ITT population (acute study placebo patients only) in Tables 14.4.2d and 14.4.2e, respectively, Section 11.

Summary statistics for change from acute study baseline in CGI-Severity of Illness score for week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined are presented for patients with a primary diagnosis of MDD (ITT population) in Table 56. The median CGI-Severity of Illness score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints for the overall population and for both acute study treatment groups. There were no notable differences between acute study treatment groups or age groups in the median change from acute study baseline in CGI-Severity of Illness for the week 24 OC and week 24 LOCF datasets.

Table 55 Number (%) of Patients in Each Category of CGI-Severity of Illness Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD) Continued…

	Acute Study Baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	(N=50)		(N=66)		(N=116)		(N=27)		(N=23)		(N=50)		(N=49)		(N=64)		(N=113)	
Normally not at all ill	0	-	0	-	0	-	9	(33.3)	7	(30.4)	16	(32.0)	10	(20.4)	12	(18.8)	22	(19.5)
Borderline mentally ill	0	-	0	-	0	-	13	(48.1)	8	(34.8)	21	(42.0)	20	(40.8)	20	(31.3)	40	(35.4)
Mildly ill	1	(2.0)	2	(3.0)	3	(2.6)	4	(14.8)	5	(21.7)	9	(18.0)	11	(22.4)	11	(17.2)	22	(19.5)
Moderately ill	36	(72.0)	48	(72.7)	84	(72.4)	1	(3.7)	2	(8.7)	3	(6.0)	7	(14.3)	17	(26.6)	24	(21.2)
Markedly ill	12	(24.0)	15	(22.7)	27	(23.3)	0	-	1	(4.3)	1	(2.0)	0	-	4	(6.3)	4	(3.5)
Severely ill	1	(2.0)	1	(1.5)	2	(1.7)	0	-	0	-	0	-	1	(2.0)	0	-	1	(0.9)
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	50	(100)	66	(100)	116	(100)	27	(100)	23	(100)	50	(100)	49	(100)	64	(100)	113	(100)
Age Group: Children	(N=25)		(N=36)		(N=61)		(N=13)		(N=10)		(N=23)		(N=24)		(N=35)		(N=59)	
Normally not at all ill	0	-	0	-	0	-	5	(38.5)	2	(20.0)	7	(30.4)	5	(20.8)	6	(17.1)	11	(18.6)
Borderline mentally ill	0	-	0	-	0	-	7	(53.8)	4	(40.0)	11	(47.8)	11	(45.8)	13	(37.1)	24	(40.7)
Mildly ill	0	-	2	(5.6)	2	(3.3)	1	(7.7)	2	(20.0)	3	(13.0)	6	(25.0)	6	(17.1)	12	(20.3)
Moderately ill	19	(76.0)	26	(72.2)	45	(73.8)	0	-	2	(20.0)	2	(8.7)	2	(8.3)	9	(25.7)	11	(18.6)
Markedly ill	5	(20.0)	7	(19.4)	12	(19.7)	0	-	0	-	0	-	0	-	1	(2.9)	1	(1.7)
Severely ill	1	(4.0)	1	(2.8)	2	(3.3)	0	-	0	-	0	-	0	-	0	-	0	-
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	25	(100)	36	(100)	61	(100)	13	(100)	10	(100)	23	(100)	24	(100)	35	(100)	59	(100)

Source Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N: number of patients with an acute study baseline, week 24 OC or LOCF assessment.

Table 55 Number (%) of Patients in Each Category of CGI-Severity of Illness Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute Study Baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents	**(N=25)**		**(N=30)**		**(N=55)**		**(N=14)**		**(N=13)**		**(N=27)**		**(N=25)**		**(N=29)**		**(N=54)**	
Normally not at all ill	0	-	0	-	0	-	4	(28.6)	5	(38.5)	9	(33.3)	5	(20.0)	6	(20.7)	11	(20.4)
Borderline mentally ill	0	-	0	-	0	-	6	(42.9)	4	(30.8)	10	(37.0)	9	(36.0)	7	(24.1)	16	(29.6)
Mildly ill	1	(4.0)	0	-	1	(1.8)	3	(21.4)	3	(23.1)	6	(22.2)	5	(20.0)	5	(17.2)	10	(18.5)
Moderately ill	17	(68.0)	22	(73.3)	39	(70.9)	1	(7.1)	0	-	1	(3.7)	5	(20.0)	8	(27.6)	13	(24.1)
Markedly ill	7	(28.0)	8	(26.7)	15	(27.3)	0	-	1	(7.7)	1	(3.7)	0	-	3	(10.3)	3	(5.6)
Severely ill	0	-	0	-	0	-	0	-	0	-	0	-	1	(4.0)	0	-	1	(1.9)
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	25	(100)	30	(100)	55	(100)	14	(100)	13	(100)	27	(100)	25	(100)	29	(100)	54	(100)

Source Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N: number of patients with an acute study baseline, week 24 OC or LOCF assessment

Table 56 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI-Severity of Illness Score by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	Median	Range	N	Mean	Median	Range	N	Mean	Median	Range
Age Group: Total												
Acute Study Baseline	50	4.3	4.0	3 to 6	66	4.2	4.0	3 to 6	116	4.2	4.0	3 to 6
Change from Acute Study Baseline to:												
Week 24 OC	27	-2.4	-2.0	-5 to 0	23	-2.0	-2.0	-4 to 0	50	-2.2	-2.0	-5 to 0
Week 24 LOCF	49	-1.9	-2.0	-5 to 2	64	-1.5	-2.0	-4 to 1	113	-1.7	-2.0	-5 to 2
Age Group: Children												
Acute Study Baseline	25	4.3	4.0	4 to 6	36	4.2	4.0	3 to 6	61	4.2	4.0	3 to 6
Change from Acute Study Baseline to:												
Week 24 OC	13	-2.6	-2.0	-5 to -1	10	-1.8	-2.0	-4 to 0	23	-2.3	-2.0	-5 to 0
Week 24 LOCF	24	-2.0	-2.0	-5 to 0	35	-1.6	-2.0	-4 to 0	59	-1.8	-2.0	-5 to 0
Age Group: Adolescents												
Acute Study Baseline	25	4.2	4.0	3 to 5	30	4.3	4.0	4 to 5	55	4.3	4.0	3 to 5
Change from Acute Study Baseline to:												
Week 24 OC	14	-2.2	–2.0	-4 to 0	13	-2.2	-2.0	-4 to 0	27	-2.2	-2.0	-4 to 0
Week 24 LOCF	25	-1.7	-2.0	-4 to 2	29	-1.4	-1.0	-4 to 1	54	-1.6	-2.0	-4 to 2

Source Table 14.4.3b, Section 11; Listing 14.4.1, Appendix C

Summary statistics for change from acute study treatment phase endpoint in CGI-Severity of Illness score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined are presented for patients with a primary diagnosis of MDD (PPX population) in Table 57. The median change from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints was 0.0, indicating no further change in CGI-Severity of Illness score during the open-label treatment phase of study 716.

Table 57 Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI-Severity of Illness Score by Age Group (PPX Population with Primary Diagnosis of MDD)

	Paroxetine			
	N	**Mean**	**Median**	**Range**
Age Group: Total				
Acute Study Treatment Phase Endpoint	50	2.6	2.0	1 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	27	-0.6	0.0	-4 to 1
Week 24 LOCF	49	-0.1	0.0	-4 to 3
Age Group: Children				
Acute Study Treatment Phase Endpoint	25	2.5	2.0	1 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	13	-0.5	0.0	-4 to 1
Week 24 LOCF	24	-0.2	0.0	-4 to 2
Age Group: Adolescents				
Acute Study Treatment Phase Endpoint	25	2.6	3.0	1 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	14	-0.7	-1.0	-3 to 1
Week 24 LOCF	25	-0.0	0.0	-3 to 3

Source Table 14.4.3d, Section 11; Listing 14.4.1; Appendix C

Summary statistics for change from acute study treatment phase endpoint in CGI-Severity of Illness score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined for patients in the acute study placebo group with a primary diagnosis of MDD are provided in Table 14.4.3e, Section 11.

6.3.4.2 CGI-Severity of Illness in Patients with a Primary Diagnosis of OCD

The number and percentage of patients in each category of the CGI-Severity of Illness score at each visit by age group and acute study treatment group is presented for the ITT population in Table 14.4.1b, Section 11. The number and percentage of patients in each category of the CGI-Severity of Illness score at each visit by age group is presented for the PPX population and ITT population (acute study placebo patients only) in Tables 14.4.1d and 14.4.1e, respectively, Section 11.

The number of patients in each category of the CGI-Severity of Illness item for patients in the ITT population with a primary diagnosis of OCD is presented in Table 58. Results are presented for acute study baseline, week 24 OC and week 24 LOCF by acute study treatment group for both age groups separately and combined.

Overall, 60.0% (15/25) of patients in the week 24 OC dataset and 31.1% (32/103) of patients in the week 24 LOCF dataset were rated as normal or borderline mentally ill, compared with no patients at acute study baseline. In the week 24 OC dataset for the combined age groups, 53.3% (8/15) of patients in the acute study paroxetine group and 70.0% (7/10) of patients in the acute study placebo group were rated as normal or borderline mentally ill. At acute study baseline, 98.1% (103/105) of patients were rated as moderately ill, markedly ill, severely ill or amongst the most extremely ill compared to no patients at the week 24 OC endpoint. Similarly, in the week 24 LOCF dataset for the combined age groups, 39.6% (17/43) of patients in the acute study paroxetine group and 25.0% (15/60) of patients in the acute study placebo group were rated as normal or borderline mentally ill. At the week 24 LOCF endpoint one patient in the acute study placebo group was rated as severely ill, and no patients were rated amongst the most extremely ill patients.

Overall 31.6% (18/57) of children and 30.4% (14/46) of adolescents were rated normal or borderline mentally ill at week 24 LOCF. Among children, at the week 24 LOCF endpoint, 37.5% (9/24) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 27.3% (9/33) of acute study placebo patients. Among adolescents, at the week 24 LOCF endpoint, 42.1% (8/19) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 22.2% (6/27) of acute study placebo patients. Among children, at the week 24 OC endpoint, 55.6% (5/9) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 66.7% (4/6) of acute study

placebo patients. Among adolescents, at the week 24 OC endpoint, 50.0% (3/6) of acute study paroxetine patients were rated normal or borderline mentally ill compared with 75.0% (3/4) of acute study placebo patients.

The number and percentage of patients by change in CGI-Severity of Illness from acute study baseline is presented for the ITT population in Table 14.4.2b, Section 11. The number and percentage of patients by change in CGI-Severity of Illness from acute study treatment phase endpoint is presented for the PPX population and ITT population (acute study placebo patients only) in Tables 14.4.2d and 14.4.2e, respectively, Section 11.

Summary statistics for change from acute study baseline in CGI-Severity of Illness score for week 24 OC and week 24 LOCF datasets by acute study treatment group for both age groups separately and combined are presented for patients with a primary diagnosis of OCD (ITT population) in Table 59. The median CGI-Severity of Illness score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints for the overall population and for both acute study treatment groups. There were no notable differences between acute study treatment groups or age groups in the median change from acute study baseline in CGI-Severity of Illness for the week 24 OC and week 24 LOCF datasets.

Table 58 Number (%) of Patients in Each Category of CGI-Severity of Illness Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD) Continued…

	Acute Study Baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	(N=44)		(N=61)		(N=105)		(N=15)		(N=10)		(N=25)		(N=43)		(N=60)		(N=103)	
Normally not at all ill	0	-	0	-	0	-	5	(33.3)	3	(30.0)	8	(32.0)	11	(25.6)	8	(13.3)	19	(18.4)
Borderline mentally ill	0	-	0	-	0	-	3	(20.0)	4	(40.0)	7	(28.0)	6	(14.0)	7	(11.7)	13	(12.6)
Mildly ill	0	-	2	(3.3)	2	(1.9)	7	(46.7)	3	(30.0)	10	(40.0)	15	(34.9)	25	(41.7)	40	(38.8)
Moderately ill	22	(50.0)	24	(39.3)	46	(43.8)	0	-	0	-	0	-	7	(16.3)	15	(25.0)	22	(21.4)
Markedly ill	19	(43.2)	25	(41.0)	44	(41.9)	0	-	0	-	0	-	4	(9.3)	4	(6.7)	8	(7.8)
Severely ill	3	(6.8)	10	(16.4)	13	(12.4)	0	-	0	-	0	-	0	-	1	(1.7)	1	(1.0)
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	44	(100)	61	(100)	105	(100)	15	(100)	10	(100)	25	(100)	43	(100)	60	(100)	103	(100)
Age Group: Children	(N=24)		(N=34)		(N=58)		(N=9)		(N=6)		(N=15)		(N=24)		(N=33)		(N=57)	
Normally not at all ill	0	-	0	-	0	-	3	(33.3)	2	(33.3)	5	(33.3)	6	(25.0)	5	(15.2)	11	(19.3)
Borderline mentally ill	0	-	0	-	0	-	2	(22.2)	2	(33.3)	4	(26.7)	3	(12.5)	4	(12.1)	7	(12.3)
Mildly ill	0	-	1	(2.9)	1	1.7	4	(44.4)	2	(33.3)	6	(40.0)	8	(33.3)	14	(42.4)	22	(38.6)
Moderately ill	14	(58.3)	15	(44.1)	29	(50.0)	0	-	0	-	0	-	6	(25.0)	8	(24.2)	14	(24.6)
Markedly ill	9	(37.5)	11	(32.4)	20	(34.5)	0	-	0	-	0	-	1	(4.2)	2	(6.1)	3	(5.3)
Severely ill	1	(4.2)	7	(20.6)	8	(13.8)	0	-	0	-	0	-	0	-	0	-	0	-
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	24	(100)	34	(100)	58	(100)	9	(100)	6	(100)	15	(100)	24	(100)	33	(100)	57	(100)

Source Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N: number of patients with an acute study baseline, week 24 OC or LOCF assessment.

Table 58 Number (%) of Patients in Each Category of CGI-Severity of Illness Item by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute Study Baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents	**(N=20)**		**(N=27)**		**(N=47)**		**(N=6)**		**(N=4)**		**(N=10)**		**(N=19)**		**(N=27)**		**(N=46)**	
Normally not at all ill	0	-	0	-	0	-	2	(33.3)	1	(25.0)	3	(30.0)	5	(26.3)	3	(11.1)	8	(17.4)
Borderline mentally ill	0	-	0	-	0	-	1	(16.7)	2	(50.0)	3	(30.0)	3	(15.8)	3	(11.1)	6	(13.0)
Mildly ill	0	-	1	(3.7)	1	(2.1)	3	(50.0)	1	(25.0)	4	(40.0)	7	(36.8)	11	(40.7)	18	(39.1)
Moderately ill	8	(40.0)	9	(33.3)	17	(36.2)	0	-	0	-	0	-	1	(5.3)	7	(25.9)	8	(17.4)
Markedly ill	10	(50.0)	14	(51.9)	24	(51.1)	0	-	0	-	0	-	3	(15.8)	2	(7.4)	5	(10.9)
Severely ill	2	(10.0)	3	(11.1)	5	(10.6)	0	-	0	-	0	-	0	-	1	(3.7)	1	(2.2)
Among most extremely ill	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
Total	20	(100)	27	(100)	47	(100)	6	(100)	4	(100)	10	(100)	19	(100)	27	(100)	46	(100)

Source Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N: number of patients with an acute study baseline, week 24 OC or LOCF assessment.

Table 59 Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI-Severity of Illness Score by Age Group and Acute Study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute Study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	Median	Range	N	Mean	Median	Range	N	Mean	Median	Range
Age Group: Total												
Acute Study Baseline	44	4.6	4.5	4 to 6	61	4.7	5.0	3 to 6	105	4.6	5.0	3 to 6
Change from Acute Study Baseline to:												
Week 24 OC	15	-2.3	-2.0	-4 to -1	10	-2.3	-2.0	-4 to -1	25	-2.3	-2.0	-4 to -1
Week 24 LOCF	43	-1.9	-2.0	-5 to 1	60	-1.7	-2.0	-5 to 2	103	-1.7	-2.0	-5 to 2
Age Group: Children												
Acute Study Baseline	24	4.5	4.0	4 to 6	34	4.7	5.0	3 to 6	58	4.6	4.0	3 to 6
Change from Acute Study Baseline to:												
Week 24 OC	9	-2.2	-2.0	-3 to -1	6	-2.2	-2.0	-3 to -1	15	-2.2	-2.0	-3 to -1
Week 24 LOCF	24	-1.8	-2.0	-4 to 1	33	-1.8	-2.0	-5 to 2	57	-1.8	-2.0	-5 to 2
Age Group: Adolescents												
Acute Study Baseline	20	4.7	5.0	4 to 6	27	4.7	5.0	3 to 6	47	4.7	5.0	3 to 6
Change from Acute Study Baseline to:												
Week 24 OC	6	-2.3	-2.5	-4 to -1	4	-2.5	-2.0	-4 to -2	10	-2.4	-2.0	-4 to-1
Week 24 LOCF	19	-2.0	-2.0	-5 to 0	27	-1.5	-1.0	-5 to 0	46	-1.7	-1.5	-5 to 0

Source Table 14.4.3b, Section 11; Listing 14.4.1, Appendix C

Summary statistics for change from acute study treatment phase endpoint in CGI-Severity of Illness score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined are presented for patients with a primary diagnosis of OCD (PPX population) in Table 60. The median change from acute study treatment phase endpoint to the week 24 OC and week 24 LOCF endpoints was 0.0, indicating no further change in CGI-Severity of Illness score during the open-label treatment phase of study 716.

Table 60 Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI-Severity of Illness Score by Age Group (PPX Population with Primary Diagnosis of OCD)

	Paroxetine			
	N	**Mean**	**Median**	**Range**
Age Group: Children				
Acute Study Treatment Phase Endpoint	24	2.8	3.0	1 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	9	-0.2	0.0	-2 to 1
Week 24 LOCF	24	-0.1	0.0	-3 to 2
Age Group: Adolescents				
Acute Study Treatment Phase Endpoint	20	3.7	4.0	2 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	6	-1.2	-1.0	-2 to 0
Week 24 LOCF	19	-0.9	-1.0	-3 to 0
Age Group: Total				
Acute Study Treatment Phase Endpoint	44	3.2	3.0	1 to 5
Change from Acute Study Treatment Phase Endpoint to:				
Week 24 OC	15	-0.6	0.0	-2 to 1
Week 24 LOCF	43	-0.5	0.0	-3 to 2

Source Table 14.4.3d, Section 11; Listing 14.4.1; Appendix C

Summary statistics for change from acute study treatment phase endpoint in CGI-Severity of Illness score for the week 24 OC and week 24 LOCF datasets for both age groups separately and combined for patients in the acute study placebo group with a primary diagnosis of OCD are provided in Source Table 14.4.3e, Section 11.

6.3.5 Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline

Table 61 presents summary statistics for the change in CDRS-R total score from acute study treatment phase endpoint (pre-taper phase) to study 716 baseline by dose level at the end of the acute study treatment phase by acute study treatment group and age group for the ITT population. As the CDRS-R was specific to MDD, only those patients entering from the acute study 701 are included in this summary.

The mean CDRS-R total score increased from acute study treatment phase endpoint to study 716 baseline for each ending dose level. However, as the numbers involved are small it is difficult to draw any meaningful conclusions. There was no clear relationship between the dose level at the end of the acute study treatment phase, the acute study treatment group or age group in the change in CDRS-R total score from acute study treatment phase endpoint to study 716 baseline.

6.3.6 Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline

Table 62 presents summary statistics for the change in CY-BOCS total score from acute study treatment phase endpoint (pre-taper phase) to study 716 baseline by dose level at the end of the acute study treatment phase by acute study treatment group and age group for the ITT population. As the CY-BOCS was specific to OCD, only those patients entering from the acute study 704 are included in this summary.

For the combined age groups, the mean CY-BOCS total score increased from acute study treatment phase endpoint to study 716 baseline for both acute study treatment groups for each ending dose level. In the paroxetine acute study treatment group there were differences between children and adolescents in the mean change in CY-BOCS total score from acute study treatment phase endpoint to study 716 baseline. In general, children on paroxetine had a greater increase in CY-BOCS total score from acute study treatment phase endpoint to study 716 baseline compared to adolescents. However, as the numbers involved are small it is difficult to draw any meaningful conclusions.

There was no clear relationship between the dose level at the end of the acute study treatment phase and the change in CY-BOCS total score from acute study treatment phase endpoint to study 716 baseline.

Table 61 Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline by Dose Level, Acute Study Treatment Group and Age Group (ITT Population with Primary Diagnosis of MDD)

		Acute Study Treatment Group											
		Paroxetine				Placebo				Total			
Daily Dose **	Age Group	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
2 (20 mg)	Total	15	4.9	(9.28)	-4 to 30	15	2.4	(12.19)	-9 to 44	30	2.7	(10.72)	-9 to 44
	Children	8	7.1	(12.09)	-4 to 30	8	4.4	(16.69)	-9 to 44	16	5.8	(14.15)	-9 to 44
	Adolescent	7	2.4	(4.08)	-2 to 8	7	0.1	(3.24)	-3 to 6	14	1.3	(3.73)	-3 to 8
3 (30 mg)	Total	15	0.0	(11.61)	-24 to 24	22	1.6	(6.69)	-10 to 18	37	1.0	(8.90)	-24 to 24
	Children	5	3.4	(11.37)	-14 to 15	10	1.5	(7.59)	-10 to 18	15	2.1	(8.65)	-14 to 18
	Adolescent	10	-1.7	(11.94)	-24 to 24	12	1.8	(6.20)	-7 to 14	22	0.2	(9.18)	-24 to 24
4 (40 mg)	Total	10	2.8	(8.02)	-13 to 16	5	9.0	(9.59)	-4 to 18	15	4.9	(8.77)	-13 to 18
	Children	5	0.0	(9.30)	-13 to 12	2	10.5	(10.61)	3 to 18	7	3.0	(10.13)	-13 to 18
	Adolescent	5	5.6	(6.23)	0 to 16	3	8.0	(11.14)	-4 to 18	8	6.5	(7.69)	- 4 to 18
5 (50 mg)	Total	3	8.0	(15.62)	-2 to 26	11	7.0	(11.25)	-5 to 28	14	7.2	(11.62)	-5 to 28
	Children	1	26.0	-	26 to 26	6	3.8	(8.93)	-3 to 21	7	7.0	(11.69)	-3 to 26
	Adolescent	2	-1.0	(1.41)	-2 to 0	5	10.8	(13.55)	-5 to 28	7	7.4	(12.49)	-5 to 28

Source Table 14.5.1, Section 11; Listing 14.1.1, Appendix C

** Dose level at acute study treatment phase endpoint

Table 62 Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline by Dose Level, Acute Study Treatment Group and Age Group (ITT Population with Primary Diagnosis of OCD)

		Acute Study Treatment Group											
		Paroxetine				Placebo				Total			
Daily Dose **	**Age Group**	**N**	**Mean**	**(SD)**	**Range**	**N**	**Mean**	**(SD)**	**Range**	**N**	**Mean**	**(SD)**	**Range**
2 (20mg)	Total	11	1.6	(4.76)	-6 to 11	7	2.4	(6.02)	-4 to 15	18	1.9	(5.13)	-6 to15
	Children	9	2.4	(4.50)	-4 to 11	5	4.2	(6.22)	0 to15	14	3.1	(5.01)	-4 to15
	Adolescent	2	-2.0	(5.66)	-6 to 2	2	-2.0	(2.83)	-4 to 0	4	-2.0	(3.65)	-6 to 2
3 (30 mg)	Total	6	2.3	(5.68)	-3 to 13	5	5.4	(9.99)	0 to 23	11	3.7	(7.66)	-3 to 23
	Children	5	2.8	(6.22)	-3 to 13	1	0.0	-	0 to 0	6	2.3	(5.68)	-3 to13
	Adolescent	1	0.0	-	0 to 0	4	6.8	(11.00)	0 to 23	5	5.4	(9.99)	0 to 23
4 (40 mg)	Total	8	1.0	(5.42)	-6 to 13	14	1.9	3.76	-3 to 10	22	1.5	4.33	-6 to 13
	Children	2	6.5	(9.19)	0 to 13	10	1.4	3.44	-3 to 9	12	2.3	4.61	-3 to 13
	Adolescent	6	-0.8	(2.86)	-6 to 2	4	3.0	4.83	-1 to 10	10	0.7	4.03	-6 to 10
5 (50 mg)	Total	14	3.2	(5.48)	-1 to 15	31	2.7	(5.62)	-9 to 15	45	2.9	(5.52)	-9 to 15
	Children	5	3.6	(6.54)	-1 to 15	14	2.3	(7.13)	-9 to 15	19	2.6	(6.82)	-9 to 15
	Adolescent	9	3.0	(5.22)	-1 to 14	17	3.1	(4.19)	-4 to 10	26	3.0	(4.47)	-4 to 14

Source Table 14.5.2, Section 11; Listing 14.2.1, Appendix C

** Dose level at acute study treatment phase endpoint

7 Discussion

The primary objective of this multicenter, open-label, 6-month extension study was to assess the long-term (24 weeks) safety of paroxetine in pediatric patients with MDD or OCD. The long term efficacy of paroxetine in these patient populations was also evaluated informally as a secondary objective. Children and adolescents who completed paroxetine study 701, 704, or 715, and who chose to enter this study were considered eligible if they met all the inclusion criteria and none of the exclusion criteria. Patients who entered study 716 from study 715 (paroxetine forced titration open-label pharmacokinetic study) are not included in this interim report because the database for 715 was finalized after the study 716 database. Patients from study 715 will be included in the final clinical study report for study 716. In addition, the interim database does not include patients from acute study 704 who did not have a study 716 CRF study conclusion page or did not have a completed study 716 week 4 CRF received in-house at GlaxoSmithKline by the clinical cut-off date of October 1, 2001. All patients from study 701 are included.

This interim safety database includes a substantial amount of paroxetine exposure data in pediatric patients. It includes complete or partial data from 223 patients (117 MDD patients and 106 OCD patients) of the 261 total patients enrolled in the study. The mean number of days of exposure to open-label treatment phase study medication (i.e, excluding acute study dosing and taper phase dosing) alone was more than three months (106.9 days, range 2 to 197 days). For patients who had received paroxetine in their acute study, the overall mean number of days of exposure to paroxetine (including taper) was 199.5 days (range 65 to 304; 193.6 days in children and 206.0 days in adolescents). This includes data from 62 patients with overall paroxetine exposure (i.e., acute study exposure plus open label exposure, and including taper phase dosing) ranging from 24 weeks to 10 months total duration, also with both children (ages 7 to 11) and adolescents (ages 12 to 17) well represented. The overall mean daily dose of paroxetine to which patients were exposed was 22.2 mg/day, which is representative of that which occurs in clinical practice. For patients with a primary diagnosis of MDD, the overall mean daily dose of paroxetine was 20.9 mg/day, and for patients with a primary diagnosis of OCD, the overall mean dose of paroxetine was 23.7 mg/day.

Safety

The safety profile of paroxetine observed in pediatric patients with MDD or OCD following longer-term administration in this study was similar to that observed in

the acute studies [2], [4], [5], [7]. The results of this study indicate that paroxetine is safe and generally well-tolerated when used in children and adolescents over a period of up to 24 weeks over the dose range of 10-50 mg/day. Although fewer numbers of patients were exposed to paroxetine for periods exceeding 6 months, the safety data generated from patients with exposure exceeding 6 months appears to be consistent with those data generated from patients exposed to paroxetine for shorter durations. There were no deaths or any unexpected safety findings. Overall, 72.9% (161/221) of patients reported a gender-non-specific emergent adverse event during the open-label treatment phase: 75.5% (71/94) of patients who had received paroxetine in the acute study and 70.9% (90/127) of patients who had received placebo in the acute study. Overall, the most common (>10%) gender-non-specific adverse events during the open-label treatment phase were headache (21.7%), respiratory disorder (18.1%), infection (12.7%), and trauma (10.0%), and for the most part this held true irrespective of whether the patient had received paroxetine or placebo in the acute study. For patients who had received paroxetine in the acute study, the most common (>10%) adverse events were headache, respiratory disorder, infection, trauma, and nausea, while the most common adverse events for patients who had received placebo in the acute study were respiratory disorder, headache, infection and nervousness.

The majority of adverse events were mild to moderate in intensity, with 11.3% (25/221) of the patients experiencing an adverse event considered by the investigator to be severe in nature. The proportion of patients reporting a gender-non-specific severe emergent adverse event during the open-label treatment phase were similar between patients coming from the two acute study treatment groups. Overall, 5.4% (12/223) of patients experienced at least one serious adverse event during study 716 (or within 30 days of the last dose of open-label study medication, including taper). The proportion of patients reporting at least one serious adverse event did not differ based on acute study treatment assignment: 5.2% (5/96) of patients who had received paroxetine in the acute study and 5.5% (7/127) of patients who had received placebo in the acute study. Of the 14 serious adverse events reported, 12 were reported during the open-label treatment phase. Serious adverse events leading to the withdrawal of patients were emotional lability, depression, hostility, hallucinations and psychosis.

Approximately half (47.1%, 104/221) of the open-label treatment phase adverse events were considered by the investigator to be related or possibly related to the study treatment, and again there was no difference between patients coming from the two acute study treatment groups in this regard.

Although the early withdrawal rate in this study was quite high (55.6%, 124/223), this did not appear to be due to safety/tolerability issues but instead appears to be due to a higher than expected drop-out rate due to miscellaneous reasons (i.e., 28.5% total withdrawal rate due to 'lost to follow-up', 'protocol deviation' or 'other' reasons). Overall, 14.9% (33/221) of patients were withdrawn from the study during the open-label treatment phase because of an adverse event, which is not substantially different from the withdrawal due to adverse event rates observed in the paroxetine groups in acute studies 701 (9.9%) and 704 (10.2%). However, the proportion of patients withdrawn because of an adverse event was higher in patients who had received placebo in the acute study (18.9%, 24/127) than in patients who had received paroxetine in the acute study (9.6%, 9/94). Not unexpectedly for antidepressants with a predominant action on serotonin uptake, adverse events that resulted in withdrawal were primarily associated with the nervous system (36/42 adverse events that resulted in withdrawal from the study were associated with the nervous system). Of those adverse events leading to withdrawal of two or more patients in the open-label extension study, only the adverse event 'hallucination' (which led to the withdrawal of two patients in the open-label extension study) was unique to the extension study (i.e, was not reported in either acute study 701 or acute study 704).

There were no unexpected safety findings during the taper or follow-up phase. Approximately one-third (32.8%) of the patients with open-label taper phase/follow-up phase data available experienced an adverse event during the taper and/or follow-up phases. However, the proportion of patients reporting at least one gender-non-specific adverse event during the taper phase or follow-up phase was higher in patients who had received paroxetine in the acute study than in patients who had received placebo in the acute study [40.0% (20/50) compared 27.5% (19/69)] which suggests that discontinuation events may be somewhat more likely to occur following longer-term exposure. However, these data don't suggest that the character/severity of the adverse events occurring following cessation of longer-term exposure are qualitatively different than those which occur following cessation of dosing after shorter term exposure. The most common (≥5%) gender-non-specific open-label taper phase or follow-up phase adverse events for patients who had received paroxetine in the acute study were headache, abdominal pain, respiratory disorder and sinusitis. No adverse events occurred during the open-label taper phase or follow-up phase in patients who had received placebo in the acute study placebo group at a frequency of ≥ 5%. One patient who had received placebo in the acute study experienced a serious adverse event (depression) during the study 716 taper phase and one patient who also had received placebo in the acute study experienced a serious adverse event

(hostility) during the follow-up phase (one day after stopping open-label treatment).

The data from this study do not suggest that the overall likelihood of experiencing an adverse event upon longer term paroxetine exposure differs substantially between children and adolescents. The overall frequency of gender-non-specific adverse events was only slightly higher among children compared to adolescents. A total of 77.3% (92/119) of children reported gender-non-specific adverse events during the open-label treatment phase [79.6% (39/49) of patients from the acute study paroxetine group and 75.7% (53/70) of patients from the acute study placebo group] compared to 67.6% (69/102) of adolescents [71.1% (32/45) of patients from the acute study paroxetine group and 64.9% (37/57) of patients from the acute study placebo group]. However, as was the case in the two acute studies, data from this study suggest that the adverse event profile following longer term administration may differ somewhat between children and adolescents. Study 716 adverse events that occurred in children with an incidence of $\geq 5\%$ and with an incidence of at least twice that in adolescents were rhinitis, pharyngitis, hyperkinesia, fever, vomiting, and otitis media. Adverse events that occurred in adolescents with an incidence of $\geq 5\%$ and with an incidence of at least twice that in children were asthenia, somnolence, emotional lability, and asthma.

The incidence of adverse events leading to withdrawal was similar between children (15.1%, 18/119) and adolescents (14.7%, 15/102). However, the proportion of patients reporting serious adverse events was greater in children (7.6%, 9/119) compared to adolescents (2.9%, 3/104). As expected, there were a small number of gender-specific adverse events reported; these were mainly in the adolescent population.

Data from this study suggest that longer term tolerability for paroxetine is similar in patients with a primary diagnosis of MDD and patients with a primary diagnosis of OCD. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 70.7% (82/116) during the open-label treatment phase [76.0% (38/50) of patients from the acute study paroxetine group and 66.7% (44/66) of patients from the acute study placebo group]. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD was 75.2% (79/105) during the open-label treatment phase [75.0% (33/44) of patients from the acute study paroxetine group and 75.4% (46/61) of patients from the acute study placebo group]. Adverse events that occurred in patients with a primary diagnosis of MDD with an incidence of $\geq 5\%$ and with an incidence of at least twice that in patients with a

primary diagnosis of OCD were weight gain, vomiting, and emotional lability. Adverse events that occurred in patients with a primary diagnosis of OCD with an incidence of ≥ 5% and with an incidence of at least twice that in patients with a primary diagnosis of MDD were nervousness, hostility, and hyperkinesia. The clinical relevance of these findings is unclear.

Mean changes from baseline in all laboratory parameters were small in the overall study 716 population and generally comparable between patients coming from the two different acute study treatment groups. No clinically relevant patterns of change resulting from longer term exposure were clearly apparent. Similarly, clinical laboratory abnormalities meeting pre-defined potential concern criteria were clinically unremarkable (i.e., comparable to that observed following acute exposure) and similar in patients coming from the two different acute study treatment groups. Hematocrit (low) was the laboratory parameter most frequently meeting the potential clinical concern criteria.

With the exception of body weight, mean changes in all vital sign parameters were also generally small in the overall study 716 population and comparable between patients coming from the two acute study treatment groups. The mean increase in body weight was 5.4 kg (data from 59 patients) [5.8 kg in patients receiving paroxetine in the acute study (data from 31 patients) versus 5.0 kg in patients receiving placebo in the acute study (data from 28 patients)]. The clinical relevance, if any, of this magnitude of increase in mean body weight in an actively growing and maturing population such as this is not clear. The mean increase in BMI (kg/m^2) was 1.51 in the overall study 716 population (1.73 in patients who had received paroxetine in the acute study and 1.26 in patients who had received placebo in the acute study). Vital sign changes meeting pre-defined potential concern criteria upon longer term exposure were infrequent, similar between patients coming from the two acute study treatment groups, and comparable to that observed following acute exposure with the possible exception of body weight gain (≥7% increase). Overall 14.4% (21/147) of patients had a high acute study baseline assessment and an increase in weight that met the predefined clinical concern criteria during the open-label extension phase (including taper): 19.4% (12/62) of patients who received paroxetine in their acute study and 10.7% (9/85) of patients who received placebo in their acute study. However, for only four of these patients was the increase in weight considered clinically significant by the investigator and recorded as an adverse event.

Efficacy

This was primarily a safety study; there was no primary efficacy endpoint defined, although summaries were provided for several secondary endpoints. Although not formally designed to evaluate efficacy, the data do suggest that patients who responded to paroxetine treatment in the acute study in general continued to respond to paroxetine with continued administration in this follow-up, extension study.

A CGI responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to acute study baseline. The majority of patients continued to meet the CGI responder criteria at the extension phase week 24 OC and week 24 LOCF endpoints. For patients with MDD, 92.0% (46/50) of patients met the response criteria at Week 24 (67.3%, 76/113 in the LOCF dataset). In general there were no notable differences between MDD patients who had received paroxetine in the acute study versus those MDD patients who had received placebo in the acute study with respect to the number and percentage of extension phase week 24 responders based on the CGI-Global Improvement item. In the MDD LOCF dataset, the percentage of responders was slightly higher in children than in adolescents (74.6% versus 59.3%, respectively). For patients with OCD, 92.0% (23/25) of patients met the response criteria at Week 24 (68%, 70/103 in the LOCF dataset). In general there were no notable differences between OCD patients who had received paroxetine in the acute study versus those OCD patients who had received placebo in the acute study with respect to the number and percentage of extension phase week 24 responders based on the CGI-Global Improvement item. The responder rate in OCD children was comparable to that in OCD adolescents.

The change from baseline in CDRS-R total score was specific to MDD; only those patients entering from the acute study 701 were included in these summaries. The mean CDRS-R total score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints. The overall mean change from acute study baseline was a decrease of 33.4 points for week 24 OC and a decrease of 26.8 points for week 24 LOCF. There were no notable differences between patients who had received paroxetine in the acute study and patients who had received placebo in the acute study in the total study 716 population. Among children, however, patients who had received paroxetine in the acute study demonstrated a larger reduction in CDRS-R total score at week 24 (-35.1, LOCF) than did children who had received placebo in the acute study (-26.0, LOCF). The results for the PPX population, which evaluated the change in CDRS-R total score from acute study treatment phase endpoint to extension phase week 24,

showed small but further reductions in CDRS-R total scores in both the OC and LOCF datasets in the total population of patients who had received paroxetine in the acute study, indicating that the improvements in MDD symptoms experienced in the acute study were maintained during longer term paroxetine exposure.

The change from baseline in CY-BOCS total score was specific to OCD; only those patients entering from the acute study 704 were included in these summaries. The mean CY-BOCS total score decreased from acute study baseline to the week 24 OC and week 24 LOCF endpoints. The overall mean change from acute study baseline was a decrease of 15.8 points for week 24 OC and a decrease of 12.0 points for week 24 LOCF. In the LOCF datasets, the reduction in CY-BOCS total score was greater in patients who had received paroxetine in their acute study than it was in patients who had received placebo in the acute study, both in the combined age group (total) population (-17.8 versus -7.1), as well as among children (-17.3 versus -6.5) and among adolescents (-18.4 versus -7.8). The results for the PPX population, which evaluated the change in CY-BOCS total score from acute study treatment phase endpoint to extension phase week 24, suggest that adolescents who had received paroxetine in the acute study continued to demonstrate further reductions in CY-BOCS Total score during the extension phase. This did not appear to be the case among children, although the symptom reduction achieved in the acute study was maintained.

8 Conclusions

Data from this study demonstrate that paroxetine (10-50 mg/day) is safe and generally well-tolerated when used to treat children and adolescents with MDD or OCD for a period of up to 24 weeks. The adverse event profile with longer term dosing was comparable to that observed during acute (short term) dosing in earlier studies. As was the case in the prior acute studies, the long term safety data suggest that the common adverse event profile may differ somewhat between children and adolescents.

The efficacy results suggest that patients who responded to paroxetine in the acute study are likely to continue to respond to paroxetine during long term administration, however this study was not designed to evaluate this.

9 References

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10 Source Tables: Study Population

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis : MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=25)		Placebo (N=36)		Total (N=61)	
716 Baseline Only	0		0		0	
Number Entered	25	(100.0%)	36	(100.0%)	61	(100.0%)
Completed	13	(52.0%)	11	(30.6%)	24	(39.3%)
Ongoing	0		0		0	
Early Withdrawal	12	(48.0%)	25	(69.4%)	37	(60.7%)
Intention-to-Treat Population	25	(100.0%)	36	(100.0%)	61	(100.0%)
Pure Paroxetine Population	25	(100.0%)	N/A		25	(41.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis: OCD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=24)		Placebo (N=34)		Total (N=58)	
716 Baseline Only	0		0		0	
Number Entered	24	(100.0%)	34	(100.0%)	58	(100.0%)
Completed	8	(33.3%)	5	(14.7%)	13	(22.4%)
Ongoing	4	(16.7%)	7	(20.6%)	11	(19.0%)
Early Withdrawal	12	(50.0%)	22	(64.7%)	34	(58.6%)
Intention-to-Treat Population	24	(100.0%)	34	(100.0%)	58	(100.0%)
Pure Paroxetine Population	24	(100.0%)	N/A		24	(41.4%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis: Total

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=49)		Placebo (N=70)		Total (N=119)	
716 Baseline Only	0		0		0	
Number Entered	49	(100.0%)	70	(100.0%)	119	(100.0%)
Completed	21	(42.9%)	16	(22.9%)	37	(31.1%)
Ongoing	4	(8.2%)	7	(10.0%)	11	(9.2%)
Early Withdrawal	24	(49.0%)	47	(67.1%)	71	(59.7%)
Intention-to-Treat Population	49	(100.0%)	70	(100.0%)	119	(100.0%)
Pure Paroxetine Population	49	(100.0%)	N/A		49	(41.2%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=26)		Placebo (N=30)		Total (N=56)	
716 Baseline Only	0		0		0	
Number Entered	26	(100.0%)	30	(100.0%)	56	(100.0%)
Completed	13	(50.0%)	13	(43.3%)	26	(46.4%)
Ongoing	1	(3.8%)	0		1	(1.8%)
Early Withdrawal	12	(46.2%)	17	(56.7%)	29	(51.8%)
Intention-to-Treat Population	25	(96.2%)	30	(100.0%)	55	(98.2%)
Pure Paroxetine Population	25	(96.2%)	N/A		25	(44.6%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: OCD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=21)		Placebo (N=27)		Total (N=48)	
716 Baseline Only	0		0		0	
Number Entered	21	(100.0%)	27	(100.0%)	48	(100.0%)
Completed	6	(28.6%)	4	(14.8%)	10	(20.8%)
Ongoing	6	(28.6%)	8	(29.6%)	14	(29.2%)
Early Withdrawal	9	(42.9%)	15	(55.6%)	24	(50.0%)
Intention-to-Treat Population	20	(95.2%)	27	(100.0%)	47	(97.9%)
Pure Paroxetine Population	20	(95.2%)	N/A		20	(41.7%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: Total

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=47)		Placebo (N=57)		Total (N=104)	
716 Baseline Only	0		0		0	
Number Entered	47	(100.0%)	57	(100.0%)	104	(100.0%)
Completed	19	(40.4%)	17	(29.8%)	36	(34.6%)
Ongoing	7	(14.9%)	8	(14.0%)	15	(14.4%)
Early Withdrawal	21	(44.7%)	32	(56.1%)	53	(51.0%)
Intention-to-Treat Population	45	(95.7%)	57	(100.0%)	102	(98.1%)
Pure Paroxetine Population	45	(95.7%)	N/A		45	(43.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=51)		Placebo (N=66)		Total (N=117)	
716 Baseline Only	0		0		0	
Number Entered	51	(100.0%)	66	(100.0%)	117	(100.0%)
Completed	26	(51.0%)	24	(36.4%)	50	(42.7%)
Ongoing	1	(2.0%)	0		1	(0.9%)
Early Withdrawal	24	(47.1%)	42	(63.6%)	66	(56.4%)
Intention-to-Treat Population	50	(98.0%)	66	(100.0%)	116	(99.1%)
Pure Paroxetine Population	50	(98.0%)	N/A		50	(42.7%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: OCD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=45)		Placebo (N=61)		Total (N=106)	
716 Baseline Only	0		0		0	
Number Entered	45	(100.0%)	61	(100.0%)	106	(100.0%)
Completed	14	(31.1%)	9	(14.8%)	23	(21.7%)
Ongoing	10	(22.2%)	15	(24.6%)	25	(23.6%)
Early Withdrawal	21	(46.7%)	37	(60.7%)	58	(54.7%)
Intention-to-Treat Population	44	(97.8%)	61	(100.0%)	105	(99.1%)
Pure Paroxetine Population	44	(97.8%)	N/A		44	(41.5%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: Total

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=96)		Placebo (N=127)		Total (N=223)	
716 Baseline Only	0		0		0	
Number Entered	96	(100.0%)	127	(100.0%)	223	(100.0%)
Completed	40	(41.7%)	33	(26.0%)	73	(32.7%)
Ongoing	11	(11.5%)	15	(11.8%)	26	(11.7%)
Early Withdrawal	45	(46.9%)	79	(62.2%)	124	(55.6%)
Intention-to-Treat Population	94	(97.9%)	127	(100.0%)	221	(99.1%)
Pure Paroxetine Population	94	(97.9%)	N/A		94	(42.2%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Children

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=3)	Total (N=4)
716 Baseline Only	0	0	0
Number Entered	1 (100.0%)	3 (100.0%)	4 (100.0%)
Completed	1 (100.0%)	1 (33.3%)	2 (50.0%)
Ongoing	0	0	0
Early Withdrawal	0	2 (66.7%)	2 (50.0%)
Intention-to-Treat Population	1 (100.0%)	3 (100.0%)	4 (100.0%)
Pure Paroxetine Population	1 (100.0%)	N/A	1 (25.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Adolescents

Study Stage / Population	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
716 Baseline Only	0	0	0
Number Entered	2 (100.0%)	4 (100.0%)	6 (100.0%)
Completed	1 (50.0%)	2 (50.0%)	3 (50.0%)
Ongoing	0	0	0
Early Withdrawal	1 (50.0%)	2 (50.0%)	3 (50.0%)
Intention-to-Treat Population	2 (100.0%)	4 (100.0%)	6 (100.0%)
Pure Paroxetine Population	2 (100.0%)	N/A	2 (33.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=3)		Placebo (N=7)		Total (N=10)	
716 Baseline Only	0		0		0	
Number Entered	3	(100.0%)	7	(100.0%)	10	(100.0%)
Completed	2	(66.7%)	3	(42.9%)	5	(50.0%)
Ongoing	0		0		0	
Early Withdrawal	1	(33.3%)	4	(57.1%)	5	(50.0%)
Intention-to-Treat Population	3	(100.0%)	7	(100.0%)	10	(100.0%)
Pure Paroxetine Population	3	(100.0%)	N/A		3	(30.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (43 Centres)
Age Group : Children

Study Stage/Population	Paroxetine (N=48)		Placebo (N=67)		Total (N=115)	
	----------Acute Study Treatment Group----------					
716 Baseline Only	0		0		0	
Number Entered	48	(100.0%)	67	(100.0%)	115	(100.0%)
Completed	20	(41.7%)	15	(22.4%)	35	(30.4%)
Ongoing	4	(8.3%)	7	(10.4%)	11	(9.6%)
Early Withdrawal	24	(50.0%)	45	(67.2%)	69	(60.0%)
Intention-to-Treat Population	48	(100.0%)	67	(100.0%)	115	(100.0%)
Pure Paroxetine Population	48	(100.0%)	N/A		48	(41.7%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (43 Centres)
Age Group : Adolescents

Study Stage / Population	Acute Study Treatment Group: Paroxetine (N=45)		Placebo (N=53)		Total (N=98)	
716 Baseline Only	0		0		0	
Number Entered	45	(100.0%)	53	(100.0%)	98	(100.0%)
Completed	18	(40.0%)	15	(28.3%)	33	(33.7%)
Ongoing	7	(15.6%)	8	(15.1%)	15	(15.3%)
Early Withdrawal	20	(44.4%)	30	(56.6%)	50	(51.0%)
Intention-to-Treat Population	43	(95.6%)	53	(100.0%)	96	(98.0%)
Pure Paroxetine Population	43	(95.6%)	N/A		43	(43.9%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (43 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=93)		Placebo (N=120)		Total (N=213)	
716 Baseline Only	0		0		0	
Number Entered	93	(100.0%)	120	(100.0%)	213	(100.0%)
Completed	38	(40.9%)	30	(25.0%)	68	(31.9%)
Ongoing	11	(11.8%)	15	(12.5%)	26	(12.2%)
Early Withdrawal	44	(47.3%)	75	(62.5%)	119	(55.9%)
Intention-to-Treat Population	91	(97.8%)	120	(100.0%)	211	(99.1%)
Pure Paroxetine Population	91	(97.8%)	N/A		91	(42.7%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients that had a completed week 4 CRF in house by 1st October 2001 for whom a study conclusion page was not available.

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: MDD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=25)		Placebo (N=36)		Total (N=61)	
Completed Study*	13	(52.0%)	11	(30.6%)	24	(39.3%)
Adverse Experience	3	(12.0%)	6	(16.7%)	9	(14.8%)
Lack of Efficacy	2	(8.0%)	5	(13.9%)	7	(11.5%)
Protocol deviation (including non-compliance)	1	(4.0%)	1	(2.8%)	2	(3.3%)
Lost to Follow-up	3	(12.0%)	3	(8.3%)	6	(9.8%)
Other+	3	(12.0%)	10	(27.8%)	13	(21.3%)
Total withdrawn	12	(48.0%)	25	(69.4%)	37	(60.7%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: OCD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=24)		Placebo (N=34)		Total (N=58)	
Completed Study*	8	(33.3%)	5	(14.7%)	13	(22.4%)
Adverse Experience	1	(4.2%)	8	(23.5%)	9	(15.5%)
Lack of Efficacy	1	(4.2%)	5	(14.7%)	6	(10.3%)
Protocol deviation (including non-compliance)	2	(8.3%)	2	(5.9%)	4	(6.9%)
Lost to Follow-up	2	(8.3%)	4	(11.8%)	6	(10.3%)
Other+	6	(25.0%)	3	(8.8%)	9	(15.5%)
Total withdrawn	12	(50.0%)	22	(64.7%)	34	(58.6%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=49)		Placebo (N=70)		Total (N=119)	
	Acute Study Treatment Group					
Completed Study*	21	(42.9%)	16	(22.9%)	37	(31.1%)
Adverse Experience	4	(8.2%)	14	(20.0%)	18	(15.1%)
Lack of Efficacy	3	(6.1%)	10	(14.3%)	13	(10.9%)
Protocol deviation (including non-compliance)	3	(6.1%)	3	(4.3%)	6	(5.0%)
Lost to Follow-up	5	(10.2%)	7	(10.0%)	12	(10.1%)
Other+	9	(18.4%)	13	(18.6%)	22	(18.5%)
Total withdrawn	24	(49.0%)	47	(67.1%)	71	(59.7%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: MDD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=25)		Placebo (N=30)		Total (N=55)	
Completed Study*	13	(52.0%)	13	(43.3%)	26	(47.3%)
Adverse Experience	4	(16.0%)	4	(13.3%)	8	(14.5%)
Lack of Efficacy	3	(12.0%)	6	(20.0%)	9	(16.4%)
Protocol deviation (including non-compliance)	3	(12.0%)	2	(6.7%)	5	(9.1%)
Lost to Follow-up	1	(4.0%)	4	(13.3%)	5	(9.1%)
Other+	0		1	(3.3%)	1	(1.8%)
Total withdrawn	11	(44.0%)	17	(56.7%)	28	(50.9%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: OCD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=20)		Placebo (N=27)		Total (N=47)	
Completed Study*	6	(30.0%)	4	(14.8%)	10	(21.3%)
Adverse Experience	1	(5.0%)	6	(22.2%)	7	(14.9%)
Lack of Efficacy	1	(5.0%)	3	(11.1%)	4	(8.5%)
Protocol deviation (including non-compliance)	0		2	(7.4%)	2	(4.3%)
Lost to Follow-up	2	(10.0%)	1	(3.7%)	3	(6.4%)
Other+	4	(20.0%)	3	(11.1%)	7	(14.9%)
Total withdrawn	8	(40.0%)	15	(55.6%)	23	(48.9%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: Total

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=45)		Placebo (N=57)		Total (N=102)	
Completed Study*	19	(42.2%)	17	(29.8%)	36	(35.3%)
Adverse Experience	5	(11.1%)	10	(17.5%)	15	(14.7%)
Lack of Efficacy	4	(8.9%)	9	(15.8%)	13	(12.7%)
Protocol deviation (including non-compliance)	3	(6.7%)	4	(7.0%)	7	(6.9%)
Lost to Follow-up	3	(6.7%)	5	(8.8%)	8	(7.8%)
Other+	4	(8.9%)	4	(7.0%)	8	(7.8%)
Total withdrawn	19	(42.2%)	32	(56.1%)	51	(50.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: MDD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=50)		Placebo (N=66)		Total (N=116)	
Completed Study*	26	(52.0%)	24	(36.4%)	50	(43.1%)
Adverse Experience	7	(14.0%)	10	(15.2%)	17	(14.7%)
Lack of Efficacy	5	(10.0%)	11	(16.7%)	16	(13.8%)
Protocol deviation (including non-compliance)	4	(8.0%)	3	(4.5%)	7	(6.0%)
Lost to Follow-up	4	(8.0%)	7	(10.6%)	11	(9.5%)
Other+	3	(6.0%)	11	(16.7%)	14	(12.1%)
Total withdrawn	23	(46.0%)	42	(63.6%)	65	(56.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: OCD

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=44)		Placebo (N=61)		Total (N=105)	
Completed Study*	14	(31.8%)	9	(14.8%)	23	(21.9%)
Adverse Experience	2	(4.5%)	14	(23.0%)	16	(15.2%)
Lack of Efficacy	2	(4.5%)	8	(13.1%)	10	(9.5%)
Protocol deviation (including non-compliance)	2	(4.5%)	4	(6.6%)	6	(5.7%)
Lost to Follow-up	4	(9.1%)	5	(8.2%)	9	(8.6%)
Other+	10	(22.7%)	6	(9.8%)	16	(15.2%)
Total withdrawn	20	(45.5%)	37	(60.7%)	57	(54.3%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: Total

Reason For Study Conclusion	Acute Study Treatment Group: Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
Completed Study*	40	(42.6%)	33	(26.0%)	73	(33.0%)
Adverse Experience	9	(9.6%)	24	(18.9%)	33	(14.9%)
Lack of Efficacy	7	(7.4%)	19	(15.0%)	26	(11.8%)
Protocol deviation (including non-compliance)	6	(6.4%)	7	(5.5%)	13	(5.9%)
Lost to Follow-up	8	(8.5%)	12	(9.4%)	20	(9.0%)
Other+	13	(13.8%)	17	(13.4%)	30	(13.6%)
Total withdrawn	43	(45.7%)	79	(62.2%)	122	(55.2%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
+ Includes unknown and non-study-related personal reasons
Note: 'Ongoing' patients are not included in this Table

BRL 29060 - 716
Interim Output
Table 13.3.2

Number (%) of Patients Remaining/withdrawing from the Study at Each Visit by Acute Study Treatment Group

Intention-To-Treat Population

Visit	Status	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
716 Baseline	Entered	94	(100.0%)	127	(100.0%)	221	(100.0%)
Week 1	Still in Study	91	(96.8%)	122	(96.1%)	213	(96.4%)
	Withdrawn	3	(3.2%)	5	(3.9%)	8	(3.6%)
Week 2	Still in Study	91	(96.8%)	119	(93.7%)	210	(95.0%)
	Withdrawn	0		3	(2.5%)	3	(1.4%)
Week 3	Still in Study	89	(94.7%)	114	(89.8%)	203	(91.9%)
	Ongoing	0		1	(0.8%)	1	(0.5%)
	Withdrawn	2	(2.2%)	4	(3.4%)	6	(2.9%)
Week 4	Still in Study	85	(90.4%)	106	(83.5%)	191	(86.4%)
	Ongoing	0		1	(0.8%)	1	(0.5%)
	Withdrawn	4	(4.5%)	7	(6.1%)	11	(5.4%)
Week 6	Still in Study	81	(86.2%)	91	(71.7%)	172	(77.8%)
	Withdrawn	4	(4.7%)	15	(14.2%)	19	(9.9%)
Week 8	Still in Study	66	(70.2%)	73	(57.5%)	139	(62.9%)
	Ongoing	5	(5.3%)	6	(4.7%)	11	(5.0%)
	Withdrawn	10	(12.3%)	12	(13.2%)	22	(12.8%)
Week 12	Still in Study	58	(61.7%)	62	(48.8%)	120	(54.3%)
	Withdrawn	8	(12.1%)	11	(15.1%)	19	(13.7%)
Week 16	Still in Study	44	(46.8%)	46	(36.2%)	90	(40.7%)
	Ongoing	6	(6.4%)	6	(4.7%)	12	(5.4%)
	Withdrawn	8	(13.8%)	10	(16.1%)	18	(15.0%)
Week 20	Still in Study	42	(44.7%)	34	(26.8%)	76	(34.4%)
	Ongoing	0		1	(0.8%)	1	(0.5%)
	Withdrawn	2	(4.5%)	10	(21.7%)	12	(13.3%)
	Completed	0		1	(0.8%)	1	(0.5%)

Completed = Patients who completed a week 24 visit CRF, note 1 Patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients still in study for whom the last available data occurs during that week (Patients that had a completed week 4 CRF in house by 1st October 2001 and for whom a study conclusion page was not available)
Date of withdrawal = date of last dose of study medication (excluding Taper),
Efficacy assessments up to 7 days after this date are considered evaluable.

Note: Percentages for patients still in the study, ongoing or completed at each visit are based on the total no. of patients at study 716 baseline, whilst percentages for patients withdrawing at each visit are based on the total no. of patients at each visit.

BRL 29060 - 716
Interim Output
Table 13.3.2

Number (%) of Patients Remaining/withdrawing from the Study at Each Visit by Acute Study Treatment Group

Intention-To-Treat Population

Visit	Status	Acute Study Treatment Group: Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
Week 24	Still in Study	0		1	(0.8%)	1	(0.5%)
	Withdrawn	2	(4.8%)	1	(2.9%)	3	(3.9%)
	Completed	40	(42.6%)	32	(25.2%)	72	(32.6%)
Post Week 24	Withdrawn	0		1	(100.0%)	1	(100.0%)

Completed = Patients who completed a week 24 visit CRF, note 1 Patient took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
Ongoing = Patients still in study for whom the last available data occurs during that week (Patients that had a completed week 4 CRF in house by 1st October 2001 and for whom a study conclusion page was not available)
Date of withdrawal = date of last dose of study medication (excluding Taper),
Efficacy assessments up to 7 days after this date are considered evaluable.

Note: Percentages for patients still in the study, ongoing or completed at each visit are based on the total no. of patients at study 716 baseline, whilst percentages for patients withdrawing at each visit are based on the total no. of patients at each visit.

BRL 29060 - 716
Interim Output
Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Children

	Acute Study Treatment Group																							
	Paroxetine (N = 49)								Placebo (N = 70)								Total (N = 119)							
	AE		LE		Other		Total		AE		LE		Other		Total		AE		LE		Other		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																								
Week 1	0	0.0	1	2.0	1	2.0	2	4.1	0	0.0	0	0.0	2	2.9	2	2.9	0	0.0	1	0.8	3	2.5	4	3.4
Week 2	0	0.0	1	2.0	1	2.0	2	4.1	0	0.0	0	0.0	3	4.3	3	4.3	0	0.0	1	0.8	4	3.4	5	4.2
Week 3	1	2.0	1	2.0	1	2.0	3	6.1	2	2.9	0	0.0	4	5.7	6	8.6	3	2.5	1	0.8	5	4.2	9	7.6
Week 4	1	2.0	1	2.0	3	6.1	5	10.2	5	7.1	0	0.0	5	7.1	10	14.3	6	5.0	1	0.8	8	6.7	15	12.6
Week 6	2	4.1	1	2.0	4	8.2	7	14.3	8	11.4	1	1.4	9	12.9	18	25.7	10	8.4	2	1.7	13	10.9	25	21.0
Week 8	3	6.1	2	4.1	10	20.4	15	30.6	11	15.7	3	4.3	10	14.3	24	34.3	14	11.8	5	4.2	20	16.8	39	32.8
Week 12	3	6.1	2	4.1	15	30.6	20	40.8	12	17.1	8	11.4	13	18.6	33	47.1	15	12.6	10	8.4	28	23.5	53	44.5
Week 16	4	8.2	2	4.1	15	30.6	21	42.9	12	17.1	9	12.9	17	24.3	38	54.3	16	13.4	11	9.2	32	26.9	59	49.6
Week 20	4	8.2	3	6.1	16	32.7	23	46.9	14	20.0	10	14.3	21	30.0	45	64.3	18	15.1	13	10.9	37	31.1	68	57.1
Week 24	4	8.2	3	6.1	17	34.7	24	49.0	14	20.0	10	14.3	22	31.4	46	65.7	18	15.1	13	10.9	39	32.8	70	58.8
Post Week 24	4	8.2	3	6.1	17	34.7	24	49.0	14	20.0	10	14.3	23	32.9	47	67.1	18	15.1	13	10.9	40	33.6	71	59.7

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

BRL 29060 - 716
Interim Output
Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Adolescents

	Acute Study Treatment Group																							
	Paroxetine (N = 45)								Placebo (N = 57)								Total (N = 102)							
	AE		LE		Other		Total		AE		LE		Other		Total		AE		LE		Other		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																								
Week 1	0	0.0	0	0.0	1	2.2	1	2.2	1	1.8	1	1.8	1	1.8	3	5.3	1	1.0	1	1.0	2	2.0	4	3.9
Week 2	0	0.0	0	0.0	1	2.2	1	2.2	2	3.5	2	3.5	1	1.8	5	8.8	2	2.0	2	2.0	2	2.0	6	5.9
Week 3	1	2.2	0	0.0	1	2.2	2	4.4	2	3.5	2	3.5	2	3.5	6	10.5	3	2.9	2	2.0	3	2.9	8	7.8
Week 4	1	2.2	0	0.0	3	6.7	4	8.9	3	5.3	2	3.5	4	7.0	9	15.8	4	3.9	2	2.0	7	6.9	13	12.7
Week 6	2	4.4	1	2.2	3	6.7	6	13.3	5	8.8	3	5.3	8	14.0	16	28.1	7	6.9	4	3.9	11	10.8	22	21.6
Week 8	3	6.7	2	4.4	3	6.7	8	17.8	7	12.3	5	8.8	10	17.5	22	38.6	10	9.8	7	6.9	13	12.7	30	29.4
Week 12	3	6.7	3	6.7	5	11.1	11	24.4	8	14.0	6	10.5	10	17.5	24	42.1	11	10.8	9	8.8	15	14.7	35	34.3
Week 16	5	11.1	4	8.9	9	20.0	18	40.0	8	14.0	8	14.0	13	22.8	29	50.9	13	12.7	12	11.8	22	21.6	47	46.1
Week 20	5	11.1	4	8.9	9	20.0	18	40.0	10	17.5	9	15.8	13	22.8	32	56.1	15	14.7	13	12.7	22	21.6	50	49.0
Week 24	5	11.1	4	8.9	10	22.2	19	42.2	10	17.5	9	15.8	13	22.8	32	56.1	15	14.7	13	12.7	23	22.5	51	50.0
Post Week 24	5	11.1	4	8.9	10	22.2	19	42.2	10	17.5	9	15.8	13	22.8	32	56.1	15	14.7	13	12.7	23	22.5	51	50.0

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

BRL 29060 - 716
Interim Output
Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Total

	Acute Study Treatment Group																							
	Paroxetine (N = 94)								Placebo (N = 127)								Total (N = 221)							
	AE		LE		Other		Total		AE		LE		Other		Total		AE		LE		Other		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																								
Week 1	0	0.0	1	1.1	2	2.1	3	3.2	1	0.8	1	0.8	3	2.4	5	3.9	1	0.5	2	0.9	5	2.3	8	3.6
Week 2	0	0.0	1	1.1	2	2.1	3	3.2	2	1.6	2	1.6	4	3.1	8	6.3	2	0.9	3	1.4	6	2.7	11	5.0
Week 3	2	2.1	1	1.1	2	2.1	5	5.3	4	3.1	2	1.6	6	4.7	12	9.4	6	2.7	3	1.4	8	3.6	17	7.7
Week 4	2	2.1	1	1.1	6	6.4	9	9.6	8	6.3	2	1.6	9	7.1	19	15.0	10	4.5	3	1.4	15	6.8	28	12.7
Week 6	4	4.3	2	2.1	7	7.4	13	13.8	13	10.2	4	3.1	17	13.4	34	26.8	17	7.7	6	2.7	24	10.9	47	21.3
Week 8	6	6.4	4	4.3	13	13.8	23	24.5	18	14.2	8	6.3	20	15.7	46	36.2	24	10.9	12	5.4	33	14.9	69	31.2
Week 12	6	6.4	5	5.3	20	21.3	31	33.0	20	15.7	14	11.0	23	18.1	57	44.9	26	11.8	19	8.6	43	19.5	88	39.8
Week 16	9	9.6	6	6.4	24	25.5	39	41.5	20	15.7	17	13.4	30	23.6	67	52.8	29	13.1	23	10.4	54	24.4	106	48.0
Week 20	9	9.6	7	7.4	25	26.6	41	43.6	24	18.9	19	15.0	34	26.8	77	60.6	33	14.9	26	11.8	59	26.7	118	53.4
Week 24	9	9.6	7	7.4	27	28.7	43	45.7	24	18.9	19	15.0	35	27.6	78	61.4	33	14.9	26	11.8	62	28.1	121	54.8
Post Week 24	9	9.6	7	7.4	27	28.7	43	45.7	24	18.9	19	15.0	36	28.3	79	62.2	33	14.9	26	11.8	63	28.5	122	55.2

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
004	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
010	xxxxxxxxxxxx	Entered	2 (8.0%)	2 (5.6%)	4 (6.6%)
		Completed	1 (4.0%)	0	1 (1.6%)
014	xxxxxxxxxxxxxxx	Entered	1 (4.0%)	2 (5.6%)	3 (4.9%)
		Completed	0	1 (2.8%)	1 (1.6%)
019	xxxxxxxxxxxxxxx	Entered	3 (12.0%)	2 (5.6%)	5 (8.2%)
		Completed	0	1 (2.8%)	1 (1.6%)
025	xxxxxxxxxxxxxxx	Entered	3 (12.0%)	3 (8.3%)	6 (9.8%)
		Completed	2 (8.0%)	1 (2.8%)	3 (4.9%)
026	xxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
028	xxxxxxxxxxxxx	Entered	1 (4.0%)	4 (11.1%)	5 (8.2%)
		Completed	1 (4.0%)	0	1 (1.6%)
043	xxxxxxxxxxxxxxxxxxx	Entered	2 (8.0%)	1 (2.8%)	3 (4.9%)
		Completed	1 (4.0%)	0	1 (1.6%)
044	xxxxxxxxxxxx	Entered	0	2 (5.6%)	2 (3.3%)
		Completed	0	1 (2.8%)	1 (1.6%)
148	xxxxxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.6%)
151	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
159	xxxxxxxxxxxxxxx	Entered	2 (8.0%)	0	2 (3.3%)
		Completed	1 (4.0%)	0	1 (1.6%)
164	xxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
165	xxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
167	xxxxxxxxxxxxxxx	Entered	1 (4.0%)	1 (2.8%)	2 (3.3%)
		Completed	1 (4.0%)	1 (2.8%)	2 (3.3%)
169	xxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
170	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
171	xxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
172	xxxxxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.6%)
		Completed	1 (4.0%)	0	1 (1.6%)
173	xxxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.6%)
		Completed	1 (4.0%)	0	1 (1.6%)
176	xxxxxxxxxxxxxxxx	Entered	2 (8.0%)	2 (5.6%)	4 (6.6%)
		Completed	2 (8.0%)	1 (2.8%)	3 (4.9%)
179	xxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
180	xxxxxxxxxxxxx	Entered	1 (4.0%)	1 (2.8%)	2 (3.3%)
183	xxxxxxxxxxxxx	Entered	1 (4.0%)	4 (11.1%)	5 (8.2%)
		Completed	0	1 (2.8%)	1 (1.6%)
186	xxxxxxxxxxxxx	Entered	2 (8.0%)	2 (5.6%)	4 (6.6%)
		Completed	1 (4.0%)	1 (2.8%)	2 (3.3%)
192	xxxxxxxxxxxxxxx	Entered	1 (4.0%)	1 (2.8%)	2 (3.3%)
		Completed	1 (4.0%)	0	1 (1.6%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
002	xxxxxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
004	xxxxxxxxxxxxx	Entered	3 (12.5%)	1 (2.9%)	4 (6.9%)
		Completed	2 (8.3%)	0	2 (3.4%)
005	xxxxxxxxxxxxxxxx	Entered	3 (12.5%)	2 (5.9%)	5 (8.6%)
		Completed	1 (4.2%)	1 (2.9%)	2 (3.4%)
006	xxxxxxxxx	Entered	1 (4.2%)	0	1 (1.7%)
008	xxxxxxxxxxxx	Entered	1 (4.2%)	0	1 (1.7%)
009	xxxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
012	xxxxxxxxxxxxxx	Entered	1 (4.2%)	0	1 (1.7%)
		Completed	1 (4.2%)	0	1 (1.7%)
014	xxxxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
015	xxxxxxxxxxxxxxxxx	Entered	2 (8.3%)	2 (5.9%)	4 (6.9%)
		Completed	1 (4.2%)	0	1 (1.7%)
016	xxxxxxxxxxxxxxx	Entered	2 (8.3%)	4 (11.8%)	6 (10.3%)
		Completed	2 (8.3%)	0	2 (3.4%)
019	xxxxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
020	xxxxxxxxxxxx	Entered	1 (4.2%)	4 (11.8%)	5 (8.6%)
		Completed	1 (4.2%)	0	1 (1.7%)
025	xxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (2.9%)	2 (3.4%)
026	xxxxxxxxxxxxx	Entered	1 (4.2%)	1 (2.9%)	2 (3.4%)
027	xxxxxxxxxxxxx	Entered	1 (4.2%)	2 (5.9%)	3 (5.2%)
		Completed	0	1 (2.9%)	1 (1.7%)
028	xxxxxxxxxxxx	Entered	1 (4.2%)	1 (2.9%)	2 (3.4%)
		Completed	0	1 (2.9%)	1 (1.7%)
031	xxxxxxxxxxxxx	Entered	0	2 (5.9%)	2 (3.4%)
		Completed	0	1 (2.9%)	1 (1.7%)
040	xxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (2.9%)	2 (3.4%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
044	xxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
		Completed	0	1 (2.9%)	1 (1.7%)
052	xxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
055	xxxxxxxxxxxxxxxx	Entered	2 (8.3%)	3 (8.8%)	5 (8.6%)
159	xxxxxxxxxxxxxx	Entered	0	1 (2.9%)	1 (1.7%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (2.9%)	2 (3.4%)
176	xxxxxxxxxxxxxxxx	Entered	2 (8.3%)	2 (5.9%)	4 (6.9%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
002	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
004	xxxxxxxxxxxxx	Entered	3 (6.1%)	2 (2.9%)	5 (4.2%)
		Completed	2 (4.1%)	0	2 (1.7%)
005	xxxxxxxxxxxxxxxx	Entered	3 (6.1%)	2 (2.9%)	5 (4.2%)
		Completed	1 (2.0%)	1 (1.4%)	2 (1.7%)
006	xxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
008	xxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
009	xxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
010	xxxxxxxxxxxx	Entered	2 (4.1%)	2 (2.9%)	4 (3.4%)
		Completed	1 (2.0%)	0	1 (0.8%)
012	xxxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
		Completed	1 (2.0%)	0	1 (0.8%)
014	xxxxxxxxxxxxxxx	Entered	1 (2.0%)	3 (4.3%)	4 (3.4%)
		Completed	0	1 (1.4%)	1 (0.8%)
015	xxxxxxxxxxxxxxxxx	Entered	2 (4.1%)	2 (2.9%)	4 (3.4%)
		Completed	1 (2.0%)	0	1 (0.8%)
016	xxxxxxxxxxxxxxx	Entered	2 (4.1%)	4 (5.7%)	6 (5.0%)
		Completed	2 (4.1%)	0	2 (1.7%)
019	xxxxxxxxxxxxxxx	Entered	3 (6.1%)	3 (4.3%)	6 (5.0%)
		Completed	0	1 (1.4%)	1 (0.8%)
020	xxxxxxxxxxxx	Entered	1 (2.0%)	4 (5.7%)	5 (4.2%)
		Completed	1 (2.0%)	0	1 (0.8%)
025	xxxxxxxxxxxxxxx	Entered	4 (8.2%)	4 (5.7%)	8 (6.7%)
		Completed	2 (4.1%)	1 (1.4%)	3 (2.5%)
026	xxxxxxxxxxxxxx	Entered	1 (2.0%)	2 (2.9%)	3 (2.5%)
027	xxxxxxxxxxxxx	Entered	1 (2.0%)	2 (2.9%)	3 (2.5%)
		Completed	0	1 (1.4%)	1 (0.8%)
028	xxxxxxxxxxxxx	Entered	2 (4.1%)	5 (7.1%)	7 (5.9%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
028	xxxxxxxxxxxx	Completed	1 (2.0%)	1 (1.4%)	2 (1.7%)
031	xxxxxxxxxxxx	Entered	0	2 (2.9%)	2 (1.7%)
		Completed	0	1 (1.4%)	1 (0.8%)
040	xxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.4%)	2 (1.7%)
043	xxxxxxxxxxxxxxxxxx	Entered	2 (4.1%)	1 (1.4%)	3 (2.5%)
		Completed	1 (2.0%)	0	1 (0.8%)
044	xxxxxxxxxxxx	Entered	0	3 (4.3%)	3 (2.5%)
		Completed	0	2 (2.9%)	2 (1.7%)
052	xxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
055	xxxxxxxxxxxxxxxx	Entered	2 (4.1%)	3 (4.3%)	5 (4.2%)
148	xxxxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
		Completed	0	1 (1.4%)	1 (0.8%)
159	xxxxxxxxxxxxxx	Entered	2 (4.1%)	1 (1.4%)	3 (2.5%)
		Completed	1 (2.0%)	0	1 (0.8%)
164	xxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
165	xxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
167	xxxxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.4%)	2 (1.7%)
		Completed	1 (2.0%)	1 (1.4%)	2 (1.7%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.4%)	2 (1.7%)
169	xxxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
		Completed	0	1 (1.4%)	1 (0.8%)
170	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
171	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
172	xxxxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
		Completed	1 (2.0%)	0	1 (0.8%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
173	xxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.8%)
		Completed	1 (2.0%)	0	1 (0.8%)
176	xxxxxxxxxxxxxxx	Entered	4 (8.2%)	4 (5.7%)	8 (6.7%)
		Completed	2 (4.1%)	1 (1.4%)	3 (2.5%)
179	xxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.8%)
		Completed	0	1 (1.4%)	1 (0.8%)
180	xxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.4%)	2 (1.7%)
183	xxxxxxxxxxxxxx	Entered	1 (2.0%)	4 (5.7%)	5 (4.2%)
		Completed	0	1 (1.4%)	1 (0.8%)
186	xxxxxxxxxxxxx	Entered	2 (4.1%)	2 (2.9%)	4 (3.4%)
		Completed	1 (2.0%)	1 (1.4%)	2 (1.7%)
192	xxxxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.4%)	2 (1.7%)
		Completed	1 (2.0%)	0	1 (0.8%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
005	xxxxxxxxxxxxxxx x	Entered	0	1 (3.3%)	1 (1.8%)
008	xxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.8%)
010	xxxxxxxxxxx	Entered	4 (16.0%)	2 (6.7%)	6 (10.9%)
		Completed	3 (12.0%)	2 (6.7%)	5 (9.1%)
014	xxxxxxxxxxxxxxx	Entered	0	2 (6.7%)	2 (3.6%)
019	xxxxxxxxxxxxxxxx	Entered	1 (4.0%)	2 (6.7%)	3 (5.5%)
		Completed	1 (4.0%)	0	1 (1.8%)
025	xxxxxxxxxxxxxxx	Entered	3 (12.0%)	3 (10.0%)	6 (10.9%)
		Completed	1 (4.0%)	2 (6.7%)	3 (5.5%)
028	xxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.8%)
044	xxxxxxxxxxx	Entered	2 (8.0%)	1 (3.3%)	3 (5.5%)
		Completed	1 (4.0%)	0	1 (1.8%)
151	xxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.8%)
154	xxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.8%)
159	xxxxxxxxxxxxxx	Entered	1 (4.0%)	4 (13.3%)	5 (9.1%)
		Completed	0	3 (10.0%)	3 (5.5%)
164	xxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.8%)
165	xxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.8%)
167	xxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.8%)
		Completed	0	1 (3.3%)	1 (1.8%)
168	xxxxxxxxxxxxxxxx	Entered	2 (8.0%)	1 (3.3%)	3 (5.5%)
		Completed	1 (4.0%)	1 (3.3%)	2 (3.6%)
170	xxxxxxxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.8%)
		Completed	0	1 (3.3%)	1 (1.8%)
176	xxxxxxxxxxxxxxxx	Entered	1 (4.0%)	2 (6.7%)	3 (5.5%)
		Completed	1 (4.0%)	1 (3.3%)	2 (3.6%)
180	xxxxxxxxxxxxx	Entered	1 (4.0%)	0	1 (1.8%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
183	xxxxxxxxxxxxxx	Entered	3 (12.0%)	4 (13.3%)	7 (12.7%)
		Completed	3 (12.0%)	1 (3.3%)	4 (7.3%)
186	xxxxxxxxxxxxxx	Entered	1 (4.0%)	1 (3.3%)	2 (3.6%)
		Completed	1 (4.0%)	0	1 (1.8%)
192	xxxxxxxxxxxxxxx	Entered	2 (8.0%)	3 (10.0%)	5 (9.1%)
		Completed	1 (4.0%)	1 (3.3%)	2 (3.6%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
002	xxxxxxxxxxxxxxxxx	Entered	0	1 (3.7%)	1 (2.1%)
004	xxxxxxxxxxxxx	Entered	0	1 (3.7%)	1 (2.1%)
005	xxxxxxxxxxxxxxxx	Entered	1 (5.0%)	1 (3.7%)	2 (4.3%)
006	xxxxxxxxxx	Entered	2 (10.0%)	1 (3.7%)	3 (6.4%)
		Completed	1 (5.0%)	0	1 (2.1%)
008	xxxxxxxxxxxx	Entered	1 (5.0%)	1 (3.7%)	2 (4.3%)
009	xxxxxxxxxxxxxx	Entered	1 (5.0%)	0	1 (2.1%)
010	xxxxxxxxxxxx	Entered	0	2 (7.4%)	2 (4.3%)
014	xxxxxxxxxxxxxxxx	Entered	2 (10.0%)	1 (3.7%)	3 (6.4%)
		Completed	1 (5.0%)	0	1 (2.1%)
015	xxxxxxxxxxxxxxxxx	Entered	1 (5.0%)	1 (3.7%)	2 (4.3%)
016	xxxxxxxxxxxxxxx	Entered	2 (10.0%)	1 (3.7%)	3 (6.4%)
		Completed	1 (5.0%)	0	1 (2.1%)
017	xxxxxxxxxxxxxxx	Entered	1 (5.0%)	0	1 (2.1%)
		Completed	1 (5.0%)	0	1 (2.1%)
020	xxxxxxxxxxxxx	Entered	2 (10.0%)	2 (7.4%)	4 (8.5%)
		Completed	2 (10.0%)	1 (3.7%)	3 (6.4%)
025	xxxxxxxxxxxxxxx	Entered	0	2 (7.4%)	2 (4.3%)
		Completed	0	1 (3.7%)	1 (2.1%)
028	xxxxxxxxxxxxx	Entered	0	1 (3.7%)	1 (2.1%)
		Completed	0	1 (3.7%)	1 (2.1%)
031	xxxxxxxxxxxxxx	Entered	0	1 (3.7%)	1 (2.1%)
		Completed	0	1 (3.7%)	1 (2.1%)
044	xxxxxxxxxxxxx	Entered	0	1 (3.7%)	1 (2.1%)
047	xxxxxxxxxxx	Entered	1 (5.0%)	2 (7.4%)	3 (6.4%)
049	xxxxxxxxxxxxxx	Entered	2 (10.0%)	3 (11.1%)	5 (10.6%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
055	xxxxxxxxxxxxxxxx	Entered	2 (10.0%)	2 (7.4%)	4 (8.5%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (5.0%)	1 (3.7%)	2 (4.3%)
176	xxxxxxxxxxxxxxxx	Entered	1 (5.0%)	2 (7.4%)	3 (6.4%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
002	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
004	xxxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
005	xxxxxxxxxxxxxxxx	Entered	1 (2.2%)	2 (3.5%)	3 (2.9%)
006	xxxxxxxxxx	Entered	2 (4.4%)	1 (1.8%)	3 (2.9%)
		Completed	1 (2.2%)	0	1 (1.0%)
008	xxxxxxxxxxxx	Entered	2 (4.4%)	1 (1.8%)	3 (2.9%)
009	xxxxxxxxxxxxxxx	Entered	1 (2.2%)	0	1 (1.0%)
010	xxxxxxxxxxxx	Entered	4 (8.9%)	4 (7.0%)	8 (7.8%)
		Completed	3 (6.7%)	2 (3.5%)	5 (4.9%)
014	xxxxxxxxxxxxxxx	Entered	2 (4.4%)	3 (5.3%)	5 (4.9%)
		Completed	1 (2.2%)	0	1 (1.0%)
015	xxxxxxxxxxxxxxxxx	Entered	1 (2.2%)	1 (1.8%)	2 (2.0%)
016	xxxxxxxxxxxxxxx	Entered	2 (4.4%)	1 (1.8%)	3 (2.9%)
		Completed	1 (2.2%)	0	1 (1.0%)
017	xxxxxxxxxxxxxxx	Entered	1 (2.2%)	0	1 (1.0%)
		Completed	1 (2.2%)	0	1 (1.0%)
019	xxxxxxxxxxxxxxx	Entered	1 (2.2%)	2 (3.5%)	3 (2.9%)
		Completed	1 (2.2%)	0	1 (1.0%)
020	xxxxxxxxxxxx	Entered	2 (4.4%)	2 (3.5%)	4 (3.9%)
		Completed	2 (4.4%)	1 (1.8%)	3 (2.9%)
025	xxxxxxxxxxxxxxx	Entered	3 (6.7%)	5 (8.8%)	8 (7.8%)
		Completed	1 (2.2%)	3 (5.3%)	4 (3.9%)
028	xxxxxxxxxxxx	Entered	1 (2.2%)	1 (1.8%)	2 (2.0%)
		Completed	0	1 (1.8%)	1 (1.0%)
031	xxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
		Completed	0	1 (1.8%)	1 (1.0%)
044	xxxxxxxxxxx	Entered	2 (4.4%)	2 (3.5%)	4 (3.9%)
		Completed	1 (2.2%)	0	1 (1.0%)

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Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
047	xxxxxxxxxxxxx	Entered	1 (2.2%)	2 (3.5%)	3 (2.9%)
049	xxxxxxxxxxxxxx	Entered	2 (4.4%)	3 (5.3%)	5 (4.9%)
055	xxxxxxxxxxxxxxxxx	Entered	2 (4.4%)	2 (3.5%)	4 (3.9%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
154	xxxxxxxxxxxxx	Entered	1 (2.2%)	0	1 (1.0%)
159	xxxxxxxxxxxxxxxxx	Entered	1 (2.2%)	4 (7.0%)	5 (4.9%)
		Completed	0	3 (5.3%)	3 (2.9%)
164	xxxxxxxxxxxxx	Entered	1 (2.2%)	0	1 (1.0%)
165	xxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
167	xxxxxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
		Completed	0	1 (1.8%)	1 (1.0%)
168	xxxxxxxxxxxxxxxxx	Entered	3 (6.7%)	2 (3.5%)	5 (4.9%)
		Completed	1 (2.2%)	1 (1.8%)	2 (2.0%)
170	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (1.8%)	1 (1.0%)
		Completed	0	1 (1.8%)	1 (1.0%)
176	xxxxxxxxxxxxxxx	Entered	2 (4.4%)	4 (7.0%)	6 (5.9%)
		Completed	1 (2.2%)	1 (1.8%)	2 (2.0%)
180	xxxxxxxxxxxxx	Entered	1 (2.2%)	0	1 (1.0%)
183	xxxxxxxxxxxxx	Entered	3 (6.7%)	4 (7.0%)	7 (6.9%)
		Completed	3 (6.7%)	1 (1.8%)	4 (3.9%)
186	xxxxxxxxxxxxxx	Entered	1 (2.2%)	1 (1.8%)	2 (2.0%)
		Completed	1 (2.2%)	0	1 (1.0%)
192	xxxxxxxxxxxxxxx	Entered	2 (4.4%)	3 (5.3%)	5 (4.9%)
		Completed	1 (2.2%)	1 (1.8%)	2 (2.0%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
004	xxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
005	xxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
008	xxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.9%)
010	xxxxxxxxxxxx	Entered	6 (12.0%)	4 (6.1%)	10 (8.6%)
		Completed	4 (8.0%)	2 (3.0%)	6 (5.2%)
014	xxxxxxxxxxxxxxxx	Entered	1 (2.0%)	4 (6.1%)	5 (4.3%)
		Completed	0	1 (1.5%)	1 (0.9%)
019	xxxxxxxxxxxxxxxx	Entered	4 (8.0%)	4 (6.1%)	8 (6.9%)
		Completed	1 (2.0%)	1 (1.5%)	2 (1.7%)
025	xxxxxxxxxxxxxxxx	Entered	6 (12.0%)	6 (9.1%)	12 (10.3%)
		Completed	3 (6.0%)	3 (4.5%)	6 (5.2%)
026	xxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
028	xxxxxxxxxxxxx	Entered	2 (4.0%)	4 (6.1%)	6 (5.2%)
		Completed	1 (2.0%)	0	1 (0.9%)
043	xxxxxxxxxxxxxxxxxxx	Entered	2 (4.0%)	1 (1.5%)	3 (2.6%)
		Completed	1 (2.0%)	0	1 (0.9%)
044	xxxxxxxxxxxx	Entered	2 (4.0%)	3 (4.5%)	5 (4.3%)
		Completed	1 (2.0%)	1 (1.5%)	2 (1.7%)
148	xxxxxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.9%)
151	xxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.7%)
		Completed	0	1 (1.5%)	1 (0.9%)
154	xxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.9%)
159	xxxxxxxxxxxxxxx	Entered	3 (6.0%)	4 (6.1%)	7 (6.0%)
		Completed	1 (2.0%)	3 (4.5%)	4 (3.4%)
164	xxxxxxxxxxxxx	Entered	1 (2.0%)	1 (1.5%)	2 (1.7%)
165	xxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.7%)
167	xxxxxxxxxxxxxxxx	Entered	1 (2.0%)	2 (3.0%)	3 (2.6%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
167	xxxxxxxxxxxxxxx	Completed	1 (2.0%)	2 (3.0%)	3 (2.6%)
168	xxxxxxxxxxxxxxx	Entered	2 (4.0%)	1 (1.5%)	3 (2.6%)
		Completed	1 (2.0%)	1 (1.5%)	2 (1.7%)
169	xxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
		Completed	0	1 (1.5%)	1 (0.9%)
170	xxxxxxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.7%)
		Completed	0	1 (1.5%)	1 (0.9%)
171	xxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
172	xxxxxxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.9%)
		Completed	1 (2.0%)	0	1 (0.9%)
173	xxxxxxxxxx	Entered	1 (2.0%)	0	1 (0.9%)
		Completed	1 (2.0%)	0	1 (0.9%)
176	xxxxxxxxxxxxxxx	Entered	3 (6.0%)	4 (6.1%)	7 (6.0%)
		Completed	3 (6.0%)	2 (3.0%)	5 (4.3%)
179	xxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.9%)
		Completed	0	1 (1.5%)	1 (0.9%)
180	xxxxxxxxxxxx	Entered	2 (4.0%)	1 (1.5%)	3 (2.6%)
183	xxxxxxxxxxxx	Entered	4 (8.0%)	8 (12.1%)	12 (10.3%)
		Completed	3 (6.0%)	2 (3.0%)	5 (4.3%)
186	xxxxxxxxxxxx	Entered	3 (6.0%)	3 (4.5%)	6 (5.2%)
		Completed	2 (4.0%)	1 (1.5%)	3 (2.6%)
192	xxxxxxxxxxxxxx	Entered	3 (6.0%)	4 (6.1%)	7 (6.0%)
		Completed	2 (4.0%)	1 (1.5%)	3 (2.6%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
002	xxxxxxxxxxxxxxxx	Entered	0	2 (3.3%)	2 (1.9%)
004	xxxxxxxxxxxx	Entered	3 (6.8%)	2 (3.3%)	5 (4.8%)
		Completed	2 (4.5%)	0	2 (1.9%)
005	xxxxxxxxxxxxxxx	Entered	4 (9.1%)	3 (4.9%)	7 (6.7%)
		Completed	1 (2.3%)	1 (1.6%)	2 (1.9%)
006	xxxxxxxxx	Entered	3 (6.8%)	1 (1.6%)	4 (3.8%)
		Completed	1 (2.3%)	0	1 (1.0%)
008	xxxxxxxxxx	Entered	2 (4.5%)	1 (1.6%)	3 (2.9%)
009	xxxxxxxxxxxxx	Entered	1 (2.3%)	1 (1.6%)	2 (1.9%)
010	xxxxxxxxxx	Entered	0	2 (3.3%)	2 (1.9%)
012	xxxxxxxxxxxx	Entered	1 (2.3%)	0	1 (1.0%)
		Completed	1 (2.3%)	0	1 (1.0%)
014	xxxxxxxxxxxxxx	Entered	2 (4.5%)	2 (3.3%)	4 (3.8%)
		Completed	1 (2.3%)	0	1 (1.0%)
015	xxxxxxxxxxxxxxxx	Entered	3 (6.8%)	3 (4.9%)	6 (5.7%)
		Completed	1 (2.3%)	0	1 (1.0%)
016	xxxxxxxxxxxxxx	Entered	4 (9.1%)	5 (8.2%)	9 (8.6%)
		Completed	3 (6.8%)	0	3 (2.9%)
017	xxxxxxxxxxxxxx	Entered	1 (2.3%)	0	1 (1.0%)
		Completed	1 (2.3%)	0	1 (1.0%)
019	xxxxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (1.0%)
020	xxxxxxxxxxx	Entered	3 (6.8%)	6 (9.8%)	9 (8.6%)
		Completed	3 (6.8%)	1 (1.6%)	4 (3.8%)
025	xxxxxxxxxxxxxx	Entered	1 (2.3%)	3 (4.9%)	4 (3.8%)
		Completed	0	1 (1.6%)	1 (1.0%)
026	xxxxxxxxxxxx	Entered	1 (2.3%)	1 (1.6%)	2 (1.9%)
027	xxxxxxxxxxxx	Entered	1 (2.3%)	2 (3.3%)	3 (2.9%)
		Completed	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
028	xxxxxxxxxxxx	Entered	1 (2.3%)	2 (3.3%)	3 (2.9%)
		Completed	0	2 (3.3%)	2 (1.9%)
031	xxxxxxxxxxx	Entered	0	3 (4.9%)	3 (2.9%)
		Completed	0	2 (3.3%)	2 (1.9%)
040	xxxxxxxxxxxxx	Entered	1 (2.3%)	1 (1.6%)	2 (1.9%)
044	xxxxxxxxxx	Entered	0	2 (3.3%)	2 (1.9%)
		Completed	0	1 (1.6%)	1 (1.0%)
047	xxxxxxxxx	Entered	1 (2.3%)	2 (3.3%)	3 (2.9%)
049	xxxxxxxxxxxx	Entered	2 (4.5%)	3 (4.9%)	5 (4.8%)
052	xxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (1.0%)
055	xxxxxxxxxxxxxxx	Entered	4 (9.1%)	5 (8.2%)	9 (8.6%)
159	xxxxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (1.0%)
168	xxxxxxxxxxxxxxxx	Entered	2 (4.5%)	2 (3.3%)	4 (3.8%)
176	xxxxxxxxxxxxxxxx	Entered	3 (6.8%)	4 (6.6%)	7 (6.7%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
002	xxxxxxxxxxxxxxxx	Entered	0	2 (1.6%)	2 (0.9%)
004	xxxxxxxxxxxx	Entered	3 (3.2%)	3 (2.4%)	6 (2.7%)
		Completed	2 (2.1%)	0	2 (0.9%)
005	xxxxxxxxxxxxxxxx	Entered	4 (4.3%)	4 (3.1%)	8 (3.6%)
		Completed	1 (1.1%)	1 (0.8%)	2 (0.9%)
006	xxxxxxxxx	Entered	3 (3.2%)	1 (0.8%)	4 (1.8%)
		Completed	1 (1.1%)	0	1 (0.5%)
008	xxxxxxxxxx	Entered	3 (3.2%)	1 (0.8%)	4 (1.8%)
009	xxxxxxxxxxxxx	Entered	1 (1.1%)	1 (0.8%)	2 (0.9%)
010	xxxxxxxxxxx	Entered	6 (6.4%)	6 (4.7%)	12 (5.4%)
		Completed	4 (4.3%)	2 (1.6%)	6 (2.7%)
012	xxxxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
		Completed	1 (1.1%)	0	1 (0.5%)
014	xxxxxxxxxxxxxx	Entered	3 (3.2%)	6 (4.7%)	9 (4.1%)
		Completed	1 (1.1%)	1 (0.8%)	2 (0.9%)
015	xxxxxxxxxxxxxxxx	Entered	3 (3.2%)	3 (2.4%)	6 (2.7%)
		Completed	1 (1.1%)	0	1 (0.5%)
016	xxxxxxxxxxxxxx	Entered	4 (4.3%)	5 (3.9%)	9 (4.1%)
		Completed	3 (3.2%)	0	3 (1.4%)
017	xxxxxxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
		Completed	1 (1.1%)	0	1 (0.5%)
019	xxxxxxxxxxxxxx	Entered	4 (4.3%)	5 (3.9%)	9 (4.1%)
		Completed	1 (1.1%)	1 (0.8%)	2 (0.9%)
020	xxxxxxxxxxx	Entered	3 (3.2%)	6 (4.7%)	9 (4.1%)
		Completed	3 (3.2%)	1 (0.8%)	4 (1.8%)
025	xxxxxxxxxxxxxx	Entered	7 (7.4%)	9 (7.1%)	16 (7.2%)
		Completed	3 (3.2%)	4 (3.1%)	7 (3.2%)
026	xxxxxxxxxxxx	Entered	1 (1.1%)	2 (1.6%)	3 (1.4%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
027	xxxxxxxxxxxx	Entered	1 (1.1%)	2 (1.6%)	3 (1.4%)
		Completed	0	1 (0.8%)	1 (0.5%)
028	xxxxxxxxxxx	Entered	3 (3.2%)	6 (4.7%)	9 (4.1%)
		Completed	1 (1.1%)	2 (1.6%)	3 (1.4%)
031	xxxxxxxxxxx	Entered	0	3 (2.4%)	3 (1.4%)
		Completed	0	2 (1.6%)	2 (0.9%)
040	xxxxxxxxxxxx	Entered	1 (1.1%)	1 (0.8%)	2 (0.9%)
043	xxxxxxxxxxxxxxxxx	Entered	2 (2.1%)	1 (0.8%)	3 (1.4%)
		Completed	1 (1.1%)	0	1 (0.5%)
044	xxxxxxxxxx	Entered	2 (2.1%)	5 (3.9%)	7 (3.2%)
		Completed	1 (1.1%)	2 (1.6%)	3 (1.4%)
047	xxxxxxxxx	Entered	1 (1.1%)	2 (1.6%)	3 (1.4%)
049	xxxxxxxxxxxx	Entered	2 (2.1%)	3 (2.4%)	5 (2.3%)
052	xxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.5%)
055	xxxxxxxxxxxxxx	Entered	4 (4.3%)	5 (3.9%)	9 (4.1%)
148	xxxxxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
151	xxxxxxxxxxxxx	Entered	0	2 (1.6%)	2 (0.9%)
		Completed	0	1 (0.8%)	1 (0.5%)
154	xxxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
159	xxxxxxxxxxxxx	Entered	3 (3.2%)	5 (3.9%)	8 (3.6%)
		Completed	1 (1.1%)	3 (2.4%)	4 (1.8%)
164	xxxxxxxxxxx	Entered	1 (1.1%)	1 (0.8%)	2 (0.9%)
165	xxxxxxxxxxxx	Entered	0	2 (1.6%)	2 (0.9%)
167	xxxxxxxxxxxxxx	Entered	1 (1.1%)	2 (1.6%)	3 (1.4%)
		Completed	1 (1.1%)	2 (1.6%)	3 (1.4%)
168	xxxxxxxxxxxxxx	Entered	4 (4.3%)	3 (2.4%)	7 (3.2%)
		Completed	1 (1.1%)	1 (0.8%)	2 (0.9%)

BRL 29060 - 716
Interim Output
Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
169	xxxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.5%)
		Completed	0	1 (0.8%)	1 (0.5%)
170	xxxxxxxxxxxxxxxxxxx	Entered	0	2 (1.6%)	2 (0.9%)
		Completed	0	1 (0.8%)	1 (0.5%)
171	xxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.5%)
172	xxxxxxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
		Completed	1 (1.1%)	0	1 (0.5%)
173	xxxxxxxxxx	Entered	1 (1.1%)	0	1 (0.5%)
		Completed	1 (1.1%)	0	1 (0.5%)
176	xxxxxxxxxxxxxxx	Entered	6 (6.4%)	8 (6.3%)	14 (6.3%)
		Completed	3 (3.2%)	2 (1.6%)	5 (2.3%)
179	xxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.5%)
		Completed	0	1 (0.8%)	1 (0.5%)
180	xxxxxxxxxxxxxxx	Entered	2 (2.1%)	1 (0.8%)	3 (1.4%)
183	xxxxxxxxxxxxxx	Entered	4 (4.3%)	8 (6.3%)	12 (5.4%)
		Completed	3 (3.2%)	2 (1.6%)	5 (2.3%)
186	xxxxxxxxxxxxxx	Entered	3 (3.2%)	3 (2.4%)	6 (2.7%)
		Completed	2 (2.1%)	1 (0.8%)	3 (1.4%)
192	xxxxxxxxxxxxxxx	Entered	3 (3.2%)	4 (3.1%)	7 (3.2%)
		Completed	2 (2.1%)	1 (0.8%)	3 (1.4%)

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Gender	Female	14 (56.0%)	14 (38.9%)	28 (45.9%)
	Male	11 (44.0%)	22 (61.1%)	33 (54.1%)
Race	White	19 (76.0%)	30 (83.3%)	49 (80.3%)
	Black	2 (8.0%)	4 (11.1%)	6 (9.8%)
	Oriental	0	0	0
	Other	4 (16.0%)	2 (5.6%)	6 (9.8%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Gender	Female	13 (54.2%)	12 (35.3%)	25 (43.1%)
	Male	11 (45.8%)	22 (64.7%)	33 (56.9%)
Race	White	21 (87.5%)	31 (91.2%)	52 (89.7%)
	Black	2 (8.3%)	3 (8.8%)	5 (8.6%)
	Oriental	0	0	0
	Other	1 (4.2%)	0	1 (1.7%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Gender	Female	27 (55.1%)	26 (37.1%)	53 (44.5%)
	Male	22 (44.9%)	44 (62.9%)	66 (55.5%)
Race	White	40 (81.6%)	61 (87.1%)	101 (84.9%)
	Black	4 (8.2%)	7 (10.0%)	11 (9.2%)
	Oriental	0	0	0
	Other	5 (10.2%)	2 (2.9%)	7 (5.9%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Gender	Female	9 (36.0%)	15 (50.0%)	24 (43.6%)
	Male	16 (64.0%)	15 (50.0%)	31 (56.4%)
Race	White	20 (80.0%)	24 (80.0%)	44 (80.0%)
	Black	2 (8.0%)	3 (10.0%)	5 (9.1%)
	Oriental	0	0	0
	Other	3 (12.0%)	3 (10.0%)	6 (10.9%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Gender	Female	9 (45.0%)	9 (33.3%)	18 (38.3%)
	Male	11 (55.0%)	18 (66.7%)	29 (61.7%)
Race	White	17 (85.0%)	24 (88.9%)	41 (87.2%)
	Black	1 (5.0%)	1 (3.7%)	2 (4.3%)
	Oriental	0	0	0
	Other	2 (10.0%)	2 (7.4%)	4 (8.5%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Gender	Female	18 (40.0%)	24 (42.1%)	42 (41.2%)
	Male	27 (60.0%)	33 (57.9%)	60 (58.8%)
Race	White	37 (82.2%)	48 (84.2%)	85 (83.3%)
	Black	3 (6.7%)	4 (7.0%)	7 (6.9%)
	Oriental	0	0	0
	Other	5 (11.1%)	5 (8.8%)	10 (9.8%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Gender	Female	23 (46.0%)	29 (43.9%)	52 (44.8%)
	Male	27 (54.0%)	37 (56.1%)	64 (55.2%)
Race	White	39 (78.0%)	54 (81.8%)	93 (80.2%)
	Black	4 (8.0%)	7 (10.6%)	11 (9.5%)
	Oriental	0	0	0
	Other	7 (14.0%)	5 (7.6%)	12 (10.3%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Gender	Female	22 (50.0%)	21 (34.4%)	43 (41.0%)
	Male	22 (50.0%)	40 (65.6%)	62 (59.0%)
Race	White	38 (86.4%)	55 (90.2%)	93 (88.6%)
	Black	3 (6.8%)	4 (6.6%)	7 (6.7%)
	Oriental	0	0	0
	Other	3 (6.8%)	2 (3.3%)	5 (4.8%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Gender	Female	45 (47.9%)	50 (39.4%)	95 (43.0%)
	Male	49 (52.1%)	77 (60.6%)	126 (57.0%)
Race	White	77 (81.9%)	109 (85.8%)	186 (84.2%)
	Black	7 (7.4%)	11 (8.7%)	18 (8.1%)
	Oriental	0	0	0
	Other	10 (10.6%)	7 (5.5%)	17 (7.7%)

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Age (years)	N	25	36	61
	MEAN	9.2	9.4	9.3
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.34	1.29	1.31
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	25	36	61
	MEAN	140.35	138.00	138.96
	MEDIAN	137.20	137.20	137.20
	STDDEV	12.594	10.359	11.287
	MINIMUM	120.0	119.4	119.4
	MAXIMUM	165.0	160.0	165.0
	MISSING	0	0	0
Weight (kg)	N	25	36	61
	MEAN	44.41	40.20	41.93
	MEDIAN	41.90	35.20	39.10
	STDDEV	15.064	14.807	14.934
	MINIMUM	24.9	21.8	21.8
	MAXIMUM	74.0	89.0	89.0
	MISSING	0	0	0
BMI (kg/m2)	N	25	36	61
	MEAN	22.13	20.68	21.27
	MEDIAN	21.00	18.50	19.40
	STDDEV	5.484	5.616	5.563
	MINIMUM	15.1	13.6	13.6
	MAXIMUM	31.0	34.8	34.8
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Age (years)	N	24	34	58
	MEAN	8.9	9.5	9.2
	MEDIAN	9.0	10.0	9.5
	STDDEV	1.51	1.38	1.45
	MINIMUM	6	7	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	24	34	58
	MEAN	139.30	139.66	139.51
	MEDIAN	138.25	140.90	140.45
	STDDEV	13.433	10.383	11.630
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	161.3	161.0	161.3
	MISSING	0	0	0
Weight (kg)	N	24	34	58
	MEAN	38.94	37.35	38.01
	MEDIAN	29.90	33.70	33.50
	STDDEV	17.602	14.484	15.720
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	24	34	58
	MEAN	19.24	18.74	18.95
	MEDIAN	16.60	17.25	17.10
	STDDEV	5.601	4.779	5.094
	MINIMUM	13.9	13.7	13.7
	MAXIMUM	32.8	40.1	40.1
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Age (years)	N	49	70	119
	MEAN	9.0	9.4	9.3
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.42	1.32	1.37
	MINIMUM	6	7	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	49	70	119
	MEAN	139.83	138.80	139.23
	MEDIAN	137.80	139.85	139.70
	STDDEV	12.886	10.329	11.410
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	165.0	161.0	165.0
	MISSING	0	0	0
Weight (kg)	N	49	70	119
	MEAN	41.73	38.82	40.02
	MEDIAN	38.10	34.50	35.20
	STDDEV	16.419	14.615	15.383
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	49	70	119
	MEAN	20.72	19.73	20.14
	MEDIAN	18.50	18.15	18.20
	STDDEV	5.675	5.279	5.444
	MINIMUM	13.9	13.6	13.6
	MAXIMUM	32.8	40.1	40.1
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Age (years)	N	25	30	55
	MEAN	14.0	14.3	14.2
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.50	1.86	1.70
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	25	30	55
	MEAN	165.51	164.73	165.09
	MEDIAN	165.60	165.10	165.10
	STDDEV	7.532	8.209	7.846
	MINIMUM	143.5	149.9	143.5
	MAXIMUM	180.3	180.3	180.3
	MISSING	0	0	0
Weight (kg)	N	25	30	55
	MEAN	70.86	68.15	69.38
	MEDIAN	65.00	61.50	62.00
	STDDEV	21.751	23.143	22.355
	MINIMUM	40.9	40.0	40.0
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	25	30	55
	MEAN	25.66	24.83	25.21
	MEDIAN	23.10	22.30	22.80
	STDDEV	6.965	7.118	6.996
	MINIMUM	17.4	16.9	16.9
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Age (years)	N	20	27	47
	MEAN	14.6	14.1	14.3
	MEDIAN	14.5	14.0	14.0
	STDDEV	1.47	1.59	1.54
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	20	26	46
	MEAN	166.96	167.02	166.99
	MEDIAN	167.05	167.95	167.60
	STDDEV	12.782	8.507	10.449
	MINIMUM	139.5	151.3	139.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	20	26	46
	MEAN	68.45	66.63	67.42
	MEDIAN	64.85	65.00	65.00
	STDDEV	18.094	15.551	16.535
	MINIMUM	32.5	38.2	32.5
	MAXIMUM	110.9	100.9	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	20	26	46
	MEAN	24.53	23.89	24.17
	MEDIAN	22.95	22.90	22.90
	STDDEV	6.310	5.486	5.800
	MINIMUM	16.5	16.4	16.4
	MAXIMUM	41.9	37.7	41.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Age (years)	N	45	57	102
	MEAN	14.2	14.2	14.2
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.49	1.73	1.62
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	45	56	101
	MEAN	166.15	165.79	165.95
	MEDIAN	166.00	167.60	166.40
	STDDEV	10.101	8.351	9.126
	MINIMUM	139.5	149.9	139.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	45	56	101
	MEAN	69.78	67.45	68.49
	MEDIAN	65.00	62.45	62.70
	STDDEV	20.023	19.822	19.846
	MINIMUM	32.5	38.2	32.5
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	1	1
BMI (kg/m2)	N	45	56	101
	MEAN	25.16	24.39	24.73
	MEDIAN	23.10	22.80	22.80
	STDDEV	6.632	6.373	6.468
	MINIMUM	16.5	16.4	16.4
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Age (years)	N	50	66	116
	MEAN	11.6	11.6	11.6
	MEDIAN	11.5	11.0	11.0
	STDDEV	2.82	2.94	2.88
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	50	66	116
	MEAN	152.93	150.15	151.35
	MEDIAN	156.85	150.55	153.35
	STDDEV	16.339	16.364	16.340
	MINIMUM	120.0	119.4	119.4
	MAXIMUM	180.3	180.3	180.3
	MISSING	0	0	0
Weight (kg)	N	50	66	116
	MEAN	57.63	52.91	54.94
	MEDIAN	56.35	50.20	52.30
	STDDEV	22.831	23.530	23.250
	MINIMUM	24.9	21.8	21.8
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	50	66	116
	MEAN	23.90	22.56	23.14
	MEDIAN	22.90	20.85	21.25
	STDDEV	6.455	6.628	6.559
	MINIMUM	15.1	13.6	13.6
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine	Placebo	Total
	Statistic	(N=44)	(N=61)	(N=105)
Age (years)	N	44	61	105
	MEAN	11.5	11.5	11.5
	MEDIAN	11.0	11.0	11.0
	STDDEV	3.22	2.73	2.93
	MINIMUM	6	7	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	44	60	104
	MEAN	151.87	151.51	151.66
	MEDIAN	152.70	151.65	152.40
	STDDEV	19.049	16.670	17.627
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	44	60	104
	MEAN	52.35	50.04	51.02
	MEDIAN	53.75	44.05	48.80
	STDDEV	23.048	20.831	21.718
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	110.9	104.0	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	44	60	104
	MEAN	21.65	20.97	21.26
	MEDIAN	19.80	19.65	19.80
	STDDEV	6.440	5.670	5.987
	MINIMUM	13.9	13.7	13.7
	MAXIMUM	41.9	40.1	41.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Age (years)	N	94	127	221
	MEAN	11.5	11.6	11.5
	MEDIAN	11.0	11.0	11.0
	STDDEV	3.00	2.83	2.90
	MINIMUM	6	7	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	94	126	220
	MEAN	152.43	150.80	151.50
	MEDIAN	154.95	151.20	152.40
	STDDEV	17.570	16.458	16.922
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	94	126	220
	MEAN	55.16	51.54	53.09
	MEDIAN	55.25	46.80	51.85
	STDDEV	22.963	22.244	22.574
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	1	1
BMI (kg/m2)	N	94	126	220
	MEAN	22.84	21.80	22.25
	MEDIAN	21.50	20.05	20.75
	STDDEV	6.512	6.218	6.351
	MINIMUM	13.9	13.6	13.6
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

BRL 29060 - 716
Interim Output
Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
716 Baseline	N	22	36	58
	MEAN	37.8	35.3	36.2
	MEDIAN	34.5	34.0	34.5
	STDDEV	15.12	12.92	13.72
	MINIMUM	18	17	17
	MAXIMUM	75	68	75
	MISSING	3	0	3

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Adolescents

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
716 Baseline	N	24	29	53
	MEAN	35.8	39.9	38.1
	MEDIAN	33.0	35.0	34.0
	STDDEV	11.55	14.92	13.54
	MINIMUM	20	19	19
	MAXIMUM	58	73	73
	MISSING	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
716 Baseline	N	46	65	111
	MEAN	36.7	37.4	37.1
	MEDIAN	34.0	35.0	34.0
	STDDEV	13.26	13.93	13.60
	MINIMUM	18	17	17
	MAXIMUM	75	73	75
	MISSING	4	1	5

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
716 Baseline	N	23	33	56
	MEAN	15.0	19.0	17.3
	MEDIAN	16.0	21.0	20.0
	STDDEV	9.65	8.38	9.06
	MINIMUM	0	0	0
	MAXIMUM	35	34	35
	MISSING	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Adolescents

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
716 Baseline	N	19	27	46
	MEAN	18.4	20.9	19.9
	MEDIAN	16.0	22.0	20.5
	STDDEV	7.65	6.50	7.03
	MINIMUM	8	0	0
	MAXIMUM	34	35	35
	MISSING	1	0	1

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
716 Baseline	N	42	60	102
	MEAN	16.5	19.9	18.5
	MEDIAN	16.0	21.0	20.0
	STDDEV	8.86	7.59	8.27
	MINIMUM	0	0	0
	MAXIMUM	35	35	35
	MISSING	2	1	3

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Children

	Primary Diagnosis											
	Major Depressive Disorder						Obsessive-Compulsive Disorder					
	Acute Study Treatment Group						Acute Study Treatment Group					
	Paroxetine (N = 25)		Placebo (N = 36)		Total (N = 61)		Paroxetine (N = 24)		Placebo (N = 34)		Total (N = 58)	
	n	%	n	%	n	%	n	%	n	%	n	%
Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.
Normal, not at all ill (1)	4	16.0	5	13.9	9	14.8	3	12.5	2	5.9	5	8.6
Borderline mentally ill (2)	4	16.0	7	19.4	11	18.0	5	20.8	1	2.9	6	10.3
Mildly ill (3)	7	28.0	5	13.9	12	19.7	3	12.5	7	20.6	10	17.2
Moderately ill (4)	6	24.0	17	47.2	23	37.7	10	41.7	13	38.2	23	39.7
Markedly ill (5)	2	8.0	2	5.6	4	6.6	3	12.5	7	20.6	10	17.2
Severely ill (6)	1	4.0	0	.	1	1.6	0	.	3	8.8	3	5.2
Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.

BRL 29060 - 716
Interim Output
Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Adolescents

	Primary Diagnosis											
	Major Depressive Disorder						Obsessive-Compulsive Disorder					
	Acute Study Treatment Group						Acute Study Treatment Group					
	Paroxetine (N = 25)		Placebo (N = 30)		Total (N = 55)		Paroxetine (N = 20)		Placebo (N = 27)		Total (N = 47)	
	n	%	n	%	n	%	n	%	n	%	n	%
Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.
Normal, not at all ill (1)	3	12.0	5	16.7	8	14.5	0	.	1	3.7	1	2.1
Borderline mentally ill (2)	3	12.0	7	23.3	10	18.2	1	5.0	0	.	1	2.1
Mildly ill (3)	12	48.0	6	20.0	18	32.7	6	30.0	3	11.1	9	19.1
Moderately ill (4)	6	24.0	11	36.7	17	30.9	9	45.0	16	59.3	25	53.2
Markedly ill (5)	1	4.0	1	3.3	2	3.6	4	20.0	6	22.2	10	21.3
Severely ill (6)	0	.	0	.	0	.	0	.	1	3.7	1	2.1
Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.

BRL 29060 - 716
Interim Output
Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Total

	Primary Diagnosis											
	Major Depressive Disorder						Obsessive-Compulsive Disorder					
	Acute Study Treatment Group						Acute Study Treatment Group					
	Paroxetine (N = 50)		Placebo (N = 66)		Total (N = 116)		Paroxetine (N = 44)		Placebo (N = 61)		Total (N = 105)	
	n	%	n	%	n	%	n	%	n	%	n	%
Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.
Normal, not at all ill (1)	7	14.0	10	15.2	17	14.7	3	6.8	3	4.9	6	5.7
Borderline mentally ill (2)	7	14.0	14	21.2	21	18.1	6	13.6	1	1.6	7	6.7
Mildly ill (3)	19	38.0	11	16.7	30	25.9	9	20.5	10	16.4	19	18.1
Moderately ill (4)	12	24.0	28	42.4	40	34.5	19	43.2	29	47.5	48	45.7
Markedly ill (5)	3	6.0	3	4.5	6	5.2	7	15.9	13	21.3	20	19.0
Severely ill (6)	1	2.0	0	.	1	0.9	0	.	4	6.6	4	3.8
Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.

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Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Total number of patients with at least one concomitant medication	Total	61 (64.9%)	81 (63.8%)	142 (64.3%)
	Total	0	1 (0.8%)	1 (0.5%)
		0	1 (0.8%)	1 (0.5%)
ALIMENTARY TRACT/METAB	Total	18 (19.1%)	28 (22.0%)	46 (20.8%)
	ACETYLSALICYLIC ACID	1 (1.1%)	3 (2.4%)	4 (1.8%)
	ALOES	2 (2.1%)	0	2 (0.9%)
	ALUMINIUM HYDROXIDE	1 (1.1%)	4 (3.1%)	5 (2.3%)
	ANTACID NOS	0	1 (0.8%)	1 (0.5%)
	ASCORBIC ACID	2 (2.1%)	0	2 (0.9%)
	ATROPINE SULFATE	1 (1.1%)	0	1 (0.5%)
	BISMUTH SUBSALICYLATE	3 (3.2%)	5 (3.9%)	8 (3.6%)
	CALCIUM CARBONATE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIMETICONE, ACTIVATED	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DIPHENOXYLATE HYDROCHLORIDE	1 (1.1%)	0	1 (0.5%)
	FAMOTIDINE	0	3 (2.4%)	3 (1.4%)
	FERROUS FUMARATE	1 (1.1%)	0	1 (0.5%)
	FLUORIDE NOS	0	1 (0.8%)	1 (0.5%)
	KAOLIN	0	1 (0.8%)	1 (0.5%)
	LOPERAMIDE HYDROCHLORIDE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MAGNESIUM HYDROXIDE	1 (1.1%)	4 (3.1%)	5 (2.3%)
	METOCLOPRAMIDE	1 (1.1%)	0	1 (0.5%)
	METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	MINERALS NOS	1 (1.1%)	0	1 (0.5%)
	NIZATIDINE	0	1 (0.8%)	1 (0.5%)
	OMEPRAZOLE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ONDANSETRON HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	OXYBUTYNIN	1 (1.1%)	0	1 (0.5%)
	PECTIN	0	1 (0.8%)	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	0	2 (1.6%)	2 (0.9%)
	RANITIDINE	0	1 (0.8%)	1 (0.5%)
	SENNA	1 (1.1%)	0	1 (0.5%)
	SENNA FRUIT	0	1 (0.8%)	1 (0.5%)
	SODIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
	TRIMETHOBENZAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	VITAMINS NOS	8 (8.5%)	6 (4.7%)	14 (6.3%)
	YELLOW PHENOLPHTHALEIN	1 (1.1%)	0	1 (0.5%)
	ZINC GLUCONATE	0	1 (0.8%)	1 (0.5%)
ANTIINFECTIVES,SYSTEMIC	Total	22 (23.4%)	26 (20.5%)	48 (21.7%)
	AMOXICILLIN	3 (3.2%)	2 (1.6%)	5 (2.3%)

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Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
ANTIINFECTIVES,SYSTEMIC	AMOXICILLIN TRIHYDRATE	3 (3.2%)	3 (2.4%)	6 (2.7%)
	AMPICILLIN	1 (1.1%)	0	1 (0.5%)
	ANTIBIOTIC NOS	2 (2.1%)	0	2 (0.9%)
	AZITHROMYCIN	4 (4.3%)	7 (5.5%)	11 (5.0%)
	BENZATHINE BENZYLPENICILLIN	0	1 (0.8%)	1 (0.5%)
	CEFALEXIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CEFALEXIN MONOHYDRATE	1 (1.1%)	0	1 (0.5%)
	CEFAZOLIN	0	1 (0.8%)	1 (0.5%)
	CEFIXIME	1 (1.1%)	0	1 (0.5%)
	CEFPROZIL MONOHYDRATE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CEFTRIAXONE SODIUM	0	1 (0.8%)	1 (0.5%)
	CEFUROXIME AXETIL	1 (1.1%)	3 (2.4%)	4 (1.8%)
	CEFUROXIME SODIUM	1 (1.1%)	0	1 (0.5%)
	CLARITHROMYCIN	0	1 (0.8%)	1 (0.5%)
	CLAVULANIC ACID	3 (3.2%)	1 (0.8%)	4 (1.8%)
	CLINDAMYCIN	2 (2.1%)	0	2 (0.9%)
	CLINDAMYCIN HYDROCHLORIDE	2 (2.1%)	0	2 (0.9%)
	DIRITHROMYCIN	1 (1.1%)	0	1 (0.5%)
	DOXYCYCLINE	1 (1.1%)	0	1 (0.5%)
	ERYTHROMYCIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
	FLUCONAZOLE	0	1 (0.8%)	1 (0.5%)
	HEPATITIS B VACCINE	0	1 (0.8%)	1 (0.5%)
	INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.8%)	1 (0.5%)
	MINOCYCLINE	0	1 (0.8%)	1 (0.5%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	OFLOXACIN	0	1 (0.8%)	1 (0.5%)
	OXYTETRACYCLINE	1 (1.1%)	0	1 (0.5%)
	PENICILLIN NOS	0	2 (1.6%)	2 (0.9%)
	SULFAMETHOXAZOLE	1 (1.1%)	0	1 (0.5%)
	TETANUS TOXOID	0	1 (0.8%)	1 (0.5%)
	TETRACYCLINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TRIMETHOPRIM	1 (1.1%)	0	1 (0.5%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.1%)	0	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.1%)	0	1 (0.5%)
BLOOD/BLOOD FORM ORGANS	Total	0	4 (3.1%)	4 (1.8%)
	ACETYLSALICYLIC ACID	0	3 (2.4%)	3 (1.4%)
	SODIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
CARDIOVASCULAR	Total	1 (1.1%)	6 (4.7%)	7 (3.2%)
	BENZOCAINE	0	2 (1.6%)	2 (0.9%)
	CLONIDINE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	LIDOCAINE	0	1 (0.8%)	1 (0.5%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.8%)	1 (0.5%)

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Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
CENTRAL NERVOUS SYSTEM	Total	39 (41.5%)	57 (44.9%)	96 (43.4%)
	ACETYLSALICYLIC ACID	4 (4.3%)	4 (3.1%)	8 (3.6%)
	ALPRAZOLAM	0	1 (0.8%)	1 (0.5%)
	ALUMINIUM HYDROXIDE	1 (1.1%)	0	1 (0.5%)
	AMPHETAMINE ASPARTATE	0	1 (0.8%)	1 (0.5%)
	AMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.5%)
	BUTALBITAL	0	1 (0.8%)	1 (0.5%)
	CAFFEINE	4 (4.3%)	2 (1.6%)	6 (2.7%)
	CHLORPHENAMINE MALEATE	2 (2.1%)	3 (2.4%)	5 (2.3%)
	CINNAMEDRINE HYDROCHLORIDE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CITALOPRAM	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CLONIDINE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	CODEINE	1 (1.1%)	0	1 (0.5%)
	CODEINE PHOSPHATE	2 (2.1%)	3 (2.4%)	5 (2.3%)
	DEXTROAMPHETAMINE SACCHARATE	0	1 (0.8%)	1 (0.5%)
	DEXTROAMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.5%)
	DEXTROMETHORPHAN	1 (1.1%)	0	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	4 (4.3%)	2 (1.6%)	6 (2.7%)
	DEXTROPROPOXYPHENE	0	1 (0.8%)	1 (0.5%)
	DICHLORALPHENAZONE	0	1 (0.8%)	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	DOXYLAMINE	1 (1.1%)	0	1 (0.5%)
	DOXYLAMINE SUCCINATE	3 (3.2%)	1 (0.8%)	4 (1.8%)
	FENTANYL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HYDROCODONE BITARTRATE	1 (1.1%)	0	1 (0.5%)
	HYDROXYZINE	0	1 (0.8%)	1 (0.5%)
	HYDROXYZINE HYDROCHLORIDE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	IBUPROFEN	19 (20.2%)	26 (20.5%)	45 (20.4%)
	ISOMETHEPTENE	0	1 (0.8%)	1 (0.5%)
	LIDOCAINE	0	1 (0.8%)	1 (0.5%)
	MAGNESIUM HYDROXIDE	1 (1.1%)	0	1 (0.5%)
	METHYLPHENIDATE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	MIDAZOLAM HYDROCHLORIDE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	MIRTAZAPINE	0	1 (0.8%)	1 (0.5%)
	MORPHINE	0	1 (0.8%)	1 (0.5%)
	MORPHINE SULFATE	1 (1.1%)	0	1 (0.5%)
	NITROUS OXIDE	0	2 (1.6%)	2 (0.9%)
	PARACETAMOL	30 (31.9%)	25 (19.7%)	55 (24.9%)
	PAROXETINE	3 (3.2%)	8 (6.3%)	11 (5.0%)
	PETHIDINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	PHENIRAMINE MALEATE	0	1 (0.8%)	1 (0.5%)
	PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	PROCAINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	PROCHLORPERAZINE	1 (1.1%)	0	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	0	3 (2.4%)	3 (1.4%)
	PROPOFOL	1 (1.1%)	2 (1.6%)	3 (1.4%)

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Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
CENTRAL NERVOUS SYSTEM	PSEUDOEPHEDRINE	1 (1.1%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	5 (5.3%)	5 (3.9%)	10 (4.5%)
	QUETIAPINE	0	1 (0.8%)	1 (0.5%)
	RISPERIDONE	0	4 (3.1%)	4 (1.8%)
	VENLAFAXINE	0	1 (0.8%)	1 (0.5%)
DERMATOLOGICALS	Total	15 (16.0%)	31 (24.4%)	46 (20.8%)
	ALOES	2 (2.1%)	0	2 (0.9%)
	BACITRACIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	BENTONITE	0	1 (0.8%)	1 (0.5%)
	BENZOCAINE	0	2 (1.6%)	2 (0.9%)
	BENZOYL PEROXIDE	1 (1.1%)	0	1 (0.5%)
	BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.5%)
	BUDESONIDE	1 (1.1%)	5 (3.9%)	6 (2.7%)
	CALAMINE	0	1 (0.8%)	1 (0.5%)
	CHLOROXYLENOL	0	1 (0.8%)	1 (0.5%)
	DIPHENHYDRAMINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIPHENHYDRAMINE HYDROCHLORIDE	7 (7.4%)	11 (8.7%)	18 (8.1%)
	ERYTHROMYCIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
	FLUTICASONE PROPIONATE	1 (1.1%)	4 (3.1%)	5 (2.3%)
	GLYCEROL	0	1 (0.8%)	1 (0.5%)
	HYDROCORTISONE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	ISOTRETINOIN	1 (1.1%)	0	1 (0.5%)
	LIDOCAINE	0	1 (0.8%)	1 (0.5%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.5%)
	MINERAL WAX	0	1 (0.8%)	1 (0.5%)
	MOMETASONE FUROATE	0	3 (2.4%)	3 (1.4%)
	NEOMYCIN SULFATE	1 (1.1%)	0	1 (0.5%)
	OXYTETRACYCLINE	1 (1.1%)	0	1 (0.5%)
	PARAFFIN, LIQUID	0	1 (0.8%)	1 (0.5%)
	PARAFFIN, SOFT	0	1 (0.8%)	1 (0.5%)
	PERMETHRIN	1 (1.1%)	0	1 (0.5%)
	PHENOL, LIQUEFIED	0	1 (0.8%)	1 (0.5%)
	POLYMYXIN B SULFATE	1 (1.1%)	0	1 (0.5%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.8%)	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	0	2 (1.6%)	2 (0.9%)
	SALICYLIC ACID	1 (1.1%)	0	1 (0.5%)
	SODIUM CITRATE	0	1 (0.8%)	1 (0.5%)
	SULFADIAZINE SILVER	1 (1.1%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
	WOOL WAX ALCOHOL	0	1 (0.8%)	1 (0.5%)
	ZINC GLUCONATE	0	1 (0.8%)	1 (0.5%)
	ZINC OXIDE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
GU SYSTEM/SEX HORMONES	Total	5 (5.3%)	4 (3.1%)	9 (4.1%)
	ANTIBIOTIC NOS	2 (2.1%)	0	2 (0.9%)
	BACITRACIN	0	1 (0.8%)	1 (0.5%)
	ETHINYLESTRADIOL	0	1 (0.8%)	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.1%)	0	1 (0.5%)
	NITROFURANTOIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	NORGESTIMATE	0	1 (0.8%)	1 (0.5%)
	OFLOXACIN	0	1 (0.8%)	1 (0.5%)
	OXYBUTYNIN	1 (1.1%)	0	1 (0.5%)
	OXYTETRACYCLINE	1 (1.1%)	0	1 (0.5%)
	TOLTERODINE TARTRATE	1 (1.1%)	0	1 (0.5%)
MUSCULO-SKELETAL	Total	23 (24.5%)	28 (22.0%)	51 (23.1%)
	CARISOPRODOL	1 (1.1%)	0	1 (0.5%)
	IBUPROFEN	19 (20.2%)	26 (20.5%)	45 (20.4%)
	MENTHOL	0	1 (0.8%)	1 (0.5%)
	METHOCARBAMOL	1 (1.1%)	0	1 (0.5%)
	NAPROXEN	1 (1.1%)	0	1 (0.5%)
	NAPROXEN SODIUM	4 (4.3%)	1 (0.8%)	5 (2.3%)
	ROFECOXIB	1 (1.1%)	0	1 (0.5%)
	SALICYLIC ACID	1 (1.1%)	0	1 (0.5%)
PARASITOLOGY	Total	1 (1.1%)	0	1 (0.5%)
	PERMETHRIN	1 (1.1%)	0	1 (0.5%)
RESPIRATORY	Total	34 (36.2%)	53 (41.7%)	87 (39.4%)
	AMINOACETIC ACID	0	1 (0.8%)	1 (0.5%)
	ANTIHISTAMINE, NOS	1 (1.1%)	0	1 (0.5%)
	BENZALKONIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
	BENZOCAINE	0	2 (1.6%)	2 (0.9%)
	BENZONATATE	0	1 (0.8%)	1 (0.5%)
	BROMPHENIRAMINE MALEATE	2 (2.1%)	2 (1.6%)	4 (1.8%)
	BUDESONIDE	1 (1.1%)	5 (3.9%)	6 (2.7%)
	CAMPHOR	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CETIRIZINE HYDROCHLORIDE	3 (3.2%)	5 (3.9%)	8 (3.6%)
	CHLORPHENAMINE MALEATE	4 (4.3%)	4 (3.1%)	8 (3.6%)
	CHLORPHENAMINE TANNATE	0	1 (0.8%)	1 (0.5%)
	CLEMASTINE FUMARATE	1 (1.1%)	0	1 (0.5%)
	CODEINE	1 (1.1%)	0	1 (0.5%)
	COUGH COLD PREPARATIONS NOS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	COUGH SYRUP/MED	0	2 (1.6%)	2 (0.9%)
	DEXTROMETHORPHAN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEXTROMETHORPHAN HYDROBROMIDE	7 (7.4%)	5 (3.9%)	12 (5.4%)
	DIMENHYDRINATE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DIPHENHYDRAMINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIPHENHYDRAMINE HYDROCHLORIDE	8 (8.5%)	13 (10.2%)	21 (9.5%)

BRL 29060 - 716
Interim Output
Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
RESPIRATORY	DOXYLAMINE	1 (1.1%)	0	1 (0.5%)
	DOXYLAMINE SUCCINATE	3 (3.2%)	1 (0.8%)	4 (1.8%)
	ECHINACEA EXTRACT	0	1 (0.8%)	1 (0.5%)
	ETHANOL	0	1 (0.8%)	1 (0.5%)
	EUCALYPTUS OIL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FEXOFENADINE HYDROCHLORIDE	4 (4.3%)	1 (0.8%)	5 (2.3%)
	FLUTICASONE PROPIONATE	1 (1.1%)	4 (3.1%)	5 (2.3%)
	GARLIC	0	1 (0.8%)	1 (0.5%)
	GUAIFENESIN	4 (4.3%)	6 (4.7%)	10 (4.5%)
	HYDROCODONE BITARTRATE	1 (1.1%)	0	1 (0.5%)
	LIDOCAINE	0	1 (0.8%)	1 (0.5%)
	LORATADINE	10 (10.6%)	10 (7.9%)	20 (9.0%)
	MENTHOL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	MEPYRAMINE MALEATE	2 (2.1%)	0	2 (0.9%)
	MEPYRAMINE TANNATE	0	1 (0.8%)	1 (0.5%)
	MOMETASONE FUROATE	0	3 (2.4%)	3 (1.4%)
	MONTELUKAST SODIUM	1 (1.1%)	3 (2.4%)	4 (1.8%)
	OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	PARACETAMOL	10 (10.6%)	8 (6.3%)	18 (8.1%)
	PHENIRAMINE MALEATE	2 (2.1%)	1 (0.8%)	3 (1.4%)
	PHENYLEPHRINE HYDROCHLORIDE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	PHENYLEPHRINE TANNATE	0	1 (0.8%)	1 (0.5%)
	PHENYLMERCURIC ACETATE	0	1 (0.8%)	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	5 (5.3%)	2 (1.6%)	7 (3.2%)
	PIRBUTEROL ACETATE	0	1 (0.8%)	1 (0.5%)
	PREDNISONE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	PSEUDOEPHEDRINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	14 (14.9%)	10 (7.9%)	24 (10.9%)
	PSEUDOEPHEDRINE SULFATE	2 (2.1%)	0	2 (0.9%)
	SALBUTAMOL	4 (4.3%)	7 (5.5%)	11 (5.0%)
	SALMETEROL HYDROXYNAPHTHOATE	0	2 (1.6%)	2 (0.9%)
	SODIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
	SORBITOL	0	1 (0.8%)	1 (0.5%)
	TERBUTALINE SULFATE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
	TRIPROLIDINE HYDROCHLORIDE	1 (1.1%)	0	1 (0.5%)
	TURPENTINE OIL	1 (1.1%)	1 (0.8%)	2 (0.9%)
SENSORY ORGANS	Total	8 (8.5%)	14 (11.0%)	22 (10.0%)
	ANTAZOLINE PHOSPHATE	0	1 (0.8%)	1 (0.5%)
	BACITRACIN	0	1 (0.8%)	1 (0.5%)
	BROMPHENIRAMINE MALEATE	1 (1.1%)	0	1 (0.5%)
	DEXAMETHASONE	1 (1.1%)	0	1 (0.5%)
	DEXTRAN	1 (1.1%)	0	1 (0.5%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
SENSORY ORGANS	ERYTHROMYCIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
	GRAMICIDIN	0	1 (0.8%)	1 (0.5%)
	HYDROCORTISONE	2 (2.1%)	4 (3.1%)	6 (2.7%)
	HYPROMELLOSE	1 (1.1%)	0	1 (0.5%)
	LIDOCAINE	0	1 (0.8%)	1 (0.5%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.5%)
	NAPHAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
	NEOMYCIN SULFATE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	OFLOXACIN	0	1 (0.8%)	1 (0.5%)
	OXYTETRACYCLINE	1 (1.1%)	0	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (1.1%)	0	1 (0.5%)
	POLYMYXIN B SULFATE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.8%)	1 (0.5%)
	SODIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
	TETRACYCLINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
SYSTEMIC HORMONAL	Total	4 (4.3%)	8 (6.3%)	12 (5.4%)
	DESMOPRESSIN	0	1 (0.8%)	1 (0.5%)
	DEXAMETHASONE	1 (1.1%)	0	1 (0.5%)
	HYDROCORTISONE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	LEVOTHYROXINE SODIUM	1 (1.1%)	0	1 (0.5%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.5%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.8%)	1 (0.5%)
	PREDNISONE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
UNCLASSIFIABLE	Total	0	1 (0.8%)	1 (0.5%)
	UNKNOWN MEDICATION	0	1 (0.8%)	1 (0.5%)
VARIOUS	Total	1 (1.1%)	0	1 (0.5%)
	PROTEINS NOS	1 (1.1%)	0	1 (0.5%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Total number of patients with at least one concomitant medication	61 (64.9%)	81 (63.8%)	142 (64.3%)
PARACETAMOL	31 (33.0%)	25 (19.7%)	56 (25.3%)
IBUPROFEN	19 (20.2%)	26 (20.5%)	45 (20.4%)
PSEUDOEPHEDRINE HYDROCHLORIDE	14 (14.9%)	10 (7.9%)	24 (10.9%)
LORATADINE	10 (10.6%)	10 (7.9%)	20 (9.0%)
DIPHENHYDRAMINE HYDROCHLORIDE	8 (8.5%)	13 (10.2%)	21 (9.5%)
VITAMINS NOS	8 (8.5%)	6 (4.7%)	14 (6.3%)
DEXTROMETHORPHAN HYDROBROMIDE	7 (7.4%)	5 (3.9%)	12 (5.4%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	5 (5.3%)	2 (1.6%)	7 (3.2%)
AZITHROMYCIN	4 (4.3%)	7 (5.5%)	11 (5.0%)
SALBUTAMOL	4 (4.3%)	7 (5.5%)	11 (5.0%)
GUAIFENESIN	4 (4.3%)	6 (4.7%)	10 (4.5%)
ACETYLSALICYLIC ACID	4 (4.3%)	4 (3.1%)	8 (3.6%)
CHLORPHENAMINE MALEATE	4 (4.3%)	4 (3.1%)	8 (3.6%)
CAFFEINE	4 (4.3%)	2 (1.6%)	6 (2.7%)
FEXOFENADINE HYDROCHLORIDE	4 (4.3%)	1 (0.8%)	5 (2.3%)
NAPROXEN SODIUM	4 (4.3%)	1 (0.8%)	5 (2.3%)
PAROXETINE	3 (3.2%)	8 (6.3%)	11 (5.0%)
BISMUTH SUBSALICYLATE	3 (3.2%)	5 (3.9%)	8 (3.6%)
CETIRIZINE HYDROCHLORIDE	3 (3.2%)	5 (3.9%)	8 (3.6%)
AMOXICILLIN TRIHYDRATE	3 (3.2%)	3 (2.4%)	6 (2.7%)
AMOXICILLIN	3 (3.2%)	2 (1.6%)	5 (2.3%)
CLAVULANIC ACID	3 (3.2%)	1 (0.8%)	4 (1.8%)
DOXYLAMINE SUCCINATE	3 (3.2%)	1 (0.8%)	4 (1.8%)
HYDROCORTISONE	2 (2.1%)	4 (3.1%)	6 (2.7%)
CODEINE PHOSPHATE	2 (2.1%)	3 (2.4%)	5 (2.3%)
BROMPHENIRAMINE MALEATE	2 (2.1%)	2 (1.6%)	4 (1.8%)
POLYMYXIN B SULFATE	2 (2.1%)	2 (1.6%)	4 (1.8%)
NEOMYCIN SULFATE	2 (2.1%)	1 (0.8%)	3 (1.4%)
PHENIRAMINE MALEATE	2 (2.1%)	1 (0.8%)	3 (1.4%)
ALOES	2 (2.1%)	0	2 (0.9%)
ANTIBIOTIC NOS	2 (2.1%)	0	2 (0.9%)
ASCORBIC ACID	2 (2.1%)	0	2 (0.9%)
CLINDAMYCIN	2 (2.1%)	0	2 (0.9%)
CLINDAMYCIN HYDROCHLORIDE	2 (2.1%)	0	2 (0.9%)
CODEINE	2 (2.1%)	0	2 (0.9%)
MEPYRAMINE MALEATE	2 (2.1%)	0	2 (0.9%)
PSEUDOEPHEDRINE SULFATE	2 (2.1%)	0	2 (0.9%)
BUDESONIDE	1 (1.1%)	5 (3.9%)	6 (2.7%)
ALUMINIUM HYDROXIDE	1 (1.1%)	4 (3.1%)	5 (2.3%)
FLUTICASONE PROPIONATE	1 (1.1%)	4 (3.1%)	5 (2.3%)
MAGNESIUM HYDROXIDE	1 (1.1%)	4 (3.1%)	5 (2.3%)
CEFUROXIME AXETIL	1 (1.1%)	3 (2.4%)	4 (1.8%)
MONTELUKAST SODIUM	1 (1.1%)	3 (2.4%)	4 (1.8%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
PHENYLEPHRINE HYDROCHLORIDE	1 (1.1%)	3 (2.4%)	4 (1.8%)
PROMETHAZINE HYDROCHLORIDE	1 (1.1%)	3 (2.4%)	4 (1.8%)
CLONIDINE	1 (1.1%)	2 (1.6%)	3 (1.4%)
DIMENHYDRINATE	1 (1.1%)	2 (1.6%)	3 (1.4%)
DIMETICONE, ACTIVATED	1 (1.1%)	2 (1.6%)	3 (1.4%)
ERYTHROMYCIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
FENTANYL	1 (1.1%)	2 (1.6%)	3 (1.4%)
HYDROXYZINE HYDROCHLORIDE	1 (1.1%)	2 (1.6%)	3 (1.4%)
MENTHOL	1 (1.1%)	2 (1.6%)	3 (1.4%)
MIDAZOLAM HYDROCHLORIDE	1 (1.1%)	2 (1.6%)	3 (1.4%)
PREDNISONE	1 (1.1%)	2 (1.6%)	3 (1.4%)
PROPOFOL	1 (1.1%)	2 (1.6%)	3 (1.4%)
BACITRACIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
CALCIUM CARBONATE	1 (1.1%)	1 (0.8%)	2 (0.9%)
CAMPHOR	1 (1.1%)	1 (0.8%)	2 (0.9%)
CEFALEXIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
CEFPROZIL MONOHYDRATE	1 (1.1%)	1 (0.8%)	2 (0.9%)
CINNAMEDRINE HYDROCHLORIDE	1 (1.1%)	1 (0.8%)	2 (0.9%)
CITALOPRAM	1 (1.1%)	1 (0.8%)	2 (0.9%)
COUGH COLD PREPARATIONS NOS	1 (1.1%)	1 (0.8%)	2 (0.9%)
DEXTROMETHORPHAN	1 (1.1%)	1 (0.8%)	2 (0.9%)
DIPHENHYDRAMINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
EUCALYPTUS OIL	1 (1.1%)	1 (0.8%)	2 (0.9%)
LOPERAMIDE HYDROCHLORIDE	1 (1.1%)	1 (0.8%)	2 (0.9%)
NITROFURANTOIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
OMEPRAZOLE	1 (1.1%)	1 (0.8%)	2 (0.9%)
PSEUDOEPHEDRINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
TETRACYCLINE	1 (1.1%)	1 (0.8%)	2 (0.9%)
TURPENTINE OIL	1 (1.1%)	1 (0.8%)	2 (0.9%)
AMPICILLIN	1 (1.1%)	0	1 (0.5%)
ANTIHISTAMINE, NOS	1 (1.1%)	0	1 (0.5%)
ATROPINE SULFATE	1 (1.1%)	0	1 (0.5%)
BENZOYL PEROXIDE	1 (1.1%)	0	1 (0.5%)
CARISOPRODOL	1 (1.1%)	0	1 (0.5%)
CEFALEXIN MONOHYDRATE	1 (1.1%)	0	1 (0.5%)
CEFIXIME	1 (1.1%)	0	1 (0.5%)
CEFUROXIME SODIUM	1 (1.1%)	0	1 (0.5%)
CLEMASTINE FUMARATE	1 (1.1%)	0	1 (0.5%)
DEXAMETHASONE	1 (1.1%)	0	1 (0.5%)
DEXTRAN	1 (1.1%)	0	1 (0.5%)
DIPHENOXYLATE HYDROCHLORIDE	1 (1.1%)	0	1 (0.5%)
DIRITHROMYCIN	1 (1.1%)	0	1 (0.5%)
DOXYCYCLINE	1 (1.1%)	0	1 (0.5%)
DOXYLAMINE	1 (1.1%)	0	1 (0.5%)
FERROUS FUMARATE	1 (1.1%)	0	1 (0.5%)
HYDROCODONE BITARTRATE	1 (1.1%)	0	1 (0.5%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
HYPROMELLOSE	1 (1.1%)	0	1 (0.5%)
ISOTRETINOIN	1 (1.1%)	0	1 (0.5%)
LEVOTHYROXINE SODIUM	1 (1.1%)	0	1 (0.5%)
MEDROXYPROGESTERONE ACETATE	1 (1.1%)	0	1 (0.5%)
METHOCARBAMOL	1 (1.1%)	0	1 (0.5%)
METOCLOPRAMIDE	1 (1.1%)	0	1 (0.5%)
MINERALS NOS	1 (1.1%)	0	1 (0.5%)
MORPHINE SULFATE	1 (1.1%)	0	1 (0.5%)
NAPROXEN	1 (1.1%)	0	1 (0.5%)
OXYBUTYNIN	1 (1.1%)	0	1 (0.5%)
OXYTETRACYCLINE	1 (1.1%)	0	1 (0.5%)
PERMETHRIN	1 (1.1%)	0	1 (0.5%)
PROCHLORPERAZINE	1 (1.1%)	0	1 (0.5%)
PROTEINS NOS	1 (1.1%)	0	1 (0.5%)
ROFECOXIB	1 (1.1%)	0	1 (0.5%)
SALICYLIC ACID	1 (1.1%)	0	1 (0.5%)
SENNA	1 (1.1%)	0	1 (0.5%)
SULFADIAZINE SILVER	1 (1.1%)	0	1 (0.5%)
SULFAMETHOXAZOLE	1 (1.1%)	0	1 (0.5%)
TOLTERODINE TARTRATE	1 (1.1%)	0	1 (0.5%)
TRIMETHOPRIM	1 (1.1%)	0	1 (0.5%)
TRIPROLIDINE HYDROCHLORIDE	1 (1.1%)	0	1 (0.5%)
YELLOW PHENOLPHTHALEIN	1 (1.1%)	0	1 (0.5%)
RISPERIDONE	0	4 (3.1%)	4 (1.8%)
FAMOTIDINE	0	3 (2.4%)	3 (1.4%)
MOMETASONE FUROATE	0	3 (2.4%)	3 (1.4%)
TRIAMCINOLONE ACETONIDE	0	3 (2.4%)	3 (1.4%)
BENZOCAINE	0	2 (1.6%)	2 (0.9%)
COUGH SYRUP/MED	0	2 (1.6%)	2 (0.9%)
NITROUS OXIDE	0	2 (1.6%)	2 (0.9%)
PENICILLIN NOS	0	2 (1.6%)	2 (0.9%)
SALMETEROL HYDROXYNAPHTHOATE	0	2 (1.6%)	2 (0.9%)
	0	1 (0.8%)	1 (0.5%)
ALPRAZOLAM	0	1 (0.8%)	1 (0.5%)
AMINOACETIC ACID	0	1 (0.8%)	1 (0.5%)
AMPHETAMINE ASPARTATE	0	1 (0.8%)	1 (0.5%)
AMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.5%)
ANTACID NOS	0	1 (0.8%)	1 (0.5%)
ANTAZOLINE PHOSPHATE	0	1 (0.8%)	1 (0.5%)
BENTONITE	0	1 (0.8%)	1 (0.5%)
BENZALKONIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
BENZATHINE BENZYLPENICILLIN	0	1 (0.8%)	1 (0.5%)
BENZONATATE	0	1 (0.8%)	1 (0.5%)
BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.5%)
BUTALBITAL	0	1 (0.8%)	1 (0.5%)
CALAMINE	0	1 (0.8%)	1 (0.5%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
CEFAZOLIN	0	1 (0.8%)	1 (0.5%)
CEFTRIAXONE SODIUM	0	1 (0.8%)	1 (0.5%)
CHLOROXYLENOL	0	1 (0.8%)	1 (0.5%)
CHLORPHENAMINE TANNATE	0	1 (0.8%)	1 (0.5%)
CLARITHROMYCIN	0	1 (0.8%)	1 (0.5%)
DESMOPRESSIN	0	1 (0.8%)	1 (0.5%)
DEXTROAMPHETAMINE SACCHARATE	0	1 (0.8%)	1 (0.5%)
DEXTROAMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.5%)
DEXTROPROPOXYPHENE	0	1 (0.8%)	1 (0.5%)
DICHLORALPHENAZONE	0	1 (0.8%)	1 (0.5%)
ECHINACEA EXTRACT	0	1 (0.8%)	1 (0.5%)
ETHANOL	0	1 (0.8%)	1 (0.5%)
ETHINYLESTRADIOL	0	1 (0.8%)	1 (0.5%)
FLUCONAZOLE	0	1 (0.8%)	1 (0.5%)
FLUORIDE NOS	0	1 (0.8%)	1 (0.5%)
GARLIC	0	1 (0.8%)	1 (0.5%)
GLYCEROL	0	1 (0.8%)	1 (0.5%)
GRAMICIDIN	0	1 (0.8%)	1 (0.5%)
HEPATITIS B VACCINE	0	1 (0.8%)	1 (0.5%)
HYDROXYZINE	0	1 (0.8%)	1 (0.5%)
INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.8%)	1 (0.5%)
ISOMETHEPTENE	0	1 (0.8%)	1 (0.5%)
KAOLIN	0	1 (0.8%)	1 (0.5%)
LIDOCAINE	0	1 (0.8%)	1 (0.5%)
MEPYRAMINE TANNATE	0	1 (0.8%)	1 (0.5%)
METHYLPHENIDATE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.5%)
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
MINERAL WAX	0	1 (0.8%)	1 (0.5%)
MINOCYCLINE	0	1 (0.8%)	1 (0.5%)
MINOCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
MIRTAZAPINE	0	1 (0.8%)	1 (0.5%)
MORPHINE	0	1 (0.8%)	1 (0.5%)
NAPHAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
NIZATIDINE	0	1 (0.8%)	1 (0.5%)
NORGESTIMATE	0	1 (0.8%)	1 (0.5%)
OFLOXACIN	0	1 (0.8%)	1 (0.5%)
ONDANSETRON HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
PARAFFIN, LIQUID	0	1 (0.8%)	1 (0.5%)
PARAFFIN, SOFT	0	1 (0.8%)	1 (0.5%)
PECTIN	0	1 (0.8%)	1 (0.5%)
PETHIDINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
PHENOL, LIQUEFIED	0	1 (0.8%)	1 (0.5%)
PHENYLEPHRINE TANNATE	0	1 (0.8%)	1 (0.5%)
PHENYLMERCURIC ACETATE	0	1 (0.8%)	1 (0.5%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
PIRBUTEROL ACETATE	0	1 (0.8%)	1 (0.5%)
PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.8%)	1 (0.5%)
PROCAINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
QUETIAPINE	0	1 (0.8%)	1 (0.5%)
RANITIDINE	0	1 (0.8%)	1 (0.5%)
SENNA FRUIT	0	1 (0.8%)	1 (0.5%)
SODIUM CHLORIDE	0	1 (0.8%)	1 (0.5%)
SODIUM CITRATE	0	1 (0.8%)	1 (0.5%)
SORBITOL	0	1 (0.8%)	1 (0.5%)
TERBUTALINE SULFATE	0	1 (0.8%)	1 (0.5%)
TETANUS TOXOID	0	1 (0.8%)	1 (0.5%)
TRIAMCINOLONE	0	1 (0.8%)	1 (0.5%)
TRIMETHOBENZAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.5%)
UNKNOWN MEDICATION	0	1 (0.8%)	1 (0.5%)
VENLAFAXINE	0	1 (0.8%)	1 (0.5%)
WOOL WAX ALCOHOL	0	1 (0.8%)	1 (0.5%)
ZINC GLUCONATE	0	1 (0.8%)	1 (0.5%)
ZINC OXIDE	0	1 (0.8%)	1 (0.5%)

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Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
Total number of patients with at least one concomitant medication during taper or follow-up	Total	51 (102.0%)	67 (97.1%)	118 (99.2%)
ALIMENTARY TRACT/METAB	Total	12 (24.0%)	16 (23.2%)	28 (23.5%)
	ACETYLSALICYLIC ACID	0	2 (2.9%)	2 (1.7%)
	ALUMINIUM HYDROXIDE	0	1 (1.4%)	1 (0.8%)
	ASCORBIC ACID	2 (4.0%)	0	2 (1.7%)
	ATROPINE SULFATE	0	1 (1.4%)	1 (0.8%)
	BISMUTH SUBSALICYLATE	1 (2.0%)	3 (4.3%)	4 (3.4%)
	CALCIUM CARBONATE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	DEXAMPHETAMINE SULFATE	1 (2.0%)	0	1 (0.8%)
	DIMETICONE, ACTIVATED	1 (2.0%)	0	1 (0.8%)
	FAMOTIDINE	0	2 (2.9%)	2 (1.7%)
	FERROUS FUMARATE	1 (2.0%)	0	1 (0.8%)
	HYOSCINE HYDROBROMIDE	0	1 (1.4%)	1 (0.8%)
	HYOSCYAMINE SULFATE	0	1 (1.4%)	1 (0.8%)
	MAGNESIUM HYDROXIDE	0	1 (1.4%)	1 (0.8%)
	MINERALS NOS	1 (2.0%)	0	1 (0.8%)
	NEOMYCIN SULFATE	1 (2.0%)	0	1 (0.8%)
	OMEPRAZOLE	1 (2.0%)	0	1 (0.8%)
	PHENOBARBITAL	0	1 (1.4%)	1 (0.8%)
	RANITIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	SENNA FRUIT	0	1 (1.4%)	1 (0.8%)
	TRIAMCINOLONE	0	1 (1.4%)	1 (0.8%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
	VITAMINS NOS	8 (16.0%)	6 (8.7%)	14 (11.8%)
ANTIINFECTIVES,SYSTEMIC	Total	11 (22.0%)	9 (13.0%)	20 (16.8%)
	AMOXICILLIN	2 (4.0%)	1 (1.4%)	3 (2.5%)
	AMOXICILLIN TRIHYDRATE	3 (6.0%)	0	3 (2.5%)
	ANTIBIOTIC NOS	1 (2.0%)	0	1 (0.8%)
	CEFALEXIN MONOHYDRATE	1 (2.0%)	0	1 (0.8%)
	CEFPROZIL MONOHYDRATE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	CLAVULANIC ACID	3 (6.0%)	0	3 (2.5%)
	CLINDAMYCIN	1 (2.0%)	0	1 (0.8%)
	DOXYCYCLINE	1 (2.0%)	0	1 (0.8%)
	ERYTHROMYCIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	HEPATITIS B VACCINE	0	1 (1.4%)	1 (0.8%)
	KETOCONAZOLE	0	1 (1.4%)	1 (0.8%)
	MINOCYCLINE	0	1 (1.4%)	1 (0.8%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

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Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
ANTIINFECTIVES,SYSTEMIC	NEOMYCIN SULFATE	1 (2.0%)	0	1 (0.8%)
	OFLOXACIN	0	1 (1.4%)	1 (0.8%)
	TETRACYCLINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
BLOOD/BLOOD FORM ORGANS	Total	0	3 (4.3%)	3 (2.5%)
	ACETYLSALICYLIC ACID	0	2 (2.9%)	2 (1.7%)
	I.V. FLUIDS	0	1 (1.4%)	1 (0.8%)
CARDIOVASCULAR	Total	2 (4.0%)	1 (1.4%)	3 (2.5%)
	CLONIDINE	1 (2.0%)	0	1 (0.8%)
	CLONIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	HYPERICUM EXTRACT	0	1 (1.4%)	1 (0.8%)
CENTRAL NERVOUS SYSTEM	Total	32 (64.0%)	39 (56.5%)	71 (59.7%)
	ACETYLSALICYLIC ACID	0	3 (4.3%)	3 (2.5%)
	AMFEBUTAMONE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	AMPHETAMINE ASPARTATE	0	2 (2.9%)	2 (1.7%)
	AMPHETAMINE SULFATE	0	2 (2.9%)	2 (1.7%)
	BUTALBITAL	0	1 (1.4%)	1 (0.8%)
	CAFFEINE	0	2 (2.9%)	2 (1.7%)
	CARBAMAZEPINE	0	1 (1.4%)	1 (0.8%)
	CHLORPROMAZINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
	CINNAMEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
	CITALOPRAM	2 (4.0%)	1 (1.4%)	3 (2.5%)
	CLONIDINE	1 (2.0%)	0	1 (0.8%)
	CLONIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	DEXAMPHETAMINE SULFATE	1 (2.0%)	0	1 (0.8%)
	DEXTROAMPHETAMINE SACCHARATE	0	2 (2.9%)	2 (1.7%)
	DEXTROAMPHETAMINE SULFATE	0	2 (2.9%)	2 (1.7%)
	DICHLORALPHENAZONE	0	1 (1.4%)	1 (0.8%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
	FLUOXETINE	0	1 (1.4%)	1 (0.8%)
	HYDROXYZINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	HYPERICUM EXTRACT	0	1 (1.4%)	1 (0.8%)
	IBUPROFEN	7 (14.0%)	11 (15.9%)	18 (15.1%)
	ISOMETHEPTENE	0	1 (1.4%)	1 (0.8%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (2.0%)	3 (4.3%)	4 (3.4%)
	MIRTAZAPINE	0	1 (1.4%)	1 (0.8%)
	OLANZAPINE	2 (4.0%)	1 (1.4%)	3 (2.5%)
	PARACETAMOL	7 (14.0%)	8 (11.6%)	15 (12.6%)
	PAROXETINE	17 (34.0%)	16 (23.2%)	33 (27.7%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
CENTRAL NERVOUS SYSTEM	QUETIAPINE	0	1 (1.4%)	1 (0.8%)
	RISPERIDONE	0	6 (8.7%)	6 (5.0%)
	SERTRALINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	VENLAFAXINE	0	1 (1.4%)	1 (0.8%)
DERMATOLOGICALS	Total	8 (16.0%)	21 (30.4%)	29 (24.4%)
	BACITRACIN	1 (2.0%)	0	1 (0.8%)
	BENZOYL PEROXIDE	1 (2.0%)	0	1 (0.8%)
	BETAMETHASONE DIPROPIONATE	0	1 (1.4%)	1 (0.8%)
	BUDESONIDE	2 (4.0%)	3 (4.3%)	5 (4.2%)
	CHLOROXYLENOL	0	1 (1.4%)	1 (0.8%)
	DIPHENHYDRAMINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	6 (8.7%)	6 (5.0%)
	ECONAZOLE NITRATE	0	1 (1.4%)	1 (0.8%)
	ERYTHROMYCIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	FLUTICASONE PROPIONATE	1 (2.0%)	4 (5.8%)	5 (4.2%)
	GRISEOFULVIN	0	1 (1.4%)	1 (0.8%)
	HYDROCORTISONE	0	1 (1.4%)	1 (0.8%)
	ISOTRETINOIN	1 (2.0%)	0	1 (0.8%)
	KETOCONAZOLE	0	1 (1.4%)	1 (0.8%)
	MOMETASONE FUROATE	0	1 (1.4%)	1 (0.8%)
	NEOMYCIN SULFATE	2 (4.0%)	0	2 (1.7%)
	POLYMYXIN B SULFATE	1 (2.0%)	0	1 (0.8%)
	SALICYLIC ACID	1 (2.0%)	0	1 (0.8%)
	TETRACYCLINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	TRIAMCINOLONE	0	1 (1.4%)	1 (0.8%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
GU SYSTEM/SEX HORMONES	Total	2 (4.0%)	5 (7.2%)	7 (5.9%)
	ANTIBIOTIC NOS	1 (2.0%)	0	1 (0.8%)
	ECONAZOLE NITRATE	0	1 (1.4%)	1 (0.8%)
	ETHINYLESTRADIOL	0	1 (1.4%)	1 (0.8%)
	HYPERICUM EXTRACT	0	1 (1.4%)	1 (0.8%)
	NITROFURANTOIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
	NORGESTIMATE	0	1 (1.4%)	1 (0.8%)
	OFLOXACIN	0	1 (1.4%)	1 (0.8%)
	TOLTERODINE TARTRATE	1 (2.0%)	0	1 (0.8%)
MUSCULO-SKELETAL	Total	10 (20.0%)	11 (15.9%)	21 (17.6%)
	IBUPROFEN	7 (14.0%)	11 (15.9%)	18 (15.1%)
	NAPROXEN SODIUM	2 (4.0%)	0	2 (1.7%)
	ROFECOXIB	1 (2.0%)	0	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
MUSCULO-SKELETAL	SALICYLIC ACID	1 (2.0%)	0	1 (0.8%)
RESPIRATORY	Total	23 (46.0%)	32 (46.4%)	55 (46.2%)
	BROMPHENIRAMINE MALEATE	1 (2.0%)	0	1 (0.8%)
	BUDESONIDE	2 (4.0%)	3 (4.3%)	5 (4.2%)
	CETIRIZINE HYDROCHLORIDE	2 (4.0%)	3 (4.3%)	5 (4.2%)
	CHLORPHENAMINE MALEATE	0	1 (1.4%)	1 (0.8%)
	CHLORPHENAMINE TANNATE	0	1 (1.4%)	1 (0.8%)
	COUGH COLD PREPARATIONS NOS	1 (2.0%)	0	1 (0.8%)
	CYPROHEPTADINE	0	1 (1.4%)	1 (0.8%)
	DEXTROMETHORPHAN HYDROBROMIDE	0	2 (2.9%)	2 (1.7%)
	DIMENHYDRINATE	1 (2.0%)	0	1 (0.8%)
	DIPHENHYDRAMINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	6 (8.7%)	6 (5.0%)
	DOXYLAMINE SUCCINATE	0	1 (1.4%)	1 (0.8%)
	ETHANOL	0	1 (1.4%)	1 (0.8%)
	FEXOFENADINE HYDROCHLORIDE	3 (6.0%)	2 (2.9%)	5 (4.2%)
	FLUTICASONE PROPIONATE	1 (2.0%)	4 (5.8%)	5 (4.2%)
	GUAIFENESIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	LORATADINE	7 (14.0%)	6 (8.7%)	13 (10.9%)
	MEPYRAMINE TANNATE	0	1 (1.4%)	1 (0.8%)
	MOMETASONE FUROATE	0	1 (1.4%)	1 (0.8%)
	MONTELUKAST SODIUM	1 (2.0%)	3 (4.3%)	4 (3.4%)
	PARACETAMOL	0	2 (2.9%)	2 (1.7%)
	PHENYLEPHRINE TANNATE	0	1 (1.4%)	1 (0.8%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	3 (6.0%)	2 (2.9%)	5 (4.2%)
	PSEUDOEPHEDRINE SULFATE	1 (2.0%)	0	1 (0.8%)
	SALBUTAMOL	3 (6.0%)	6 (8.7%)	9 (7.6%)
	SALMETEROL HYDROXYNAPHTHOATE	0	2 (2.9%)	2 (1.7%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
	TRIPROLIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
SENSORY ORGANS	Total	4 (8.0%)	8 (11.6%)	12 (10.1%)
	ANTAZOLINE PHOSPHATE	0	1 (1.4%)	1 (0.8%)
	CLONIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
	ERYTHROMYCIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	HYDROCORTISONE	0	1 (1.4%)	1 (0.8%)
	NAPHAZOLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
	NEOMYCIN SULFATE	1 (2.0%)	0	1 (0.8%)
	OFLOXACIN	0	1 (1.4%)	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
SENSORY ORGANS	TETRACYCLINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	TRIAMCINOLONE	0	1 (1.4%)	1 (0.8%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
SYSTEMIC HORMONAL	Total	1 (2.0%)	5 (7.2%)	6 (5.0%)
	DESMOPRESSIN	0	2 (2.9%)	2 (1.7%)
	HYDROCORTISONE	0	1 (1.4%)	1 (0.8%)
	LEVOTHYROXINE SODIUM	1 (2.0%)	0	1 (0.8%)
	TRIAMCINOLONE	0	1 (1.4%)	1 (0.8%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
UNCLASSIFIABLE	Total	0	1 (1.4%)	1 (0.8%)
	UNKNOWN MEDICATION	0	1 (1.4%)	1 (0.8%)
VARIOUS	Total	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HYPERICUM EXTRACT	0	1 (1.4%)	1 (0.8%)
	PROTEINS NOS	1 (2.0%)	0	1 (0.8%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

Generic Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
Total number of patients with at least one concomitant medication during taper or follow-up	51 (102.0%)	67 (97.1%)	118 (99.2%)
PAROXETINE	17 (34.0%)	16 (23.2%)	33 (27.7%)
VITAMINS NOS	8 (16.0%)	6 (8.7%)	14 (11.8%)
IBUPROFEN	7 (14.0%)	11 (15.9%)	18 (15.1%)
PARACETAMOL	7 (14.0%)	8 (11.6%)	15 (12.6%)
LORATADINE	7 (14.0%)	6 (8.7%)	13 (10.9%)
SALBUTAMOL	3 (6.0%)	6 (8.7%)	9 (7.6%)
FEXOFENADINE HYDROCHLORIDE	3 (6.0%)	2 (2.9%)	5 (4.2%)
PSEUDOEPHEDRINE HYDROCHLORIDE	3 (6.0%)	2 (2.9%)	5 (4.2%)
AMOXICILLIN TRIHYDRATE	3 (6.0%)	0	3 (2.5%)
CLAVULANIC ACID	3 (6.0%)	0	3 (2.5%)
BUDESONIDE	2 (4.0%)	3 (4.3%)	5 (4.2%)
CETIRIZINE HYDROCHLORIDE	2 (4.0%)	3 (4.3%)	5 (4.2%)
AMOXICILLIN	2 (4.0%)	1 (1.4%)	3 (2.5%)
CITALOPRAM	2 (4.0%)	1 (1.4%)	3 (2.5%)
OLANZAPINE	2 (4.0%)	1 (1.4%)	3 (2.5%)
ASCORBIC ACID	2 (4.0%)	0	2 (1.7%)
NAPROXEN SODIUM	2 (4.0%)	0	2 (1.7%)
NEOMYCIN SULFATE	2 (4.0%)	0	2 (1.7%)
FLUTICASONE PROPIONATE	1 (2.0%)	4 (5.8%)	5 (4.2%)
BISMUTH SUBSALICYLATE	1 (2.0%)	3 (4.3%)	4 (3.4%)
METHYLPHENIDATE HYDROCHLORIDE	1 (2.0%)	3 (4.3%)	4 (3.4%)
MONTELUKAST SODIUM	1 (2.0%)	3 (4.3%)	4 (3.4%)
ERYTHROMYCIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
GUAIFENESIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
CALCIUM CARBONATE	1 (2.0%)	1 (1.4%)	2 (1.7%)
CEFPROZIL MONOHYDRATE	1 (2.0%)	1 (1.4%)	2 (1.7%)
DIPHENHYDRAMINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
NITROFURANTOIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
TETRACYCLINE	1 (2.0%)	1 (1.4%)	2 (1.7%)
AMFEBUTAMONE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
ANTIBIOTIC NOS	1 (2.0%)	0	1 (0.8%)
BACITRACIN	1 (2.0%)	0	1 (0.8%)
BENZOYL PEROXIDE	1 (2.0%)	0	1 (0.8%)
BROMPHENIRAMINE MALEATE	1 (2.0%)	0	1 (0.8%)
CEFALEXIN MONOHYDRATE	1 (2.0%)	0	1 (0.8%)
CLINDAMYCIN	1 (2.0%)	0	1 (0.8%)
CLONIDINE	1 (2.0%)	0	1 (0.8%)
CLONIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
COUGH COLD PREPARATIONS NOS	1 (2.0%)	0	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

Generic Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
DEXAMPHETAMINE SULFATE	1 (2.0%)	0	1 (0.8%)
DIMENHYDRINATE	1 (2.0%)	0	1 (0.8%)
DIMETICONE, ACTIVATED	1 (2.0%)	0	1 (0.8%)
DOXYCYCLINE	1 (2.0%)	0	1 (0.8%)
FERROUS FUMARATE	1 (2.0%)	0	1 (0.8%)
HYDROXYZINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
ISOTRETINOIN	1 (2.0%)	0	1 (0.8%)
LEVOTHYROXINE SODIUM	1 (2.0%)	0	1 (0.8%)
MINERALS NOS	1 (2.0%)	0	1 (0.8%)
OMEPRAZOLE	1 (2.0%)	0	1 (0.8%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
POLYMYXIN B SULFATE	1 (2.0%)	0	1 (0.8%)
PROTEINS NOS	1 (2.0%)	0	1 (0.8%)
PSEUDOEPHEDRINE SULFATE	1 (2.0%)	0	1 (0.8%)
RANITIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
ROFECOXIB	1 (2.0%)	0	1 (0.8%)
SALICYLIC ACID	1 (2.0%)	0	1 (0.8%)
SERTRALINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
TOLTERODINE TARTRATE	1 (2.0%)	0	1 (0.8%)
TRIPROLIDINE HYDROCHLORIDE	1 (2.0%)	0	1 (0.8%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	6 (8.7%)	6 (5.0%)
RISPERIDONE	0	6 (8.7%)	6 (5.0%)
ACETYLSALICYLIC ACID	0	3 (4.3%)	3 (2.5%)
AMPHETAMINE ASPARTATE	0	2 (2.9%)	2 (1.7%)
AMPHETAMINE SULFATE	0	2 (2.9%)	2 (1.7%)
CAFFEINE	0	2 (2.9%)	2 (1.7%)
DESMOPRESSIN	0	2 (2.9%)	2 (1.7%)
DEXTROAMPHETAMINE SACCHARATE	0	2 (2.9%)	2 (1.7%)
DEXTROAMPHETAMINE SULFATE	0	2 (2.9%)	2 (1.7%)
DEXTROMETHORPHAN HYDROBROMIDE	0	2 (2.9%)	2 (1.7%)
FAMOTIDINE	0	2 (2.9%)	2 (1.7%)
SALMETEROL HYDROXYNAPHTHOATE	0	2 (2.9%)	2 (1.7%)
ALUMINIUM HYDROXIDE	0	1 (1.4%)	1 (0.8%)
ANTAZOLINE PHOSPHATE	0	1 (1.4%)	1 (0.8%)
ATROPINE SULFATE	0	1 (1.4%)	1 (0.8%)
BETAMETHASONE DIPROPIONATE	0	1 (1.4%)	1 (0.8%)
BUTALBITAL	0	1 (1.4%)	1 (0.8%)
CARBAMAZEPINE	0	1 (1.4%)	1 (0.8%)
CHLOROXYLENOL	0	1 (1.4%)	1 (0.8%)
CHLORPHENAMINE MALEATE	0	1 (1.4%)	1 (0.8%)
CHLORPHENAMINE TANNATE	0	1 (1.4%)	1 (0.8%)
CHLORPROMAZINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

Generic Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
CINNAMEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
CYPROHEPTADINE	0	1 (1.4%)	1 (0.8%)
DICHLORALPHENAZONE	0	1 (1.4%)	1 (0.8%)
DOXYLAMINE SUCCINATE	0	1 (1.4%)	1 (0.8%)
ECONAZOLE NITRATE	0	1 (1.4%)	1 (0.8%)
ETHANOL	0	1 (1.4%)	1 (0.8%)
ETHINYLESTRADIOL	0	1 (1.4%)	1 (0.8%)
FLUOXETINE	0	1 (1.4%)	1 (0.8%)
GRISEOFULVIN	0	1 (1.4%)	1 (0.8%)
HEPATITIS B VACCINE	0	1 (1.4%)	1 (0.8%)
HYDROCORTISONE	0	1 (1.4%)	1 (0.8%)
HYOSCINE HYDROBROMIDE	0	1 (1.4%)	1 (0.8%)
HYOSCYAMINE SULFATE	0	1 (1.4%)	1 (0.8%)
HYPERICUM EXTRACT	0	1 (1.4%)	1 (0.8%)
I.V. FLUIDS	0	1 (1.4%)	1 (0.8%)
ISOMETHEPTENE	0	1 (1.4%)	1 (0.8%)
KETOCONAZOLE	0	1 (1.4%)	1 (0.8%)
MAGNESIUM HYDROXIDE	0	1 (1.4%)	1 (0.8%)
MEPYRAMINE TANNATE	0	1 (1.4%)	1 (0.8%)
MINOCYCLINE	0	1 (1.4%)	1 (0.8%)
MINOCYCLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
MIRTAZAPINE	0	1 (1.4%)	1 (0.8%)
MOMETASONE FUROATE	0	1 (1.4%)	1 (0.8%)
NAPHAZOLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.8%)
NORGESTIMATE	0	1 (1.4%)	1 (0.8%)
OFLOXACIN	0	1 (1.4%)	1 (0.8%)
PHENOBARBITAL	0	1 (1.4%)	1 (0.8%)
PHENYLEPHRINE TANNATE	0	1 (1.4%)	1 (0.8%)
QUETIAPINE	0	1 (1.4%)	1 (0.8%)
SENNA FRUIT	0	1 (1.4%)	1 (0.8%)
TRIAMCINOLONE	0	1 (1.4%)	1 (0.8%)
TRIAMCINOLONE ACETONIDE	0	1 (1.4%)	1 (0.8%)
UNKNOWN MEDICATION	0	1 (1.4%)	1 (0.8%)
VENLAFAXINE	0	1 (1.4%)	1 (0.8%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

BRL 29060 - 716
Interim Output
Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Children

	Acute Study Treatment Group					
	Paroxetine (N = 49)		Placebo (N = 70)		Total (N = 119)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	46 (93.9%)	3 (6.1%)	69 (100.0%)	0	115(97.5%)	3 (2.5%)
Week 2	42 (100.0%)	0	66 (98.5%)	1 (1.5%)	108(99.1%)	1 (0.9%)
Week 3	45 (97.8%)	1 (2.2%)	62 (95.4%)	3 (4.6%)	107(96.4%)	4 (3.6%)
Week 4	43 (97.7%)	1 (2.3%)	58 (98.3%)	1 (1.7%)	101(98.1%)	2 (1.9%)
Week 6	43 (100.0%)	0	56 (98.2%)	1 (1.8%)	99 (99.0%)	1 (1.0%)
Week 8	38 (90.5%)	4 (9.5%)	48 (94.1%)	3 (5.9%)	86 (92.5%)	7 (7.5%)
Week 12	30 (93.8%)	2 (6.3%)	38 (90.5%)	4 (9.5%)	68 (91.9%)	6 (8.1%)
Week 16	25 (96.2%)	1 (3.8%)	32 (94.1%)	2 (5.9%)	57 (95.0%)	3 (5.0%)
Week 20	24 (100.0%)	0	25 (96.2%)	1 (3.8%)	49 (98.0%)	1 (2.0%)
Week 24	20 (90.9%)	2 (9.1%)	16 (84.2%)	3 (15.8%)	36 (87.8%)	5 (12.2%)
Overall*	36 (73.5%)	13 (26.5%)	52 (75.4%)	17 (24.6%)	88 (74.6%)	30 (25.4%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

BRL 29060 - 716
Interim Output
Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine (N = 45)		Placebo (N = 57)		Total (N = 102)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	42 (93.3%)	3 (6.7%)	55 (96.5%)	2 (3.5%)	97 (95.1%)	5 (4.9%)
Week 2	42 (97.7%)	1 (2.3%)	52 (98.1%)	1 (1.9%)	94 (97.9%)	2 (2.1%)
Week 3	39 (90.7%)	4 (9.3%)	49 (96.1%)	2 (3.9%)	88 (93.6%)	6 (6.4%)
Week 4	42 (97.7%)	1 (2.3%)	47 (97.9%)	1 (2.1%)	89 (97.8%)	2 (2.2%)
Week 6	40 (97.6%)	1 (2.4%)	45 (97.8%)	1 (2.2%)	85 (97.7%)	2 (2.3%)
Week 8	36 (92.3%)	3 (7.7%)	39 (95.1%)	2 (4.9%)	75 (93.8%)	5 (6.3%)
Week 12	33 (94.3%)	2 (5.7%)	34 (97.1%)	1 (2.9%)	67 (95.7%)	3 (4.3%)
Week 16	29 (93.5%)	2 (6.5%)	30 (90.9%)	3 (9.1%)	59 (92.2%)	5 (7.8%)
Week 20	21 (100.0%)	0	21 (95.5%)	1 (4.5%)	42 (97.7%)	1 (2.3%)
Week 24	18 (90.0%)	2 (10.0%)	16 (94.1%)	1 (5.9%)	34 (91.9%)	3 (8.1%)
Overall*	31 (68.9%)	14 (31.1%)	47 (82.5%)	10 (17.5%)	78 (76.5%)	24 (23.5%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

BRL 29060 - 716
Interim Output
Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Total

	Acute Study Treatment Group					
	Paroxetine (N = 94)		Placebo (N = 127)		Total (N = 221)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	88 (93.6%)	6 (6.4%)	124(98.4%)	2 (1.6%)	212(96.4%)	8 (3.6%)
Week 2	84 (98.8%)	1 (1.2%)	118(98.3%)	2 (1.7%)	202(98.5%)	3 (1.5%)
Week 3	84 (94.4%)	5 (5.6%)	111(95.7%)	5 (4.3%)	195(95.1%)	10 (4.9%)
Week 4	85 (97.7%)	2 (2.3%)	105(98.1%)	2 (1.9%)	190(97.9%)	4 (2.1%)
Week 6	83 (98.8%)	1 (1.2%)	101(98.1%)	2 (1.9%)	184(98.4%)	3 (1.6%)
Week 8	74 (91.4%)	7 (8.6%)	87 (94.6%)	5 (5.4%)	161(93.1%)	12 (6.9%)
Week 12	63 (94.0%)	4 (6.0%)	72 (93.5%)	5 (6.5%)	135(93.8%)	9 (6.3%)
Week 16	54 (94.7%)	3 (5.3%)	62 (92.5%)	5 (7.5%)	116(93.5%)	8 (6.5%)
Week 20	45 (100.0%)	0	46 (95.8%)	2 (4.2%)	91 (97.8%)	2 (2.2%)
Week 24	38 (90.5%)	4 (9.5%)	32 (88.9%)	4 (11.1%)	70 (89.7%)	8 (10.3%)
Overall*	67 (71.3%)	27 (28.7%)	99 (78.6%)	27 (21.4%)	166(75.5%)	54 (24.5%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

BRL 29060 - 716
Interim Output
Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Children

	Paroxetine (N=49)		Placebo (N=70)		Total (N=119)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	42 (89.4%)	5 (10.6%)	62 (93.9%)	4 (6.1%)	104 (92.0%)	9 (8.0%)
Week 2	37 (90.2%)	4 (9.8%)	59 (90.8%)	6 (9.2%)	96 (90.6%)	10 (9.4%)
Week 3	41 (93.2%)	3 (6.8%)	55 (88.7%)	7 (11.3%)	96 (90.6%)	10 (9.4%)
Week 4	36 (85.7%)	6 (14.3%)	48 (84.2%)	9 (15.8%)	84 (84.8%)	15 (15.2%)
Week 6	32 (84.2%)	6 (15.8%)	47 (82.5%)	10 (17.5%)	79 (83.2%)	16 (16.8%)
Week 8	29 (78.4%)	8 (21.6%)	39 (81.3%)	9 (18.8%)	68 (80.0%)	17 (20.0%)
Week 12	24 (88.9%)	3 (11.1%)	32 (84.2%)	6 (15.8%)	56 (86.2%)	9 (13.8%)
Week 16	24 (92.3%)	2 (7.7%)	24 (82.8%)	5 (17.2%)	48 (87.3%)	7 (12.7%)
Week 20	17 (85.0%)	3 (15.0%)	22 (91.7%)	2 (8.3%)	39 (88.6%)	5 (11.4%)
Week 24	16 (84.2%)	3 (15.8%)	12 (80.0%)	3 (20.0%)	28 (82.4%)	6 (17.6%)
Overall**	27 (96.4%)	1 (3.6%)	39 (88.6%)	5 (11.4%)	66 (91.7%)	6 (8.3%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

BRL 29060 - 716
Interim Output
Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Adolescents

	Paroxetine (N=45)		Placebo (N=57)		Total (N=102)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	33 (80.5%)	8 (19.5%)	43 (75.4%)	14 (24.6%)	76 (77.6%)	22 (22.4%)
Week 2	31 (77.5%)	9 (22.5%)	43 (81.1%)	10 (18.9%)	74 (79.6%)	19 (20.4%)
Week 3	33 (82.5%)	7 (17.5%)	42 (89.4%)	5 (10.6%)	75 (86.2%)	12 (13.8%)
Week 4	36 (83.7%)	7 (16.3%)	38 (84.4%)	7 (15.6%)	74 (84.1%)	14 (15.9%)
Week 6	30 (75.0%)	10 (25.0%)	40 (93.0%)	3 (7.0%)	70 (84.3%)	13 (15.7%)
Week 8	28 (77.8%)	8 (22.2%)	35 (85.4%)	6 (14.6%)	63 (81.8%)	14 (18.2%)
Week 12	26 (78.8%)	7 (21.2%)	28 (90.3%)	3 (9.7%)	54 (84.4%)	10 (15.6%)
Week 16	27 (93.1%)	2 (6.9%)	27 (87.1%)	4 (12.9%)	54 (90.0%)	6 (10.0%)
Week 20	16 (84.2%)	3 (15.8%)	17 (85.0%)	3 (15.0%)	33 (84.6%)	6 (15.4%)
Week 24	17 (89.5%)	2 (10.5%)	15 (88.2%)	2 (11.8%)	32 (88.9%)	4 (11.1%)
Overall**	26 (89.7%)	3 (10.3%)	39 (97.5%)	1 (2.5%)	65 (94.2%)	4 (5.8%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

BRL 29060 - 716
Interim Output
Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Total

	Paroxetine (N=94)		Placebo (N=127)		Total (N=221)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	75 (85.2%)	13 (14.8%)	105 (85.4%)	18 (14.6%)	180 (85.3%)	31 (14.7%)
Week 2	68 (84.0%)	13 (16.0%)	102 (86.4%)	16 (13.6%)	170 (85.4%)	29 (14.6%)
Week 3	74 (88.1%)	10 (11.9%)	97 (89.0%)	12 (11.0%)	171 (88.6%)	22 (11.4%)
Week 4	72 (84.7%)	13 (15.3%)	86 (84.3%)	16 (15.7%)	158 (84.5%)	29 (15.5%)
Week 6	62 (79.5%)	16 (20.5%)	87 (87.0%)	13 (13.0%)	149 (83.7%)	29 (16.3%)
Week 8	57 (78.1%)	16 (21.9%)	74 (83.1%)	15 (16.9%)	131 (80.9%)	31 (19.1%)
Week 12	50 (83.3%)	10 (16.7%)	60 (87.0%)	9 (13.0%)	110 (85.3%)	19 (14.7%)
Week 16	51 (92.7%)	4 (7.3%)	51 (85.0%)	9 (15.0%)	102 (88.7%)	13 (11.3%)
Week 20	33 (84.6%)	6 (15.4%)	39 (88.6%)	5 (11.4%)	72 (86.7%)	11 (13.3%)
Week 24	33 (86.8%)	5 (13.2%)	27 (84.4%)	5 (15.6%)	60 (85.7%)	10 (14.3%)
Overall**	53 (93.0%)	4 (7.0%)	78 (92.9%)	6 (7.1%)	131 (92.9%)	10 (7.1%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	56	91.8	4	6.6	0	0.0	1	1.6	0	0.0	61	100.0
Week 2	27	46.6	28	48.3	2	3.4	1	1.7	0	0.0	58	100.0
Week 3	16	28.6	25	44.6	14	25.0	1	1.8	0	0.0	56	100.0
Week 4	13	24.5	23	43.4	13	24.5	4	7.5	0	0.0	53	100.0
Week 6	11	21.2	21	40.4	15	28.8	4	7.7	1	1.9	52	100.0
Week 8	9	18.4	19	38.8	16	32.7	5	10.2	0	0.0	49	100.0
Week 12	7	16.3	17	39.5	13	30.2	5	11.6	1	2.3	43	100.0
Week 16	7	18.4	12	31.6	13	34.2	2	5.3	4	10.5	38	100.0
Week 20	5	16.1	10	32.3	9	29.0	4	12.9	3	9.7	31	100.0
Week 24	5	17.9	10	35.7	9	32.1	0	0.0	4	14.3	28	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	51	92.7	3	5.5	1	1.8	0	0.0	0	0.0	55	100.0
Week 2	15	29.4	32	62.7	4	7.8	0	0.0	0	0.0	51	100.0
Week 3	8	15.7	26	51.0	16	31.4	1	2.0	0	0.0	51	100.0
Week 4	6	11.8	24	47.1	18	35.3	3	5.9	0	0.0	51	100.0
Week 6	4	8.3	22	45.8	19	39.6	1	2.1	2	4.2	48	100.0
Week 8	3	6.7	17	37.8	19	42.2	6	13.3	0	0.0	45	100.0
Week 12	2	4.9	16	39.0	16	39.0	6	14.6	1	2.4	41	100.0
Week 16	2	5.4	12	32.4	17	45.9	6	16.2	0	0.0	37	100.0
Week 20	2	6.3	12	37.5	8	25.0	9	28.1	1	3.1	32	100.0
Week 24	1	3.7	11	40.7	7	25.9	6	22.2	2	7.4	27	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	107	92.2	7	6.0	1	0.9	1	0.9	0	0.0	116	100.0
Week 2	42	38.5	60	55.0	6	5.5	1	0.9	0	0.0	109	100.0
Week 3	24	22.4	51	47.7	30	28.0	2	1.9	0	0.0	107	100.0
Week 4	19	18.3	47	45.2	31	29.8	7	6.7	0	0.0	104	100.0
Week 6	15	15.0	43	43.0	34	34.0	5	5.0	3	3.0	100	100.0
Week 8	12	12.8	36	38.3	35	37.2	11	11.7	0	0.0	94	100.0
Week 12	9	10.7	33	39.3	29	34.5	11	13.1	2	2.4	84	100.0
Week 16	9	12.0	24	32.0	30	40.0	8	10.7	4	5.3	75	100.0
Week 20	7	11.1	22	34.9	17	27.0	13	20.6	4	6.3	63	100.0
Week 24	6	10.9	21	38.2	16	29.1	6	10.9	6	10.9	55	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	56	96.6	2	3.4	0	0.0	0	0.0	0	0.0	58	100.0
Week 2	16	31.4	32	62.7	3	5.9	0	0.0	0	0.0	51	100.0
Week 3	10	18.2	29	52.7	14	25.5	2	3.6	0	0.0	55	100.0
Week 4	7	13.5	24	46.2	14	26.9	5	9.6	2	3.8	52	100.0
Week 6	7	14.0	19	38.0	15	30.0	6	12.0	3	6.0	50	100.0
Week 8	6	13.6	13	29.5	16	36.4	4	9.1	5	11.4	44	100.0
Week 12	2	6.5	13	41.9	10	32.3	2	6.5	4	12.9	31	100.0
Week 16	2	8.3	11	45.8	5	20.8	4	16.7	2	8.3	24	100.0
Week 20	3	15.8	9	47.4	3	15.8	3	15.8	1	5.3	19	100.0
Week 24	3	20.0	7	46.7	2	13.3	3	20.0	0	0.0	15	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	44	93.6	3	6.4	0	0.0	0	0.0	0	0.0	47	100.0
Week 2	7	15.6	33	73.3	5	11.1	0	0.0	0	0.0	45	100.0
Week 3	1	2.3	19	44.2	19	44.2	4	9.3	0	0.0	43	100.0
Week 4	3	7.1	8	19.0	16	38.1	11	26.2	4	9.5	42	100.0
Week 6	1	2.4	7	17.1	12	29.3	11	26.8	10	24.4	41	100.0
Week 8	1	2.7	8	21.6	7	18.9	11	29.7	10	27.0	37	100.0
Week 12	1	3.4	6	20.7	5	17.2	5	17.2	12	41.4	29	100.0
Week 16	1	3.7	7	25.9	6	22.2	3	11.1	10	37.0	27	100.0
Week 20	1	7.7	4	30.8	3	23.1	1	7.7	4	30.8	13	100.0
Week 24	0	0.0	3	30.0	3	30.0	1	10.0	3	30.0	10	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	100	95.2	5	4.8	0	0.0	0	0.0	0	0.0	105	100.0
Week 2	23	24.0	65	67.7	8	8.3	0	0.0	0	0.0	96	100.0
Week 3	11	11.2	48	49.0	33	33.7	6	6.1	0	0.0	98	100.0
Week 4	10	10.6	32	34.0	30	31.9	16	17.0	6	6.4	94	100.0
Week 6	8	8.8	26	28.6	27	29.7	17	18.7	13	14.3	91	100.0
Week 8	7	8.6	21	25.9	23	28.4	15	18.5	15	18.5	81	100.0
Week 12	3	5.0	19	31.7	15	25.0	7	11.7	16	26.7	60	100.0
Week 16	3	5.9	18	35.3	11	21.6	7	13.7	12	23.5	51	100.0
Week 20	4	12.5	13	40.6	6	18.8	4	12.5	5	15.6	32	100.0
Week 24	3	12.0	10	40.0	5	20.0	4	16.0	3	12.0	25	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	112	94.1	6	5.0	0	0.0	1	0.8	0	0.0	119	100.0
Week 2	43	39.4	60	55.0	5	4.6	1	0.9	0	0.0	109	100.0
Week 3	26	23.4	54	48.6	28	25.2	3	2.7	0	0.0	111	100.0
Week 4	20	19.0	47	44.8	27	25.7	9	8.6	2	1.9	105	100.0
Week 6	18	17.6	40	39.2	30	29.4	10	9.8	4	3.9	102	100.0
Week 8	15	16.1	32	34.4	32	34.4	9	9.7	5	5.4	93	100.0
Week 12	9	12.2	30	40.5	23	31.1	7	9.5	5	6.8	74	100.0
Week 16	9	14.5	23	37.1	18	29.0	6	9.7	6	9.7	62	100.0
Week 20	8	16.0	19	38.0	12	24.0	7	14.0	4	8.0	50	100.0
Week 24	8	18.6	17	39.5	11	25.6	3	7.0	4	9.3	43	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	95	93.1	6	5.9	1	1.0	0	0.0	0	0.0	102	100.0
Week 2	22	22.9	65	67.7	9	9.4	0	0.0	0	0.0	96	100.0
Week 3	9	9.6	45	47.9	35	37.2	5	5.3	0	0.0	94	100.0
Week 4	9	9.7	32	34.4	34	36.6	14	15.1	4	4.3	93	100.0
Week 6	5	5.6	29	32.6	31	34.8	12	13.5	12	13.5	89	100.0
Week 8	4	4.9	25	30.5	26	31.7	17	20.7	10	12.2	82	100.0
Week 12	3	4.3	22	31.4	21	30.0	11	15.7	13	18.6	70	100.0
Week 16	3	4.7	19	29.7	23	35.9	9	14.1	10	15.6	64	100.0
Week 20	3	6.7	16	35.6	11	24.4	10	22.2	5	11.1	45	100.0
Week 24	1	2.7	14	37.8	10	27.0	7	18.9	5	13.5	37	100.0

BRL 29060 - 716
Interim Output
Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	207	93.7	12	5.4	1	0.5	1	0.5	0	0.0	221	100.0
Week 2	65	31.7	125	61.0	14	6.8	1	0.5	0	0.0	205	100.0
Week 3	35	17.1	99	48.3	63	30.7	8	3.9	0	0.0	205	100.0
Week 4	29	14.6	79	39.9	61	30.8	23	11.6	6	3.0	198	100.0
Week 6	23	12.0	69	36.1	61	31.9	22	11.5	16	8.4	191	100.0
Week 8	19	10.9	57	32.6	58	33.1	26	14.9	15	8.6	175	100.0
Week 12	12	8.3	52	36.1	44	30.6	18	12.5	18	12.5	144	100.0
Week 16	12	9.5	42	33.3	41	32.5	15	11.9	16	12.7	126	100.0
Week 20	11	11.6	35	36.8	23	24.2	17	17.9	9	9.5	95	100.0
Week 24	9	11.3	31	38.8	21	26.3	10	12.5	9	11.3	80	100.0

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
10 (16.4%)	17 (27.9%)	23 (37.7%)	4 (6.6%)	7 (11.5%)	61 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
6 (10.9%)	10 (18.2%)	22 (40.0%)	12 (21.8%)	5 (9.1%)	55 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
16 (13.8%)	27 (23.3%)	45 (38.8%)	16 (13.8%)	12 (10.3%)	116 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
4 (6.9%)	21 (36.2%)	19 (32.8%)	8 (13.8%)	6 (10.3%)	58 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
3 (6.4%)	6 (12.8%)	10 (21.3%)	10 (21.3%)	18 (38.3%)	47 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
7 (6.7%)	27 (25.7%)	29 (27.6%)	18 (17.1%)	24 (22.9%)	105 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
14 (11.8%)	38 (31.9%)	42 (35.3%)	12 (10.1%)	13 (10.9%)	119 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
9 (8.8%)	16 (15.7%)	32 (31.4%)	22 (21.6%)	23 (22.5%)	102 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
23 (10.4%)	54 (24.4%)	74 (33.5%)	34 (15.4%)	36 (16.3%)	221 (100.0%)

BRL 29060 - 716
Interim Output
Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Children

Days	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
>= 1	49 (100.0%)	70 (100.0%)	119 (100.0%)
> 7	48 (98.0%)	69 (98.6%)	117 (98.3%)
> 14	47 (95.9%)	67 (95.7%)	114 (95.8%)
> 21	46 (93.9%)	64 (91.4%)	110 (92.4%)
> 28	46 (93.9%)	62 (88.6%)	108 (90.8%)
> 42	43 (87.8%)	56 (80.0%)	99 (83.2%)
> 56	41 (83.7%)	46 (65.7%)	87 (73.1%)
> 70	31 (63.3%)	40 (57.1%)	71 (59.7%)
> 84	29 (59.2%)	36 (51.4%)	65 (54.6%)
> 112	24 (49.0%)	29 (41.4%)	53 (44.5%)
> 140	23 (46.9%)	21 (30.0%)	44 (37.0%)
> 168	15 (30.6%)	13 (18.6%)	28 (23.5%)
> 182	5 (10.2%)	6 (8.6%)	11 (9.2%)
Overall Mean	114.2	97.4	104.3
Minimum	2	2	2
Maximum	194	197	197

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Adolescents

Days	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
>= 1	45 (100.0%)	57 (100.0%)	102 (100.0%)
> 7	44 (97.8%)	56 (98.2%)	100 (98.0%)
> 14	44 (97.8%)	53 (93.0%)	97 (95.1%)
> 21	43 (95.6%)	52 (91.2%)	95 (93.1%)
> 28	43 (95.6%)	51 (89.5%)	94 (92.2%)
> 42	40 (88.9%)	44 (77.2%)	84 (82.4%)
> 56	37 (82.2%)	38 (66.7%)	75 (73.5%)
> 70	35 (77.8%)	33 (57.9%)	68 (66.7%)
> 84	35 (77.8%)	33 (57.9%)	68 (66.7%)
> 112	27 (60.0%)	27 (47.4%)	54 (52.9%)
> 140	20 (44.4%)	18 (31.6%)	38 (37.3%)
> 168	11 (24.4%)	11 (19.3%)	22 (21.6%)
> 182	3 (6.7%)	0 (0.0%)	3 (2.9%)
Overall Mean	121.6	100.6	109.9
Minimum	2	2	2
Maximum	184	182	184

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Total

Days	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
>= 1	94 (100.0%)	127 (100.0%)	221 (100.0%)
> 7	92 (97.9%)	125 (98.4%)	217 (98.2%)
> 14	91 (96.8%)	120 (94.5%)	211 (95.5%)
> 21	89 (94.7%)	116 (91.3%)	205 (92.8%)
> 28	89 (94.7%)	113 (89.0%)	202 (91.4%)
> 42	83 (88.3%)	100 (78.7%)	183 (82.8%)
> 56	78 (83.0%)	84 (66.1%)	162 (73.3%)
> 70	66 (70.2%)	73 (57.5%)	139 (62.9%)
> 84	64 (68.1%)	69 (54.3%)	133 (60.2%)
> 112	51 (54.3%)	56 (44.1%)	107 (48.4%)
> 140	43 (45.7%)	39 (30.7%)	82 (37.1%)
> 168	26 (27.7%)	24 (18.9%)	50 (22.6%)
> 182	8 (8.5%)	6 (4.7%)	14 (6.3%)
Overall Mean	117.7	98.8	106.9
Minimum	2	2	2
Maximum	194	197	197

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Children

Days	Paroxetine (N=49)
>= 1	49 (100.0%)
> 7	49 (100.0%)
> 14	49 (100.0%)
> 21	49 (100.0%)
> 28	49 (100.0%)
> 42	49 (100.0%)
> 56	49 (100.0%)
> 70	48 (98.0%)
> 84	46 (93.9%)
> 112	42 (85.7%)
> 140	30 (61.2%)
> 168	25 (51.0%)
> 182	24 (49.0%)
> 196	24 (49.0%)
> 224	20 (40.8%)
> 238	10 (20.4%)
> 252	2 (4.1%)
> 266	0 (0.0%)
Overall Mean	178.8
Minimum	58
Maximum	265

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Adolescents

Days	Paroxetine (N=45)
>= 1	45 (100.0%)
> 7	45 (100.0%)
> 14	45 (100.0%)
> 21	45 (100.0%)
> 28	45 (100.0%)
> 42	45 (100.0%)
> 56	45 (100.0%)
> 70	45 (100.0%)
> 84	43 (95.6%)
> 112	39 (86.7%)
> 140	35 (77.8%)
> 168	30 (66.7%)
> 182	26 (57.8%)
> 196	20 (44.4%)
> 224	16 (35.6%)
> 238	6 (13.3%)
> 252	2 (4.4%)
> 266	0 (0.0%)
Overall Mean	185.7
Minimum	73
Maximum	264

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Total

Days	Paroxetine (N=94)
>= 1	94 (100.0%)
> 7	94 (100.0%)
> 14	94 (100.0%)
> 21	94 (100.0%)
> 28	94 (100.0%)
> 42	94 (100.0%)
> 56	94 (100.0%)
> 70	93 (98.9%)
> 84	89 (94.7%)
> 112	81 (86.2%)
> 140	65 (69.1%)
> 168	55 (58.5%)
> 182	50 (53.2%)
> 196	44 (46.8%)
> 224	36 (38.3%)
> 238	16 (17.0%)
> 252	4 (4.3%)
> 266	0 (0.0%)
Overall Mean	182.1
Minimum	58
Maximum	265

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Children

Days	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
>= 1	49 (100.0%)	70 (100.0%)	119 (100.0%)
> 7	48 (98.0%)	69 (98.6%)	117 (98.3%)
> 14	47 (95.9%)	67 (95.7%)	114 (95.8%)
> 21	46 (93.9%)	65 (92.9%)	111 (93.3%)
> 28	46 (93.9%)	63 (90.0%)	109 (91.6%)
> 42	43 (87.8%)	56 (80.0%)	99 (83.2%)
> 56	41 (83.7%)	48 (68.6%)	89 (74.8%)
> 70	32 (65.3%)	43 (61.4%)	75 (63.0%)
> 84	29 (59.2%)	37 (52.9%)	66 (55.5%)
> 112	24 (49.0%)	29 (41.4%)	53 (44.5%)
> 140	23 (46.9%)	23 (32.9%)	46 (38.7%)
> 168	17 (34.7%)	15 (21.4%)	32 (26.9%)
> 182	9 (18.4%)	8 (11.4%)	17 (14.3%)
> 196	2 (4.1%)	2 (2.9%)	4 (3.4%)
Overall Mean	117.6	100.6	107.6
Minimum	2	2	2
Maximum	210	201	210

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Adolescents

Days	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
>= 1	45 (100.0%)	57 (100.0%)	102 (100.0%)
> 7	44 (97.8%)	56 (98.2%)	100 (98.0%)
> 14	44 (97.8%)	53 (93.0%)	97 (95.1%)
> 21	43 (95.6%)	52 (91.2%)	95 (93.1%)
> 28	43 (95.6%)	51 (89.5%)	94 (92.2%)
> 42	40 (88.9%)	45 (78.9%)	85 (83.3%)
> 56	37 (82.2%)	39 (68.4%)	76 (74.5%)
> 70	35 (77.8%)	33 (57.9%)	68 (66.7%)
> 84	35 (77.8%)	33 (57.9%)	68 (66.7%)
> 112	28 (62.2%)	27 (47.4%)	55 (53.9%)
> 140	21 (46.7%)	18 (31.6%)	39 (38.2%)
> 168	14 (31.1%)	12 (21.1%)	26 (25.5%)
> 182	9 (20.0%)	6 (10.5%)	15 (14.7%)
> 196	2 (4.4%)	1 (1.8%)	3 (2.9%)
Overall Mean	126.7	103.1	113.5
Minimum	2	2	2
Maximum	211	202	211

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Total

Days	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
>= 1	94 (100.0%)	127 (100.0%)	221 (100.0%)
> 7	92 (97.9%)	125 (98.4%)	217 (98.2%)
> 14	91 (96.8%)	120 (94.5%)	211 (95.5%)
> 21	89 (94.7%)	117 (92.1%)	206 (93.2%)
> 28	89 (94.7%)	114 (89.8%)	203 (91.9%)
> 42	83 (88.3%)	101 (79.5%)	184 (83.3%)
> 56	78 (83.0%)	87 (68.5%)	165 (74.7%)
> 70	67 (71.3%)	76 (59.8%)	143 (64.7%)
> 84	64 (68.1%)	70 (55.1%)	134 (60.6%)
> 112	52 (55.3%)	56 (44.1%)	108 (48.9%)
> 140	44 (46.8%)	41 (32.3%)	85 (38.5%)
> 168	31 (33.0%)	27 (21.3%)	58 (26.2%)
> 182	18 (19.1%)	14 (11.0%)	32 (14.5%)
> 196	4 (4.3%)	3 (2.4%)	7 (3.2%)
Overall Mean	121.9	101.7	110.3
Minimum	2	2	2
Maximum	211	202	211

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Children

Days	Paroxetine (N=49)
>= 1	49 (100.0%)
> 7	49 (100.0%)
> 14	49 (100.0%)
> 21	49 (100.0%)
> 28	49 (100.0%)
> 42	49 (100.0%)
> 56	49 (100.0%)
> 70	48 (98.0%)
> 84	47 (95.9%)
> 112	43 (87.8%)
> 140	36 (73.5%)
> 168	28 (57.1%)
> 182	26 (53.1%)
> 196	25 (51.0%)
> 224	21 (42.9%)
> 238	18 (36.7%)
> 252	14 (28.6%)
> 266	8 (16.3%)
> 280	1 (2.0%)
> 294	0 (0.0%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	193.6
Minimum	65
Maximum	282

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Adolescents

Days	Paroxetine (N=45)
>= 1	45 (100.0%)
> 7	45 (100.0%)
> 14	45 (100.0%)
> 21	45 (100.0%)
> 28	45 (100.0%)
> 42	45 (100.0%)
> 56	45 (100.0%)
> 70	45 (100.0%)
> 84	44 (97.8%)
> 112	41 (91.1%)
> 140	39 (86.7%)
> 168	34 (75.6%)
> 182	31 (68.9%)
> 196	26 (57.8%)
> 224	20 (44.4%)
> 238	16 (35.6%)
> 252	11 (24.4%)
> 266	6 (13.3%)
> 280	3 (6.7%)
> 294	1 (2.2%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	206.0
Minimum	74
Maximum	304

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Total

Days	Paroxetine (N=94)
>= 1	94 (100.0%)
> 7	94 (100.0%)
> 14	94 (100.0%)
> 21	94 (100.0%)
> 28	94 (100.0%)
> 42	94 (100.0%)
> 56	94 (100.0%)
> 70	93 (98.9%)
> 84	91 (96.8%)
> 112	84 (89.4%)
> 140	75 (79.8%)
> 168	62 (66.0%)
> 182	57 (60.6%)
> 196	51 (54.3%)
> 224	41 (43.6%)
> 238	34 (36.2%)
> 252	25 (26.6%)
> 266	14 (14.9%)
> 280	4 (4.3%)
> 294	1 (1.1%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	199.5
Minimum	65
Maximum	304

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	61	11.1	4.51
Week 2	58	16.0	6.47
Week 3	56	20.0	7.86
Week 4	53	21.5	8.86
Week 6	52	22.9	9.57
Week 8	49	23.5	9.03
Week 12	43	24.4	9.83
Week 16	38	25.8	11.77
Week 20	32	26.4	11.93
Week 24	28	25.7	12.30
Overall Mean	61	20.0	7.33

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	55	10.9	3.48
Week 2	51	17.8	5.77
Week 3	51	22.0	7.22
Week 4	51	23.5	7.70
Week 6	48	24.8	8.50
Week 8	45	26.2	8.06
Week 12	41	27.1	8.73
Week 16	37	27.3	8.04
Week 20	32	28.4	10.19
Week 24	27	28.9	10.50
Overall Mean	55	22.0	6.70

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	116	11.0	4.04
Week 2	109	16.9	6.19
Week 3	107	20.9	7.59
Week 4	104	22.5	8.33
Week 6	100	23.8	9.08
Week 8	94	24.8	8.64
Week 12	84	25.7	9.35
Week 16	75	26.5	10.07
Week 20	64	27.4	11.06
Week 24	55	27.3	11.46
Overall Mean	116	20.9	7.08

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	58	10.3	1.84
Week 2	51	17.5	5.60
Week 3	55	21.5	7.56
Week 4	52	24.4	9.78
Week 6	50	25.8	10.71
Week 8	44	27.5	11.64
Week 12	31	27.7	11.17
Week 16	24	27.1	11.22
Week 20	19	24.7	11.24
Week 24	15	23.3	10.47
Overall Mean	58	21.0	7.41

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	47	10.6	2.47
Week 2	45	19.6	5.20
Week 3	43	26.0	6.95
Week 4	42	31.2	10.64
Week 6	41	35.4	11.20
Week 8	37	35.7	11.91
Week 12	29	37.2	13.06
Week 16	27	35.2	13.41
Week 20	13	32.3	14.23
Week 24	10	34.0	12.65
Overall Mean	47	27.0	8.40

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	105	10.5	2.14
Week 2	96	18.4	5.49
Week 3	98	23.5	7.61
Week 4	94	27.4	10.67
Week 6	91	30.1	11.88
Week 8	81	31.2	12.39
Week 12	60	32.3	12.94
Week 16	51	31.4	12.96
Week 20	32	27.8	12.89
Week 24	25	27.6	12.34
Overall Mean	105	23.7	8.38

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	119	10.8	3.48
Week 2	109	16.7	6.09
Week 3	111	20.7	7.71
Week 4	105	23.0	9.40
Week 6	102	24.3	10.20
Week 8	93	25.4	10.48
Week 12	74	25.8	10.47
Week 16	62	26.3	11.49
Week 20	51	25.8	11.59
Week 24	43	24.9	11.62
Overall Mean	119	20.5	7.36

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	102	10.8	3.05
Week 2	96	18.6	5.55
Week 3	94	23.8	7.35
Week 4	93	27.0	9.87
Week 6	89	29.7	11.12
Week 8	82	30.5	10.99
Week 12	70	31.3	11.79
Week 16	64	30.6	11.25
Week 20	45	29.6	11.47
Week 24	37	30.3	11.18
Overall Mean	102	24.3	7.89

BRL 29060 - 716
Interim Output
Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	221	10.8	3.28
Week 2	205	17.6	5.91
Week 3	205	22.1	7.69
Week 4	198	24.8	9.81
Week 6	191	26.8	10.94
Week 8	175	27.8	10.99
Week 12	144	28.5	11.42
Week 16	126	28.5	11.53
Week 20	96	27.6	11.63
Week 24	80	27.4	11.66
Overall Mean	221	22.2	7.83

BRL 29060 - 716
Interim Output
Table 13.10.7

Mean Daily Dosage (mg/day) of Paroxetine at Week 24 LOCF Endpoint for CY-BOCS/CDRS-R Total Score
by Primary Diagnosis and Age Group
Intention-To-Treat Population

Primary Diagnosis	Age Group	N	Mean	Std Dev
MDD (CDRS-R)	Children	41	24.9	12.27
	Adolescents	41	28.0	10.77
	Total	82	26.5	11.59
OCD (CY-BOCS)	Children	24	21.7	8.68
	Adolescents	20	30.5	13.56
	Total	44	25.7	11.89

Summary Statistics for the visit making up each patient’s LOCF assessment

11 Source Tables: Efficacy Results

BRL 29060 - 716
Interim Output
Table 14.1.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline in CDRS-R Total Score by Age Group and Acute Study Treatment Group
Intention-To-Treat Population with Primary Diagnosis of MDD

		Paroxetine (N=50)			Placebo (N=66)			Total (N=116)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Baseline	N	25	25	50	36	30	66	61	55	116
	MEAN	58.5	62.2	60.4	59.7	61.3	60.4	59.2	61.7	60.4
	MEDIAN	58.0	59.0	58.0	58.5	61.0	60.5	58.0	60.0	59.0
	STDDEV	6.80	11.65	9.63	8.04	7.92	7.97	7.53	9.71	8.68
	MINIMUM	47	45	45	45	46	45	45	45	45
	MAXIMUM	78	84	84	82	87	87	82	87	87
	MISSING	0	0	0	0	0	0	0	0	0
Week 24	N	13	14	27	9	13	22	22	27	49
	MEAN	24.2	29.1	26.7	25.9	25.5	25.6	24.9	27.3	26.2
	MEDIAN	24.0	23.5	24.0	24.0	23.0	23.0	24.0	23.0	23.0
	STDDEV	4.36	12.74	9.80	6.92	8.54	7.74	5.46	10.87	8.86
	MINIMUM	18	18	18	18	20	18	18	18	18
	MAXIMUM	33	61	61	41	51	51	41	61	61
	MISSING	0	0	0	2	0	2	2	0	2
Week 24 LOCF	N	15	21	36	26	20	46	41	41	82
	MEAN	25.2	35.6	31.3	33.7	37.4	35.3	30.6	36.5	33.5
	MEDIAN	26.0	31.0	26.5	30.0	28.5	29.5	28.0	30.0	28.0
	STDDEV	4.87	16.42	13.81	12.94	19.90	16.24	11.41	17.99	15.26
	MINIMUM	18	18	18	18	20	18	18	18	18
	MAXIMUM	34	72	72	62	86	86	62	86	86
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Baseline to Week 24	N	13	14	27	9	13	22	22	27	49
	MEAN	-36.7	-30.4	-33.4	-33.2	-33.5	-33.4	-35.3	-31.9	-33.4
	MEDIAN	-35.0	-30.0	-34.0	-31.0	-36.0	-35.5	-34.5	-35.0	-35.0
	STDDEV	8.19	17.61	14.01	9.59	10.01	9.60	8.74	14.27	12.11
	MINIMUM	-52	-54	-54	-51	-46	-51	-52	-54	-54
	MAXIMUM	-24	2	2	-22	-8	-8	-22	2	2
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Baseline to Week 24 LOCF Endpoint	N	15	21	36	26	20	46	41	41	82
	MEAN	-35.1	-24.4	-28.9	-26.0	-24.2	-25.2	-29.3	-24.3	-26.8
	MEDIAN	-34.0	-26.0	-31.0	-25.0	-29.0	-26.0	-31.0	-26.0	-29.5
	STDDEV	8.83	19.03	16.34	14.65	16.18	15.18	13.46	17.48	15.71
	MINIMUM	-52	-54	-54	-51	-46	-51	-52	-54	-54
	MAXIMUM	-20	13	13	1	3	3	1	13	13
	MISSING	0	0	0	0	0	0	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.1.1d

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CDRS-R Total Score by Age Group
Pure Paroxetine Population with Primary Diagnosis of MDD

		Paroxetine (N=50)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	25	25	50
	MEAN	33.2	34.5	33.9
	MEDIAN	31.0	31.0	31.0
	STDDEV	11.95	12.72	12.23
	MINIMUM	18	19	18
	MAXIMUM	63	71	71
	MISSING	0	0	0
Week 24	N	13	14	27
	MEAN	24.2	29.1	26.7
	MEDIAN	24.0	23.5	24.0
	STDDEV	4.36	12.74	9.80
	MINIMUM	18	18	18
	MAXIMUM	33	61	61
	MISSING	0	0	0
Week 24 LOCF	N	15	21	36
	MEAN	25.2	35.6	31.3
	MEDIAN	26.0	31.0	26.5
	STDDEV	4.87	16.42	13.81
	MINIMUM	18	18	18
	MAXIMUM	34	72	72
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24	N	13	14	27
	MEAN	-8.2	-5.6	-6.8
	MEDIAN	-1.0	-6.5	-2.0
	STDDEV	13.87	15.66	14.60
	MINIMUM	-37	-30	-37
	MAXIMUM	3	30	30
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	15	21	36
	MEAN	-8.3	0.7	-3.1
	MEDIAN	-2.0	-1.0	-1.5
	STDDEV	12.89	18.29	16.67
	MINIMUM	-37	-30	-37
	MAXIMUM	3	33	33
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.1.1e

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CDRS-R Total Score by Age Group
Intention-to-Treat Population with Primary Diagnosis of MDD and Acute Study Treatment Group of Placebo

		Placebo (N=66)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	36	29	65
	MEAN	32.7	36.6	34.4
	MEDIAN	31.5	35.0	33.0
	STDDEV	10.47	12.83	11.65
	MINIMUM	18	18	18
	MAXIMUM	51	65	65
	MISSING	0	1	1
Week 24	N	9	13	22
	MEAN	25.9	25.5	25.6
	MEDIAN	24.0	23.0	23.0
	STDDEV	6.92	8.54	7.74
	MINIMUM	18	20	18
	MAXIMUM	41	51	51
	MISSING	2	0	2
Week 24 LOCF	N	26	20	46
	MEAN	33.7	37.4	35.3
	MEDIAN	30.0	28.5	29.5
	STDDEV	12.94	19.90	16.24
	MINIMUM	18	20	18
	MAXIMUM	62	86	86
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24	N	9	13	22
	MEAN	-7.0	-5.2	-6.0
	MEDIAN	-2.0	-7.0	-4.5
	STDDEV	10.01	14.97	12.93
	MINIMUM	-25	-31	-31
	MAXIMUM	3	29	29
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	26	19	45
	MEAN	0.5	1.1	0.7
	MEDIAN	-1.0	1.0	0.0
	STDDEV	14.81	18.23	16.15
	MINIMUM	-25	-31	-31
	MAXIMUM	38	45	45
	MISSING	0	1	1

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.2.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline in CY-BOCS Total Score by Age Group and Acute Study Treatment Group
Intention-to-Treat Population with Primary Diagnosis of OCD

		Paroxetine (N=44)			Placebo (N=61)			Total (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Baseline	N	24	20	44	34	27	61	58	47	105
	MEAN	23.9	26.6	25.1	25.1	24.4	24.8	24.6	25.3	24.9
	MEDIAN	23.0	25.0	24.0	25.0	25.0	25.0	24.0	25.0	24.0
	STDDEV	4.62	4.63	4.76	5.23	4.54	4.91	4.98	4.65	4.83
	MINIMUM	18	20	18	16	16	16	16	16	16
	MAXIMUM	34	36	36	37	37	37	37	37	37
	MISSING	0	0	0	0	0	0	0	0	0
Week 24	N	8	6	14	5	4	9	13	10	23
	MEAN	8.5	7.2	7.9	7.8	8.0	7.9	8.2	7.5	7.9
	MEDIAN	11.0	7.5	9.0	8.0	7.0	8.0	10.0	7.5	8.0
	STDDEV	7.07	4.45	5.92	6.50	7.48	6.49	6.58	5.46	6.00
	MINIMUM	0	0	0	0	0	0	0	0	0
	MAXIMUM	17	13	17	16	18	18	17	18	18
	MISSING	1	0	1	1	0	1	2	0	2
Week 24 LOCF	N	11	9	20	13	11	24	24	20	44
	MEAN	7.5	9.0	8.2	14.2	16.5	15.3	11.1	13.2	12.0
	MEDIAN	10.0	8.0	9.0	16.0	18.0	16.5	12.5	11.5	12.5
	STDDEV	7.16	8.38	7.56	7.50	9.47	8.35	7.97	9.57	8.69
	MINIMUM	0	0	0	0	0	0	0	0	0
	MAXIMUM	17	28	28	24	34	34	24	34	34
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Baseline to Week 24	N	8	6	14	5	4	9	13	10	23
	MEAN	-15.3	-19.8	-17.2	-12.6	-15.0	-13.7	-14.2	-17.9	-15.8
	MEDIAN	-14.0	-19.0	-16.5	-10.0	-15.5	-10.0	-14.0	-19.0	-14.0
	STDDEV	6.50	7.52	7.07	6.91	8.29	7.16	6.51	7.78	7.16
	MINIMUM	-25	-29	-29	-20	-23	-23	-25	-29	-29
	MAXIMUM	-8	-10	-8	-6	-6	-6	-6	-6	-6
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Baseline to Week 24 LOCF Endpoint	N	11	9	20	13	11	24	24	20	44
	MEAN	-17.3	-18.4	-17.8	-6.5	-7.8	-7.1	-11.4	-12.6	-12.0
	MEDIAN	-19.0	-19.0	-19.0	-6.0	-6.0	-6.0	-10.5	-10.0	-10.0
	STDDEV	6.66	8.65	7.43	7.38	7.99	7.52	8.83	9.72	9.15
	MINIMUM	-27	-29	-29	-20	-23	-23	-27	-29	-29
	MAXIMUM	-8	-2	-2	2	3	3	2	3	3
	MISSING	0	0	0	0	0	0	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.2.1d

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CY-BOCS Total Score by Age Group
Pure Paroxetine Population with Primary Diagnosis of OCD

		Paroxetine (N=44)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	24	20	44
	MEAN	12.0	17.0	14.3
	MEDIAN	12.5	18.0	14.0
	STDDEV	8.56	7.67	8.45
	MINIMUM	0	3	0
	MAXIMUM	34	34	34
	MISSING	0	0	0
Week 24	N	8	6	14
	MEAN	8.5	7.2	7.9
	MEDIAN	11.0	7.5	9.0
	STDDEV	7.07	4.45	5.92
	MINIMUM	0	0	0
	MAXIMUM	17	13	17
	MISSING	1	0	1
Week 24 LOCF	N	11	9	20
	MEAN	7.5	9.0	8.2
	MEDIAN	10.0	8.0	9.0
	STDDEV	7.16	8.38	7.56
	MINIMUM	0	0	0
	MAXIMUM	17	28	28
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24	N	8	6	14
	MEAN	0.4	-6.8	-2.7
	MEDIAN	-0.5	-7.0	-1.5
	STDDEV	2.45	3.37	4.61
	MINIMUM	-2	-10	-10
	MAXIMUM	4	-1	4
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	11	9	20
	MEAN	-1.5	-7.2	-4.1
	MEDIAN	0.0	-8.0	-2.0
	STDDEV	6.46	3.56	5.97
	MINIMUM	-20	-12	-20
	MAXIMUM	4	-1	4
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.2.1e

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CY-BOCS Total Score by Age Group
Intention-to-Treat Population with Primary Diagnosis of OCD and Acute Study Treatment Group of Placebo

		Placebo (N=61)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	33	27	60
	MEAN	16.5	17.7	17.0
	MEDIAN	16.0	19.0	17.5
	STDDEV	8.05	7.23	7.65
	MINIMUM	0	0	0
	MAXIMUM	33	36	36
	MISSING	1	0	1
Week 24	N	5	4	9
	MEAN	7.8	8.0	7.9
	MEDIAN	8.0	7.0	8.0
	STDDEV	6.50	7.48	6.49
	MINIMUM	0	0	0
	MAXIMUM	16	18	18
	MISSING	1	0	1
Week 24 LOCF	N	13	11	24
	MEAN	14.2	16.5	15.3
	MEDIAN	16.0	18.0	16.5
	STDDEV	7.50	9.47	8.35
	MINIMUM	0	0	0
	MAXIMUM	24	34	34
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24	N	5	4	9
	MEAN	-3.2	-2.5	-2.9
	MEDIAN	-3.0	-2.5	-3.0
	STDDEV	9.31	4.20	7.08
	MINIMUM	-15	-7	-15
	MAXIMUM	10	2	10
	MISSING	0	0	0
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	13	11	24
	MEAN	-0.4	-1.2	-0.8
	MEDIAN	0.0	-1.0	-1.0
	STDDEV	6.79	4.17	5.64
	MINIMUM	-15	-7	-15
	MAXIMUM	10	6	10
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																							
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	4	19.0	2	10.0	6	14.6	7	21.2	4	15.4	11	18.6	11	20.4	6	13.0	17	17.0				
	Much Improved (2)	6	28.6	3	15.0	9	22.0	12	36.4	5	19.2	17	28.8	18	33.3	8	17.4	26	26.0				
	Minimally improved (3)	8	38.1	10	50.0	18	43.9	10	30.3	8	30.8	18	30.5	18	33.3	18	39.1	36	36.0				
	No change (4)	3	14.3	2	10.0	5	12.2	2	6.1	9	34.6	11	18.6	5	9.3	11	23.9	16	16.0				
	Minimally worse (5)	0	.	3	15.0	3	7.3	1	3.0	0	.	1	1.7	1	1.9	3	6.5	4	4.0				
	Much worse (6)	0	.	0	.	0	.	1	3.0	0	.	1	1.7	1	1.9	0	.	1	1.0				
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	21	100.0	20	100.0	41	100.0	33	100.0	26	100.0	59	100.0	54	100.0	46	100.0	100	100.0				
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 2	Very much improved (1)	6	28.6	4	18.2	10	23.3	11	34.4	4	16.0	15	26.3	17	32.1	8	17.0	25	25.0		
	Much Improved (2)	4	19.0	7	31.8	11	25.6	9	28.1	11	44.0	20	35.1	13	24.5	18	38.3	31	31.0		
	Minimally improved (3)	9	42.9	10	45.5	19	44.2	7	21.9	6	24.0	13	22.8	16	30.2	16	34.0	32	32.0		
	No change (4)	2	9.5	1	4.5	3	7.0	2	6.3	4	16.0	6	10.5	4	7.5	5	10.6	9	9.0		
	Minimally worse (5)	0	.	0	.	0	.	1	3.1	0	.	1	1.8	1	1.9	0	.	1	1.0		
	Much worse (6)	0	.	0	.	0	.	2	6.3	0	.	2	3.5	2	3.8	0	.	2	2.0		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	21	100.0	22	100.0	43	100.0	32	100.0	25	100.0	57	100.0	53	100.0	47	100.0	100	100.0		
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	5	25.0	4	16.7	9	20.5	10	32.3	3	13.6	13	24.5	15	29.4	7	15.2	22	22.7		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 3	Much Improved (2)	9	45.0	11	45.8	20	45.5	13	41.9	11	50.0	24	45.3	22	43.1	22	47.8	44	45.4		
	Minimally improved (3)	5	25.0	7	29.2	12	27.3	7	22.6	4	18.2	11	20.8	12	23.5	11	23.9	23	23.7		
	No change (4)	1	5.0	2	8.3	3	6.8	0	.	3	13.6	3	5.7	1	2.0	5	10.9	6	6.2		
	Minimally worse (5)	0	.	0	.	0	.	1	3.2	1	4.5	2	3.8	1	2.0	1	2.2	2	2.1		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	20	100.0	24	100.0	44	100.0	31	100.0	22	100.0	53	100.0	51	100.0	46	100.0	97	100.0		
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	8	34.8	4	18.2	12	26.7	12	38.7	4	16.7	16	29.1	20	37.0	8	17.4	28	28.0		
	Much Improved (2)	7	30.4	13	59.1	20	44.4	9	29.0	11	45.8	20	36.4	16	29.6	24	52.2	40	40.0		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 4	Minimally improved (3)	7	30.4	2	9.1	9	20.0	4	12.9	5	20.8	9	16.4	11	20.4	7	15.2	18	18.0		
	No change (4)	1	4.3	2	9.1	3	6.7	3	9.7	3	12.5	6	10.9	4	7.4	5	10.9	9	9.0		
	Minimally worse (5)	0	.	1	4.5	1	2.2	3	9.7	0	.	3	5.5	3	5.6	1	2.2	4	4.0		
	Much worse (6)	0	.	0	.	0	.	0	.	1	4.2	1	1.8	0	.	1	2.2	1	1.0		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	23	100.0	22	100.0	45	100.0	31	100.0	24	100.0	55	100.0	54	100.0	46	100.0	100	100.0		
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	7	35.0	5	25.0	12	30.0	11	40.7	6	30.0	17	36.2	18	38.3	11	27.5	29	33.3		
	Much Improved (2)	8	40.0	11	55.0	19	47.5	11	40.7	9	45.0	20	42.6	19	40.4	20	50.0	39	44.8		
	Minimally improved (3)	4	20.0	3	15.0	7	17.5	3	11.1	3	15.0	6	12.8	7	14.9	6	15.0	13	14.9		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit																					
Week 8	No change (4)	1	5.0	1	5.0	2	5.0	2	7.4	2	10.0	4	8.5	3	6.4	3	7.5	6	6.9		
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	20	100.0	20	100.0	40	100.0	27	100.0	20	100.0	47	100.0	47	100.0	40	100.0	87	100.0		
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	5	29.4	8	42.1	13	36.1	6	27.3	5	27.8	11	27.5	11	28.2	13	35.1	24	31.6		
	Much Improved (2)	9	52.9	8	42.1	17	47.2	11	50.0	10	55.6	21	52.5	20	51.3	18	48.6	38	50.0		
	Minimally improved (3)	0	.	0	.	0	.	0	.	2	11.1	2	5.0	0	.	2	5.4	2	2.6		
	No change (4)	2	11.8	1	5.3	3	8.3	5	22.7	1	5.6	6	15.0	7	17.9	2	5.4	9	11.8		
	Minimally worse (5)	1	5.9	1	5.3	2	5.6	0	.	0	.	0	.	1	2.6	1	2.7	2	2.6		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
Visit																							
Week 12	Much worse (6)	0	.	1	5.3	1	2.8	0	.	0	.	0	.	0	.	1	2.7	1	1.3				
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	17	100.0	19	100.0	36	100.0	22	100.0	18	100.0	40	100.0	39	100.0	37	100.0	76	100.0				
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Very much improved (1)	6	40.0	7	38.9	13	39.4	6	28.6	4	25.0	10	27.0	12	33.3	11	32.4	23	32.9				
	Much Improved (2)	7	46.7	5	27.8	12	36.4	12	57.1	8	50.0	20	54.1	19	52.8	13	38.2	32	45.7				
	Minimally improved (3)	1	6.7	4	22.2	5	15.2	0	.	2	12.5	2	5.4	1	2.8	6	17.6	7	10.0				
	No change (4)	1	6.7	2	11.1	3	9.1	3	14.3	1	6.3	4	10.8	4	11.1	3	8.8	7	10.0				
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Much worse (6)	0	.	0	.	0	.	0	.	1	6.3	1	2.7	0	.	1	2.9	1	1.4				
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total																				
Week 16		15	100.0	18	100.0	33	100.0	21	100.0	16	100.0	37	100.0	36	100.0	34	100.0	70	100.0		
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	6	46.2	6	42.9	12	44.4	6	35.3	6	46.2	12	40.0	12	40.0	12	44.4	24	42.1		
	Much Improved (2)	7	53.8	6	42.9	13	48.1	8	47.1	5	38.5	13	43.3	15	50.0	11	40.7	26	45.6		
	Minimally improved (3)	0	.	1	7.1	1	3.7	0	.	1	7.7	1	3.3	0	.	2	7.4	2	3.5		
	No change (4)	0	.	0	.	0	.	2	11.8	0	.	2	6.7	2	6.7	0	.	2	3.5		
	Minimally worse (5)	0	.	1	7.1	1	3.7	1	5.9	0	.	1	3.3	1	3.3	1	3.7	2	3.5		
	Much worse (6)	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	3.7	1	1.8		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	13	100.0	14	100.0	27	100.0	17	100.0	13	100.0	30	100.0	30	100.0	27	100.0	57	100.0		
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 24	Very much improved (1)	8	61.5	7	50.0	15	55.6	3	30.0	6	46.2	9	39.1	11	47.8	13	48.1	24	48.0		
	Much Improved (2)	5	38.5	5	35.7	10	37.0	6	60.0	6	46.2	12	52.2	11	47.8	11	40.7	22	44.0		
	Minimally improved (3)	0	.	1	7.1	1	3.7	1	10.0	0	.	1	4.3	1	4.3	1	3.7	2	4.0		
	No change (4)	0	.	1	7.1	1	3.7	0	.	1	7.7	1	4.3	0	.	2	7.4	2	4.0		
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	13	100.0	14	100.0	27	100.0	10	100.0	13	100.0	23	100.0	23	100.0	27	100.0	50	100.0		
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	9	37.5	9	36.0	18	36.7	9	25.7	6	20.7	15	23.4	18	30.5	15	27.8	33	29.2		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 24 LOCF	Much Improved (2)	10	41.7	6	24.0	16	32.7	16	45.7	11	37.9	27	42.2	26	44.1	17	31.5	43	38.1		
	Minimally improved (3)	3	12.5	5	20.0	8	16.3	5	14.3	4	13.8	9	14.1	8	13.6	9	16.7	17	15.0		
	No change (4)	2	8.3	3	12.0	5	10.2	4	11.4	4	13.8	8	12.5	6	10.2	7	13.0	13	11.5		
	Minimally worse (5)	0	.	0	.	0	.	1	2.9	2	6.9	3	4.7	1	1.7	2	3.7	3	2.7		
	Much worse (6)	0	.	1	4.0	1	2.0	0	.	2	6.9	2	3.1	0	.	3	5.6	3	2.7		
	Very much worse (7)	0	.	1	4.0	1	2.0	0	.	0	.	0	.	0	.	1	1.9	1	0.9		
	Total	24	100.0	25	100.0	49	100.0	35	100.0	29	100.0	64	100.0	59	100.0	54	100.0	113	100.0		

BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
Visit																							
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Very much improved (1)	4	21.1	2	10.5	6	15.8	2	7.1	0	.	2	3.9	6	12.8	2	4.8	8	9.0				
	Much Improved (2)	5	26.3	4	21.1	9	23.7	9	32.1	1	4.3	10	19.6	14	29.8	5	11.9	19	21.3				
	Minimally improved (3)	4	21.1	5	26.3	9	23.7	10	35.7	11	47.8	21	41.2	14	29.8	16	38.1	30	33.7				
	No change (4)	5	26.3	6	31.6	11	28.9	5	17.9	10	43.5	15	29.4	10	21.3	16	38.1	26	29.2				
	Minimally worse (5)	1	5.3	2	10.5	3	7.9	1	3.6	1	4.3	2	3.9	2	4.3	3	7.1	5	5.6				
	Much worse (6)	0	.	0	.	0	.	1	3.6	0	.	1	2.0	1	2.1	0	.	1	1.1				
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	19	100.0	19	100.0	38	100.0	28	100.0	23	100.0	51	100.0	47	100.0	42	100.0	89	100.0				
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 2	Very much improved (1)	2	11.8	2	12.5	4	12.1	5	17.2	0	.	5	9.4	7	15.2	2	5.0	9	10.5		
	Much Improved (2)	6	35.3	5	31.3	11	33.3	9	31.0	7	29.2	16	30.2	15	32.6	12	30.0	27	31.4		
	Minimally improved (3)	5	29.4	5	31.3	10	30.3	8	27.6	11	45.8	19	35.8	13	28.3	16	40.0	29	33.7		
	No change (4)	3	17.6	4	25.0	7	21.2	5	17.2	5	20.8	10	18.9	8	17.4	9	22.5	17	19.8		
	Minimally worse (5)	1	5.9	0	.	1	3.0	2	6.9	1	4.2	3	5.7	3	6.5	1	2.5	4	4.7		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	17	100.0	16	100.0	33	100.0	29	100.0	24	100.0	53	100.0	46	100.0	40	100.0	86	100.0		
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	5	26.3	3	20.0	8	23.5	5	15.6	2	9.5	7	13.2	10	19.6	5	13.9	15	17.2		

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BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit																					
Week 3	Much Improved (2)	6	31.6	4	26.7	10	29.4	13	40.6	11	52.4	24	45.3	19	37.3	15	41.7	34	39.1		
	Minimally improved (3)	6	31.6	5	33.3	11	32.4	11	34.4	7	33.3	18	34.0	17	33.3	12	33.3	29	33.3		
	No change (4)	1	5.3	2	13.3	3	8.8	3	9.4	1	4.8	4	7.5	4	7.8	3	8.3	7	8.0		
	Minimally worse (5)	0	.	1	6.7	1	2.9	0	.	0	.	0	.	0	.	1	2.8	1	1.1		
	Much worse (6)	1	5.3	0	.	1	2.9	0	.	0	.	0	.	1	2.0	0	.	1	1.1		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	19	100.0	15	100.0	34	100.0	32	100.0	21	100.0	53	100.0	51	100.0	36	100.0	87	100.0		
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	7	30.4	3	15.8	10	23.8	7	25.0	2	8.3	9	17.3	14	27.5	5	11.6	19	20.2		
	Much Improved (2)	8	34.8	8	42.1	16	38.1	11	39.3	12	50.0	23	44.2	19	37.3	20	46.5	39	41.5		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit																					
Week 4	Minimally improved (3)	7	30.4	6	31.6	13	31.0	6	21.4	6	25.0	12	23.1	13	25.5	12	27.9	25	26.6		
	No change (4)	0	.	2	10.5	2	4.8	4	14.3	4	16.7	8	15.4	4	7.8	6	14.0	10	10.6		
	Minimally worse (5)	1	4.3	0	.	1	2.4	0	.	0	.	0	.	1	2.0	0	.	1	1.1		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	23	100.0	19	100.0	42	100.0	28	100.0	24	100.0	52	100.0	51	100.0	43	100.0	94	100.0		
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	7	35.0	6	35.3	13	35.1	8	38.1	4	25.0	12	32.4	15	36.6	10	30.3	25	33.8		
	Much Improved (2)	6	30.0	6	35.3	12	32.4	6	28.6	5	31.3	11	29.7	12	29.3	11	33.3	23	31.1		
	Minimally improved (3)	5	25.0	4	23.5	9	24.3	5	23.8	5	31.3	10	27.0	10	24.4	9	27.3	19	25.7		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit																					
Week 8	No change (4)	0	.	1	5.9	1	2.7	1	4.8	1	6.3	2	5.4	1	2.4	2	6.1	3	4.1		
	Minimally worse (5)	2	10.0	0	.	2	5.4	1	4.8	0	.	1	2.7	3	7.3	0	.	3	4.1		
	Much worse (6)	0	.	0	.	0	.	0	.	1	6.3	1	2.7	0	.	1	3.0	1	1.4		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	20	100.0	17	100.0	37	100.0	21	100.0	16	100.0	37	100.0	41	100.0	33	100.0	74	100.0		
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	7	63.6	3	27.3	10	45.5	7	43.8	5	45.5	12	44.4	14	51.9	8	36.4	22	44.9		
	Much Improved (2)	3	27.3	5	45.5	8	36.4	4	25.0	4	36.4	8	29.6	7	25.9	9	40.9	16	32.7		
	Minimally improved (3)	1	9.1	2	18.2	3	13.6	2	12.5	2	18.2	4	14.8	3	11.1	4	18.2	7	14.3		
	No change (4)	0	.	0	.	0	.	2	12.5	0	.	2	7.4	2	7.4	0	.	2	4.1		
	Minimally worse (5)	0	.	1	9.1	1	4.5	1	6.3	0	.	1	3.7	1	3.7	1	4.5	2	4.1		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit																					
Week 12	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	11	100.0	11	100.0	22	100.0	16	100.0	11	100.0	27	100.0	27	100.0	22	100.0	49	100.0		
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	5	50.0	2	16.7	7	31.8	5	55.6	7	53.8	12	54.5	10	52.6	9	36.0	19	43.2		
	Much Improved (2)	3	30.0	7	58.3	10	45.5	1	11.1	5	38.5	6	27.3	4	21.1	12	48.0	16	36.4		
	Minimally improved (3)	1	10.0	3	25.0	4	18.2	3	33.3	1	7.7	4	18.2	4	21.1	4	16.0	8	18.2		
	No change (4)	1	10.0	0	.	1	4.5	0	.	0	.	0	.	1	5.3	0	.	1	2.3		
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Visit	Total																				
Week 16		10	100.0	12	100.0	22	100.0	9	100.0	13	100.0	22	100.0	19	100.0	25	100.0	44	100.0		
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	4	57.1	0	.	4	40.0	5	71.4	3	60.0	8	66.7	9	64.3	3	37.5	12	54.5		
	Much Improved (2)	2	28.6	2	66.7	4	40.0	2	28.6	0	.	2	16.7	4	28.6	2	25.0	6	27.3		
	Minimally improved (3)	1	14.3	0	.	1	10.0	0	.	1	20.0	1	8.3	1	7.1	1	12.5	2	9.1		
	No change (4)	0	.	0	.	0	.	0	.	1	20.0	1	8.3	0	.	1	12.5	1	4.5		
	Minimally worse (5)	0	.	1	33.3	1	10.0	0	.	0	.	0	.	0	.	1	12.5	1	4.5		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	7	100.0	3	100.0	10	100.0	7	100.0	5	100.0	12	100.0	14	100.0	8	100.0	22	100.0		
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 24	Very much improved (1)	5	55.6	3	50.0	8	53.3	5	83.3	4	100.0	9	90.0	10	66.7	7	70.0	17	68.0		
	Much Improved (2)	3	33.3	2	33.3	5	33.3	1	16.7	0	.	1	10.0	4	26.7	2	20.0	6	24.0		
	Minimally improved (3)	1	11.1	1	16.7	2	13.3	0	.	0	.	0	.	1	6.7	1	10.0	2	8.0		
	No change (4)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	9	100.0	6	100.0	15	100.0	6	100.0	4	100.0	10	100.0	15	100.0	10	100.0	25	100.0		
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Very much improved (1)	9	37.5	7	36.8	16	37.2	13	39.4	8	29.6	21	35.0	22	38.6	15	32.6	37	35.9		

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Interim Output
Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																					
Week 24 LOCF	Much Improved (2)	7	29.2	7	36.8	14	32.6	9	27.3	10	37.0	19	31.7	16	28.1	17	37.0	33	32.0		
	Minimally improved (3)	5	20.8	5	26.3	10	23.3	6	18.2	3	11.1	9	15.0	11	19.3	8	17.4	19	18.4		
	No change (4)	1	4.2	0	.	1	2.3	4	12.1	4	14.8	8	13.3	5	8.8	4	8.7	9	8.7		
	Minimally worse (5)	2	8.3	0	.	2	4.7	1	3.0	0	.	1	1.7	3	5.3	0	.	3	2.9		
	Much worse (6)	0	.	0	.	0	.	0	.	2	7.4	2	3.3	0	.	2	4.3	2	1.9		
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	24	100.0	19	100.0	43	100.0	33	100.0	27	100.0	60	100.0	57	100.0	46	100.0	103	100.0		

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group								
	Paroxetine (N = 25)			Placebo (N = 36)			Total (N = 61)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	10	47.6	21	19	57.6	33	29	53.7	54
Week 2	10	47.6	21	20	62.5	32	30	56.6	53
Week 3	14	70.0	20	23	74.2	31	37	72.5	51
Week 4	15	65.2	23	21	67.7	31	36	66.7	54
Week 8	15	75.0	20	22	81.5	27	37	78.7	47
Week 12	14	82.4	17	17	77.3	22	31	79.5	39
Week 16	13	86.7	15	18	85.7	21	31	86.1	36
Week 20	13	100.0	13	14	82.4	17	27	90.0	30
Week 24	13	100.0	13	9	90.0	10	22	95.7	23
Week 24 LOCF	19	79.2	24	25	71.4	35	44	74.6	59

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group								
	Paroxetine (N = 25)			Placebo (N = 30)			Total (N = 55)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	5	25.0	20	9	34.6	26	14	30.4	46
Week 2	11	50.0	22	15	60.0	25	26	55.3	47
Week 3	15	62.5	24	14	63.6	22	29	63.0	46
Week 4	17	77.3	22	15	62.5	24	32	69.6	46
Week 8	16	80.0	20	15	75.0	20	31	77.5	40
Week 12	16	84.2	19	15	83.3	18	31	83.8	37
Week 16	12	66.7	18	12	75.0	16	24	70.6	34
Week 20	12	85.7	14	11	84.6	13	23	85.2	27
Week 24	12	85.7	14	12	92.3	13	24	88.9	27
Week 24 LOCF	15	60.0	25	17	58.6	29	32	59.3	54

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group								
	Paroxetine (N = 50)			Placebo (N = 66)			Total (N = 116)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	15	36.6	41	28	47.5	59	43	43.0	100
Week 2	21	48.8	43	35	61.4	57	56	56.0	100
Week 3	29	65.9	44	37	69.8	53	66	68.0	97
Week 4	32	71.1	45	36	65.5	55	68	68.0	100
Week 8	31	77.5	40	37	78.7	47	68	78.2	87
Week 12	30	83.3	36	32	80.0	40	62	81.6	76
Week 16	25	75.8	33	30	81.1	37	55	78.6	70
Week 20	25	92.6	27	25	83.3	30	50	87.7	57
Week 24	25	92.6	27	21	91.3	23	46	92.0	50
Week 24 LOCF	34	69.4	49	42	65.6	64	76	67.3	113

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group								
	Paroxetine (N = 24)			Placebo (N = 34)			Total (N = 58)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	9	47.4	19	11	39.3	28	20	42.6	47
Week 2	8	47.1	17	14	48.3	29	22	47.8	46
Week 3	11	57.9	19	18	56.3	32	29	56.9	51
Week 4	15	65.2	23	18	64.3	28	33	64.7	51
Week 8	13	65.0	20	14	66.7	21	27	65.9	41
Week 12	10	90.9	11	11	68.8	16	21	77.8	27
Week 16	8	80.0	10	6	66.7	9	14	73.7	19
Week 20	6	85.7	7	7	100.0	7	13	92.9	14
Week 24	8	88.9	9	6	100.0	6	14	93.3	15
Week 24 LOCF	16	66.7	24	22	66.7	33	38	66.7	57

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group								
	Paroxetine (N = 20)			Placebo (N = 27)			Total (N = 47)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	6	31.6	19	1	4.3	23	7	16.7	42
Week 2	7	43.8	16	7	29.2	24	14	35.0	40
Week 3	7	46.7	15	13	61.9	21	20	55.6	36
Week 4	11	57.9	19	14	58.3	24	25	58.1	43
Week 8	12	70.6	17	9	56.3	16	21	63.6	33
Week 12	8	72.7	11	9	81.8	11	17	77.3	22
Week 16	9	75.0	12	12	92.3	13	21	84.0	25
Week 20	2	66.7	3	3	60.0	5	5	62.5	8
Week 24	5	83.3	6	4	100.0	4	9	90.0	10
Week 24 LOCF	14	73.7	19	18	66.7	27	32	69.6	46

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group								
	Paroxetine (N = 44)			Placebo (N = 61)			Total (N = 105)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	15	39.5	38	12	23.5	51	27	30.3	89
Week 2	15	45.5	33	21	39.6	53	36	41.9	86
Week 3	18	52.9	34	31	58.5	53	49	56.3	87
Week 4	26	61.9	42	32	61.5	52	58	61.7	94
Week 8	25	67.6	37	23	62.2	37	48	64.9	74
Week 12	18	81.8	22	20	74.1	27	38	77.6	49
Week 16	17	77.3	22	18	81.8	22	35	79.5	44
Week 20	8	80.0	10	10	83.3	12	18	81.8	22
Week 24	13	86.7	15	10	100.0	10	23	92.0	25
Week 24 LOCF	30	69.8	43	40	66.7	60	70	68.0	103

Note: Responders are patients who have a score of 1 or 2

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Acute Baseline	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Borderline mentally ill (2)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Mildly ill (3)	0	.	1	4.0	1	2.0	2	5.6	0	.	2	3.0	2	3.3	1	1.8	3	2.6		
	Moderately ill (4)	19	76.0	17	68.0	36	72.0	26	72.2	22	73.3	48	72.7	45	73.8	39	70.9	84	72.4		
	Markedly ill (5)	5	20.0	7	28.0	12	24.0	7	19.4	8	26.7	15	22.7	12	19.7	15	27.3	27	23.3		
	Severely ill (6)	1	4.0	0	.	1	2.0	1	2.8	0	.	1	1.5	2	3.3	0	.	2	1.7		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	25	100.0	25	100.0	50	100.0	36	100.0	30	100.0	66	100.0	61	100.0	55	100.0	116	100.0		

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	1	5.0	4	9.8	5	15.2	2	7.7	7	11.9	8	14.8	3	6.5	11	11.0		
	Borderline mentally ill (2)	5	23.8	3	15.0	8	19.5	6	18.2	8	30.8	14	23.7	11	20.4	11	23.9	22	22.0		
	Mildly ill (3)	5	23.8	6	30.0	11	26.8	10	30.3	5	19.2	15	25.4	15	27.8	11	23.9	26	26.0		
	Moderately ill (4)	6	28.6	10	50.0	16	39.0	11	33.3	11	42.3	22	37.3	17	31.5	21	45.7	38	38.0		
	Markedly ill (5)	2	9.5	0	.	2	4.9	1	3.0	0	.	1	1.7	3	5.6	0	.	3	3.0		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	21	100.0	20	100.0	41	100.0	33	100.0	26	100.0	59	100.0	54	100.0	46	100.0	100	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	19.0	3	13.6	7	16.3	8	25.0	4	16.0	12	21.1	12	22.6	7	14.9	19	19.0		
	Borderline mentally ill (2)	3	14.3	5	22.7	8	18.6	4	12.5	5	20.0	9	15.8	7	13.2	10	21.3	17	17.0		
	Mildly ill (3)	6	28.6	7	31.8	13	30.2	10	31.3	9	36.0	19	33.3	16	30.2	16	34.0	32	32.0		
	Moderately ill (4)	7	33.3	7	31.8	14	32.6	8	25.0	7	28.0	15	26.3	15	28.3	14	29.8	29	29.0		
	Markedly ill (5)	1	4.8	0	.	1	2.3	2	6.3	0	.	2	3.5	3	5.7	0	.	3	3.0		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	21	100.0	22	100.0	43	100.0	32	100.0	25	100.0	57	100.0	53	100.0	47	100.0	100	100.0		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	20.0	2	8.3	6	13.6	8	25.8	4	18.2	12	22.6	12	23.5	6	13.0	18	18.6				
	Borderline mentally ill (2)	6	30.0	9	37.5	15	34.1	6	19.4	5	22.7	11	20.8	12	23.5	14	30.4	26	26.8				
	Mildly ill (3)	4	20.0	11	45.8	15	34.1	11	35.5	8	36.4	19	35.8	15	29.4	19	41.3	34	35.1				
	Moderately ill (4)	6	30.0	2	8.3	8	18.2	6	19.4	5	22.7	11	20.8	12	23.5	7	15.2	19	19.6				
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	20	100.0	24	100.0	44	100.0	31	100.0	22	100.0	53	100.0	51	100.0	46	100.0	97	100.0				

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	17.4	2	9.1	6	13.3	8	25.8	3	12.5	11	20.0	12	22.2	5	10.9	17	17.0
	Borderline mentally ill (2)	9	39.1	10	45.5	19	42.2	10	32.3	9	37.5	19	34.5	19	35.2	19	41.3	38	38.0
	Mildly ill (3)	5	21.7	7	31.8	12	26.7	7	22.6	7	29.2	14	25.5	12	22.2	14	30.4	26	26.0
	Moderately ill (4)	5	21.7	1	4.5	6	13.3	5	16.1	4	16.7	9	16.4	10	18.5	5	10.9	15	15.0
	Markedly ill (5)	0	.	2	9.1	2	4.4	1	3.2	1	4.2	2	3.6	1	1.9	3	6.5	4	4.0
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	23	100.0	22	100.0	45	100.0	31	100.0	24	100.0	55	100.0	54	100.0	46	100.0	100	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	6	30.0	9	22.5	7	25.9	5	25.0	12	25.5	10	21.3	11	27.5	21	24.1		
	Borderline mentally ill (2)	6	30.0	6	30.0	12	30.0	9	33.3	7	35.0	16	34.0	15	31.9	13	32.5	28	32.2		
	Mildly ill (3)	8	40.0	6	30.0	14	35.0	7	25.9	5	25.0	12	25.5	15	31.9	11	27.5	26	29.9		
	Moderately ill (4)	3	15.0	2	10.0	5	12.5	4	14.8	3	15.0	7	14.9	7	14.9	5	12.5	12	13.8		
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	20	100.0	20	100.0	40	100.0	27	100.0	20	100.0	47	100.0	47	100.0	40	100.0	87	100.0		

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	23.5	5	26.3	9	25.0	5	22.7	7	38.9	12	30.0	9	23.1	12	32.4	21	27.6				
	Borderline mentally ill (2)	4	23.5	6	31.6	10	27.8	7	31.8	5	27.8	12	30.0	11	28.2	11	29.7	22	28.9				
	Mildly ill (3)	8	47.1	7	36.8	15	41.7	8	36.4	2	11.1	10	25.0	16	41.0	9	24.3	25	32.9				
	Moderately ill (4)	0	.	1	5.3	1	2.8	1	4.5	4	22.2	5	12.5	1	2.6	5	13.5	6	7.9				
	Markedly ill (5)	1	5.9	0	.	1	2.8	1	4.5	0	.	1	2.5	2	5.1	0	.	2	2.6				
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	17	100.0	19	100.0	36	100.0	22	100.0	18	100.0	40	100.0	39	100.0	37	100.0	76	100.0				

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BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	26.7	4	22.2	8	24.2	3	14.3	7	43.8	10	27.0	7	19.4	11	32.4	18	25.7		
	Borderline mentally ill (2)	5	33.3	5	27.8	10	30.3	9	42.9	5	31.3	14	37.8	14	38.9	10	29.4	24	34.3		
	Mildly ill (3)	5	33.3	6	33.3	11	33.3	7	33.3	0	.	7	18.9	12	33.3	6	17.6	18	25.7		
	Moderately ill (4)	1	6.7	3	16.7	4	12.1	2	9.5	4	25.0	6	16.2	3	8.3	7	20.6	10	14.3		
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	15	100.0	18	100.0	33	100.0	21	100.0	16	100.0	37	100.0	36	100.0	34	100.0	70	100.0		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																					
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)									
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total					
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Normal, not at all ill (1)	5	38.5	4	28.6	9	33.3	3	17.6	4	30.8	7	23.3	8	26.7	8	29.6	16	28.1				
	Borderline mentally ill (2)	5	38.5	6	42.9	11	40.7	9	52.9	5	38.5	14	46.7	14	46.7	11	40.7	25	43.9				
	Mildly ill (3)	3	23.1	3	21.4	6	22.2	4	23.5	2	15.4	6	20.0	7	23.3	5	18.5	12	21.1				
	Moderately ill (4)	0	.	1	7.1	1	3.7	1	5.9	1	7.7	2	6.7	1	3.3	2	7.4	3	5.3				
	Markedly ill (5)	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	3.7	1	1.8				
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.				
	Total	13	100.0	14	100.0	27	100.0	17	100.0	13	100.0	30	100.0	30	100.0	27	100.0	57	100.0				

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	5	38.5	4	28.6	9	33.3	2	20.0	5	38.5	7	30.4	7	30.4	9	33.3	16	32.0		
	Borderline mentally ill (2)	7	53.8	6	42.9	13	48.1	4	40.0	4	30.8	8	34.8	11	47.8	10	37.0	21	42.0		
	Mildly ill (3)	1	7.7	3	21.4	4	14.8	2	20.0	3	23.1	5	21.7	3	13.0	6	22.2	9	18.0		
	Moderately ill (4)	0	.	1	7.1	1	3.7	2	20.0	0	.	2	8.7	2	8.7	1	3.7	3	6.0		
	Markedly ill (5)	0	.	0	.	0	.	0	.	1	7.7	1	4.3	0	.	1	3.7	1	2.0		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	13	100.0	14	100.0	27	100.0	10	100.0	13	100.0	23	100.0	23	100.0	27	100.0	50	100.0		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.8	5	20.0	10	20.4	6	17.1	6	20.7	12	18.8	11	18.6	11	20.4	22	19.5		
	Borderline mentally ill (2)	11	45.8	9	36.0	20	40.8	13	37.1	7	24.1	20	31.3	24	40.7	16	29.6	40	35.4		
	Mildly ill (3)	6	25.0	5	20.0	11	22.4	6	17.1	5	17.2	11	17.2	12	20.3	10	18.5	22	19.5		
	Moderately ill (4)	2	8.3	5	20.0	7	14.3	9	25.7	8	27.6	17	26.6	11	18.6	13	24.1	24	21.2		
	Markedly ill (5)	0	.	0	.	0	.	1	2.9	3	10.3	4	6.3	1	1.7	3	5.6	4	3.5		
	Severely ill (6)	0	.	1	4.0	1	2.0	0	.	0	.	0	.	0	.	1	1.9	1	0.9		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	24	100.0	25	100.0	49	100.0	35	100.0	29	100.0	64	100.0	59	100.0	54	100.0	113	100.0		

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Acute Baseline	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Borderline mentally ill (2)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Mildly ill (3)	0	.	0	.	0	.	1	2.9	1	3.7	2	3.3	1	1.7	1	2.1	2	1.9		
	Moderately ill (4)	14	58.3	8	40.0	22	50.0	15	44.1	9	33.3	24	39.3	29	50.0	17	36.2	46	43.8		
	Markedly ill (5)	9	37.5	10	50.0	19	43.2	11	32.4	14	51.9	25	41.0	20	34.5	24	51.1	44	41.9		
	Severely ill (6)	1	4.2	2	10.0	3	6.8	7	20.6	3	11.1	10	16.4	8	13.8	5	10.6	13	12.4		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	24	100.0	20	100.0	44	100.0	34	100.0	27	100.0	61	100.0	58	100.0	47	100.0	105	100.0		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.8	0	.	3	7.9	1	3.6	0	.	1	2.0	4	8.5	0	.	4	4.5		
	Borderline mentally ill (2)	2	10.5	1	5.3	3	7.9	1	3.6	1	4.3	2	3.9	3	6.4	2	4.8	5	5.6		
	Mildly ill (3)	4	21.1	5	26.3	9	23.7	6	21.4	1	4.3	7	13.7	10	21.3	6	14.3	16	18.0		
	Moderately ill (4)	7	36.8	8	42.1	15	39.5	14	50.0	15	65.2	29	56.9	21	44.7	23	54.8	44	49.4		
	Markedly ill (5)	3	15.8	5	26.3	8	21.1	5	17.9	5	21.7	10	19.6	8	17.0	10	23.8	18	20.2		
	Severely ill (6)	0	.	0	.	0	.	1	3.6	1	4.3	2	3.9	1	2.1	1	2.4	2	2.2		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	19	100.0	19	100.0	38	100.0	28	100.0	23	100.0	51	100.0	47	100.0	42	100.0	89	100.0		

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BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	1	5.9	1	6.3	2	6.1	3	10.3	0	.	3	5.7	4	8.7	1	2.5	5	5.8		
	Borderline mentally ill (2)	3	17.6	2	12.5	5	15.2	2	6.9	2	8.3	4	7.5	5	10.9	4	10.0	9	10.5		
	Mildly ill (3)	4	23.5	5	31.3	9	27.3	9	31.0	4	16.7	13	24.5	13	28.3	9	22.5	22	25.6		
	Moderately ill (4)	8	47.1	6	37.5	14	42.4	8	27.6	15	62.5	23	43.4	16	34.8	21	52.5	37	43.0		
	Markedly ill (5)	1	5.9	2	12.5	3	9.1	6	20.7	2	8.3	8	15.1	7	15.2	4	10.0	11	12.8		
	Severely ill (6)	0	.	0	.	0	.	1	3.4	1	4.2	2	3.8	1	2.2	1	2.5	2	2.3		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	17	100.0	16	100.0	33	100.0	29	100.0	24	100.0	53	100.0	46	100.0	40	100.0	86	100.0		

(CONTINUED)

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Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Normal, not at all ill (1)	3	15.8	1	6.7	4	11.8	3	9.4	2	9.5	5	9.4	6	11.8	3	8.3	9	10.3		
	Borderline mentally ill (2)	2	10.5	2	13.3	4	11.8	1	3.1	2	9.5	3	5.7	3	5.9	4	11.1	7	8.0		
	Mildly ill (3)	6	31.6	4	26.7	10	29.4	12	37.5	8	38.1	20	37.7	18	35.3	12	33.3	30	34.5		
	Moderately ill (4)	8	42.1	5	33.3	13	38.2	11	34.4	8	38.1	19	35.8	19	37.3	13	36.1	32	36.8		
	Markedly ill (5)	0	.	3	20.0	3	8.8	5	15.6	0	.	5	9.4	5	9.8	3	8.3	8	9.2		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	4.8	1	1.9	0	.	1	2.8	1	1.1		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	19	100.0	15	100.0	34	100.0	32	100.0	21	100.0	53	100.0	51	100.0	36	100.0	87	100.0		

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	17.4	3	15.8	7	16.7	4	14.3	1	4.2	5	9.6	8	15.7	4	9.3	12	12.8		
	Borderline mentally ill (2)	3	13.0	1	5.3	4	9.5	3	10.7	3	12.5	6	11.5	6	11.8	4	9.3	10	10.6		
	Mildly ill (3)	8	34.8	6	31.6	14	33.3	11	39.3	7	29.2	18	34.6	19	37.3	13	30.2	32	34.0		
	Moderately ill (4)	6	26.1	6	31.6	12	28.6	9	32.1	10	41.7	19	36.5	15	29.4	16	37.2	31	33.0		
	Markedly ill (5)	2	8.7	3	15.8	5	11.9	1	3.6	2	8.3	3	5.8	3	5.9	5	11.6	8	8.5		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	4.2	1	1.9	0	.	1	2.3	1	1.1		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	23	100.0	19	100.0	42	100.0	28	100.0	24	100.0	52	100.0	51	100.0	43	100.0	94	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	5	29.4	8	21.6	4	19.0	2	12.5	6	16.2	7	17.1	7	21.2	14	18.9		
	Borderline mentally ill (2)	3	15.0	1	5.9	4	10.8	3	14.3	3	18.8	6	16.2	6	14.6	4	12.1	10	13.5		
	Mildly ill (3)	8	40.0	5	29.4	13	35.1	8	38.1	5	31.3	13	35.1	16	39.0	10	30.3	26	35.1		
	Moderately ill (4)	4	20.0	4	23.5	8	21.6	4	19.0	5	31.3	9	24.3	8	19.5	9	27.3	17	23.0		
	Markedly ill (5)	2	10.0	2	11.8	4	10.8	2	9.5	0	.	2	5.4	4	9.8	2	6.1	6	8.1		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	6.3	1	2.7	0	.	1	3.0	1	1.4		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	20	100.0	17	100.0	37	100.0	21	100.0	16	100.0	37	100.0	41	100.0	33	100.0	74	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	36.4	1	9.1	5	22.7	2	12.5	2	18.2	4	14.8	6	22.2	3	13.6	9	18.4		
	Borderline mentally ill (2)	2	18.2	2	18.2	4	18.2	2	12.5	4	36.4	6	22.2	4	14.8	6	27.3	10	20.4		
	Mildly ill (3)	4	36.4	6	54.5	10	45.5	8	50.0	4	36.4	12	44.4	12	44.4	10	45.5	22	44.9		
	Moderately ill (4)	1	9.1	2	18.2	3	13.6	4	25.0	0	.	4	14.8	5	18.5	2	9.1	7	14.3		
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	9.1	1	3.7	0	.	1	4.5	1	2.0		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	11	100.0	11	100.0	22	100.0	16	100.0	11	100.0	27	100.0	27	100.0	22	100.0	49	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	30.0	1	8.3	4	18.2	2	22.2	4	30.8	6	27.3	5	26.3	5	20.0	10	22.7		
	Borderline mentally ill (2)	2	20.0	2	16.7	4	18.2	2	22.2	1	7.7	3	13.6	4	21.1	3	12.0	7	15.9		
	Mildly ill (3)	4	40.0	6	50.0	10	45.5	3	33.3	7	53.8	10	45.5	7	36.8	13	52.0	20	45.5		
	Moderately ill (4)	1	10.0	2	16.7	3	13.6	2	22.2	0	.	2	9.1	3	15.8	2	8.0	5	11.4		
	Markedly ill (5)	0	.	1	8.3	1	4.5	0	.	0	.	0	.	0	.	1	4.0	1	2.3		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	7.7	1	4.5	0	.	1	4.0	1	2.3		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	10	100.0	12	100.0	22	100.0	9	100.0	13	100.0	22	100.0	19	100.0	25	100.0	44	100.0		

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	42.9	0	.	3	30.0	2	28.6	3	60.0	5	41.7	5	35.7	3	37.5	8	36.4		
	Borderline mentally ill (2)	1	14.3	0	.	1	10.0	1	14.3	0	.	1	8.3	2	14.3	0	.	2	9.1		
	Mildly ill (3)	3	42.9	3	100.0	6	60.0	4	57.1	0	.	4	33.3	7	50.0	3	37.5	10	45.5		
	Moderately ill (4)	0	.	0	.	0	.	0	.	2	40.0	2	16.7	0	.	2	25.0	2	9.1		
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	7	100.0	3	100.0	10	100.0	7	100.0	5	100.0	12	100.0	14	100.0	8	100.0	22	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Normal, not at all ill (1)	3	33.3	2	33.3	5	33.3	2	33.3	1	25.0	3	30.0	5	33.3	3	30.0	8	32.0		
	Borderline mentally ill (2)	2	22.2	1	16.7	3	20.0	2	33.3	2	50.0	4	40.0	4	26.7	3	30.0	7	28.0		
	Mildly ill (3)	4	44.4	3	50.0	7	46.7	2	33.3	1	25.0	3	30.0	6	40.0	4	40.0	10	40.0		
	Moderately ill (4)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	9	100.0	6	100.0	15	100.0	6	100.0	4	100.0	10	100.0	15	100.0	10	100.0	25	100.0		

(CONTINUED)

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Interim Output
Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																			
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)							
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total			
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	6	25.0	5	26.3	11	25.6	5	15.2	3	11.1	8	13.3	11	19.3	8	17.4	19	18.4		
	Borderline mentally ill (2)	3	12.5	3	15.8	6	14.0	4	12.1	3	11.1	7	11.7	7	12.3	6	13.0	13	12.6		
	Mildly ill (3)	8	33.3	7	36.8	15	34.9	14	42.4	11	40.7	25	41.7	22	38.6	18	39.1	40	38.8		
	Moderately ill (4)	6	25.0	1	5.3	7	16.3	8	24.2	7	25.9	15	25.0	14	24.6	8	17.4	22	21.4		
	Markedly ill (5)	1	4.2	3	15.8	4	9.3	2	6.1	2	7.4	4	6.7	3	5.3	5	10.9	8	7.8		
	Severely ill (6)	0	.	0	.	0	.	0	.	1	3.7	1	1.7	0	.	1	2.2	1	1.0		
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.		
	Total	24	100.0	19	100.0	43	100.0	33	100.0	27	100.0	60	100.0	57	100.0	46	100.0	103	100.0		

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	24.0	5	20.0	11	22.0
	Borderline mentally ill (2)	9	36.0	7	28.0	16	32.0
	Mildly ill (3)	3	12.0	7	28.0	10	20.0
	Moderately ill (4)	5	20.0	5	20.0	10	20.0
	Markedly ill (5)	2	8.0	1	4.0	3	6.0
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	25	100.0	25	100.0	50	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	1	5.0	4	9.8
	Borderline mentally ill (2)	5	23.8	3	15.0	8	19.5
	Mildly ill (3)	5	23.8	6	30.0	11	26.8
	Moderately ill (4)	6	28.6	10	50.0	16	39.0
	Markedly ill (5)	2	9.5	0	.	2	4.9
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	20	100.0	41	100.0

(CONTINUED)

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	19.0	3	13.6	7	16.3
	Borderline mentally ill (2)	3	14.3	5	22.7	8	18.6
	Mildly ill (3)	6	28.6	7	31.8	13	30.2
	Moderately ill (4)	7	33.3	7	31.8	14	32.6
	Markedly ill (5)	1	4.8	0	.	1	2.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	22	100.0	43	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	20.0	2	8.3	6	13.6
	Borderline mentally ill (2)	6	30.0	9	37.5	15	34.1
	Mildly ill (3)	4	20.0	11	45.8	15	34.1
	Moderately ill (4)	6	30.0	2	8.3	8	18.2
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	24	100.0	44	100.0

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	17.4	2	9.1	6	13.3
	Borderline mentally ill (2)	9	39.1	10	45.5	19	42.2
	Mildly ill (3)	5	21.7	7	31.8	12	26.7
	Moderately ill (4)	5	21.7	1	4.5	6	13.3
	Markedly ill (5)	0	.	2	9.1	2	4.4
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	23	100.0	22	100.0	45	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	6	30.0	9	22.5
	Borderline mentally ill (2)	6	30.0	6	30.0	12	30.0
	Mildly ill (3)	8	40.0	6	30.0	14	35.0
	Moderately ill (4)	3	15.0	2	10.0	5	12.5
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	20	100.0	40	100.0

(CONTINUED)

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	23.5	5	26.3	9	25.0
	Borderline mentally ill (2)	4	23.5	6	31.6	10	27.8
	Mildly ill (3)	8	47.1	7	36.8	15	41.7
	Moderately ill (4)	0	.	1	5.3	1	2.8
	Markedly ill (5)	1	5.9	0	.	1	2.8
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	17	100.0	19	100.0	36	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	26.7	4	22.2	8	24.2
	Borderline mentally ill (2)	5	33.3	5	27.8	10	30.3
	Mildly ill (3)	5	33.3	6	33.3	11	33.3
	Moderately ill (4)	1	6.7	3	16.7	4	12.1
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	15	100.0	18	100.0	33	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	38.5	4	28.6	9	33.3
	Borderline mentally ill (2)	5	38.5	6	42.9	11	40.7
	Mildly ill (3)	3	23.1	3	21.4	6	22.2
	Moderately ill (4)	0	.	1	7.1	1	3.7
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	14	100.0	27	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	38.5	4	28.6	9	33.3
	Borderline mentally ill (2)	7	53.8	6	42.9	13	48.1
	Mildly ill (3)	1	7.7	3	21.4	4	14.8
	Moderately ill (4)	0	.	1	7.1	1	3.7
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	14	100.0	27	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.8	5	20.0	10	20.4
	Borderline mentally ill (2)	11	45.8	9	36.0	20	40.8
	Mildly ill (3)	6	25.0	5	20.0	11	22.4
	Moderately ill (4)	2	8.3	5	20.0	7	14.3
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	4.0	1	2.0
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	24	100.0	25	100.0	49	100.0

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.8	0	.	5	11.4
	Borderline mentally ill (2)	4	16.7	3	15.0	7	15.9
	Mildly ill (3)	6	25.0	6	30.0	12	27.3
	Moderately ill (4)	8	33.3	6	30.0	14	31.8
	Markedly ill (5)	1	4.2	5	25.0	6	13.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	24	100.0	20	100.0	44	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.8	0	.	3	7.9
	Borderline mentally ill (2)	2	10.5	1	5.3	3	7.9
	Mildly ill (3)	4	21.1	5	26.3	9	23.7
	Moderately ill (4)	7	36.8	8	42.1	15	39.5
	Markedly ill (5)	3	15.8	5	26.3	8	21.1
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	19	100.0	19	100.0	38	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	1	5.9	1	6.3	2	6.1
	Borderline mentally ill (2)	3	17.6	2	12.5	5	15.2
	Mildly ill (3)	4	23.5	5	31.3	9	27.3
	Moderately ill (4)	8	47.1	6	37.5	14	42.4
	Markedly ill (5)	1	5.9	2	12.5	3	9.1
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	17	100.0	16	100.0	33	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.8	1	6.7	4	11.8
	Borderline mentally ill (2)	2	10.5	2	13.3	4	11.8
	Mildly ill (3)	6	31.6	4	26.7	10	29.4
	Moderately ill (4)	8	42.1	5	33.3	13	38.2
	Markedly ill (5)	0	.	3	20.0	3	8.8
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	19	100.0	15	100.0	34	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	17.4	3	15.8	7	16.7
	Borderline mentally ill (2)	3	13.0	1	5.3	4	9.5
	Mildly ill (3)	8	34.8	6	31.6	14	33.3
	Moderately ill (4)	6	26.1	6	31.6	12	28.6
	Markedly ill (5)	2	8.7	3	15.8	5	11.9
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	23	100.0	19	100.0	42	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	5	29.4	8	21.6
	Borderline mentally ill (2)	3	15.0	1	5.9	4	10.8
	Mildly ill (3)	8	40.0	5	29.4	13	35.1
	Moderately ill (4)	4	20.0	4	23.5	8	21.6
	Markedly ill (5)	2	10.0	2	11.8	4	10.8
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	17	100.0	37	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	36.4	1	9.1	5	22.7
	Borderline mentally ill (2)	2	18.2	2	18.2	4	18.2
	Mildly ill (3)	4	36.4	6	54.5	10	45.5
	Moderately ill (4)	1	9.1	2	18.2	3	13.6
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	11	100.0	11	100.0	22	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	30.0	1	8.3	4	18.2
	Borderline mentally ill (2)	2	20.0	2	16.7	4	18.2
	Mildly ill (3)	4	40.0	6	50.0	10	45.5
	Moderately ill (4)	1	10.0	2	16.7	3	13.6
	Markedly ill (5)	0	.	1	8.3	1	4.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	10	100.0	12	100.0	22	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	42.9	0	.	3	30.0
	Borderline mentally ill (2)	1	14.3	0	.	1	10.0
	Mildly ill (3)	3	42.9	3	100.0	6	60.0
	Moderately ill (4)	0	.	0	.	0	.
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	7	100.0	3	100.0	10	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	33.3	2	33.3	5	33.3
	Borderline mentally ill (2)	2	22.2	1	16.7	3	20.0
	Mildly ill (3)	4	44.4	3	50.0	7	46.7
	Moderately ill (4)	0	.	0	.	0	.
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	9	100.0	6	100.0	15	100.0

(CONTINUED)

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Interim Output
Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	25.0	5	26.3	11	25.6
	Borderline mentally ill (2)	3	12.5	3	15.8	6	14.0
	Mildly ill (3)	8	33.3	7	36.8	15	34.9
	Moderately ill (4)	6	25.0	1	5.3	7	16.3
	Markedly ill (5)	1	4.2	3	15.8	4	9.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	24	100.0	19	100.0	43	100.0

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	16.7	5	17.2	11	16.9
	Borderline mentally ill (2)	7	19.4	7	24.1	14	21.5
	Mildly ill (3)	6	16.7	6	20.7	12	18.5
	Moderately ill (4)	16	44.4	11	37.9	27	41.5
	Markedly ill (5)	1	2.8	0	.	1	1.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	36	100.0	29	100.0	65	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	15.2	2	7.7	7	11.9
	Borderline mentally ill (2)	6	18.2	8	30.8	14	23.7
	Mildly ill (3)	10	30.3	5	19.2	15	25.4
	Moderately ill (4)	11	33.3	11	42.3	22	37.3
	Markedly ill (5)	1	3.0	0	.	1	1.7
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	33	100.0	26	100.0	59	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.0	4	16.0	12	21.1
	Borderline mentally ill (2)	4	12.5	5	20.0	9	15.8
	Mildly ill (3)	10	31.3	9	36.0	19	33.3
	Moderately ill (4)	8	25.0	7	28.0	15	26.3
	Markedly ill (5)	2	6.3	0	.	2	3.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	32	100.0	25	100.0	57	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.8	4	18.2	12	22.6
	Borderline mentally ill (2)	6	19.4	5	22.7	11	20.8
	Mildly ill (3)	11	35.5	8	36.4	19	35.8
	Moderately ill (4)	6	19.4	5	22.7	11	20.8
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	31	100.0	22	100.0	53	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.8	3	12.5	11	20.0
	Borderline mentally ill (2)	10	32.3	9	37.5	19	34.5
	Mildly ill (3)	7	22.6	7	29.2	14	25.5
	Moderately ill (4)	5	16.1	4	16.7	9	16.4
	Markedly ill (5)	1	3.2	1	4.2	2	3.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	31	100.0	24	100.0	55	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	7	25.9	5	25.0	12	25.5
	Borderline mentally ill (2)	9	33.3	7	35.0	16	34.0
	Mildly ill (3)	7	25.9	5	25.0	12	25.5
	Moderately ill (4)	4	14.8	3	15.0	7	14.9
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	27	100.0	20	100.0	47	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	22.7	7	38.9	12	30.0
	Borderline mentally ill (2)	7	31.8	5	27.8	12	30.0
	Mildly ill (3)	8	36.4	2	11.1	10	25.0
	Moderately ill (4)	1	4.5	4	22.2	5	12.5
	Markedly ill (5)	1	4.5	0	.	1	2.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	22	100.0	18	100.0	40	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	7	43.8	10	27.0
	Borderline mentally ill (2)	9	42.9	5	31.3	14	37.8
	Mildly ill (3)	7	33.3	0	.	7	18.9
	Moderately ill (4)	2	9.5	4	25.0	6	16.2
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	16	100.0	37	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	17.6	4	30.8	7	23.3
	Borderline mentally ill (2)	9	52.9	5	38.5	14	46.7
	Mildly ill (3)	4	23.5	2	15.4	6	20.0
	Moderately ill (4)	1	5.9	1	7.7	2	6.7
	Markedly ill (5)	0	.	1	7.7	1	3.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	17	100.0	13	100.0	30	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	20.0	5	38.5	7	30.4
	Borderline mentally ill (2)	4	40.0	4	30.8	8	34.8
	Mildly ill (3)	2	20.0	3	23.1	5	21.7
	Moderately ill (4)	2	20.0	0	.	2	8.7
	Markedly ill (5)	0	.	1	7.7	1	4.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	10	100.0	13	100.0	23	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	17.1	6	20.7	12	18.8
	Borderline mentally ill (2)	13	37.1	7	24.1	20	31.3
	Mildly ill (3)	6	17.1	5	17.2	11	17.2
	Moderately ill (4)	9	25.7	8	27.6	17	26.6
	Markedly ill (5)	1	2.9	3	10.3	4	6.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	35	100.0	29	100.0	64	100.0

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	9.1	1	3.7	4	6.7
	Borderline mentally ill (2)	5	15.2	2	7.4	7	11.7
	Mildly ill (3)	8	24.2	5	18.5	13	21.7
	Moderately ill (4)	12	36.4	15	55.6	27	45.0
	Markedly ill (5)	5	15.2	3	11.1	8	13.3
	Severely ill (6)	0	.	1	3.7	1	1.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	33	100.0	27	100.0	60	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	1	3.6	0	.	1	2.0
	Borderline mentally ill (2)	1	3.6	1	4.3	2	3.9
	Mildly ill (3)	6	21.4	1	4.3	7	13.7
	Moderately ill (4)	14	50.0	15	65.2	29	56.9
	Markedly ill (5)	5	17.9	5	21.7	10	19.6
	Severely ill (6)	1	3.6	1	4.3	2	3.9
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	28	100.0	23	100.0	51	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	10.3	0	.	3	5.7
	Borderline mentally ill (2)	2	6.9	2	8.3	4	7.5
	Mildly ill (3)	9	31.0	4	16.7	13	24.5
	Moderately ill (4)	8	27.6	15	62.5	23	43.4
	Markedly ill (5)	6	20.7	2	8.3	8	15.1
	Severely ill (6)	1	3.4	1	4.2	2	3.8
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	29	100.0	24	100.0	53	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	9.4	2	9.5	5	9.4
	Borderline mentally ill (2)	1	3.1	2	9.5	3	5.7
	Mildly ill (3)	12	37.5	8	38.1	20	37.7
	Moderately ill (4)	11	34.4	8	38.1	19	35.8
	Markedly ill (5)	5	15.6	0	.	5	9.4
	Severely ill (6)	0	.	1	4.8	1	1.9
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	32	100.0	21	100.0	53	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	14.3	1	4.2	5	9.6
	Borderline mentally ill (2)	3	10.7	3	12.5	6	11.5
	Mildly ill (3)	11	39.3	7	29.2	18	34.6
	Moderately ill (4)	9	32.1	10	41.7	19	36.5
	Markedly ill (5)	1	3.6	2	8.3	3	5.8
	Severely ill (6)	0	.	1	4.2	1	1.9
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	28	100.0	24	100.0	52	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	19.0	2	12.5	6	16.2
	Borderline mentally ill (2)	3	14.3	3	18.8	6	16.2
	Mildly ill (3)	8	38.1	5	31.3	13	35.1
	Moderately ill (4)	4	19.0	5	31.3	9	24.3
	Markedly ill (5)	2	9.5	0	.	2	5.4
	Severely ill (6)	0	.	1	6.3	1	2.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	16	100.0	37	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	12.5	2	18.2	4	14.8
	Borderline mentally ill (2)	2	12.5	4	36.4	6	22.2
	Mildly ill (3)	8	50.0	4	36.4	12	44.4
	Moderately ill (4)	4	25.0	0	.	4	14.8
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	9.1	1	3.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	16	100.0	11	100.0	27	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	22.2	4	30.8	6	27.3
	Borderline mentally ill (2)	2	22.2	1	7.7	3	13.6
	Mildly ill (3)	3	33.3	7	53.8	10	45.5
	Moderately ill (4)	2	22.2	0	.	2	9.1
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	7.7	1	4.5
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	9	100.0	13	100.0	22	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	28.6	3	60.0	5	41.7
	Borderline mentally ill (2)	1	14.3	0	.	1	8.3
	Mildly ill (3)	4	57.1	0	.	4	33.3
	Moderately ill (4)	0	.	2	40.0	2	16.7
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	7	100.0	5	100.0	12	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	33.3	1	25.0	3	30.0
	Borderline mentally ill (2)	2	33.3	2	50.0	4	40.0
	Mildly ill (3)	2	33.3	1	25.0	3	30.0
	Moderately ill (4)	0	.	0	.	0	.
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	6	100.0	4	100.0	10	100.0

(CONTINUED)

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Interim Output
Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	15.2	3	11.1	8	13.3
	Borderline mentally ill (2)	4	12.1	3	11.1	7	11.7
	Mildly ill (3)	14	42.4	11	40.7	25	41.7
	Moderately ill (4)	8	24.2	7	25.9	15	25.0
	Markedly ill (5)	2	6.1	2	7.4	4	6.7
	Severely ill (6)	0	.	1	3.7	1	1.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	33	100.0	27	100.0	60	100.0

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 1	-4	2	9.5	0	.	2	4.9	2	6.1	1	3.8	3	5.1	4	7.4	1	2.2	5	5.0
	-3	2	9.5	2	10.0	4	9.8	7	21.2	3	11.5	10	16.9	9	16.7	5	10.9	14	14.0
	-2	5	23.8	4	20.0	9	22.0	4	12.1	7	26.9	11	18.6	9	16.7	11	23.9	20	20.0
	-1	5	23.8	6	30.0	11	26.8	8	24.2	7	26.9	15	25.4	13	24.1	13	28.3	26	26.0
	0	6	28.6	7	35.0	13	31.7	10	30.3	8	30.8	18	30.5	16	29.6	15	32.6	31	31.0
	1	1	4.8	1	5.0	2	4.9	2	6.1	0	.	2	3.4	3	5.6	1	2.2	4	4.0
	Total	21	100.0	20	100.0	41	100.0	33	100.0	26	100.0	59	100.0	54	100.0	46	100.0	100	100.0
Week 2	-5	0	.	0	.	0	.	1	3.1	0	.	1	1.8	1	1.9	0	.	1	1.0
	-4	2	9.5	0	.	2	4.7	2	6.3	3	12.0	5	8.8	4	7.5	3	6.4	7	7.0
	-3	2	9.5	5	22.7	7	16.3	8	25.0	1	4.0	9	15.8	10	18.9	6	12.8	16	16.0
	-2	5	23.8	7	31.8	12	27.9	1	3.1	7	28.0	8	14.0	6	11.3	14	29.8	20	20.0
	-1	5	23.8	3	13.6	8	18.6	11	34.4	9	36.0	20	35.1	16	30.2	12	25.5	28	28.0
	0	6	28.6	7	31.8	13	30.2	7	21.9	5	20.0	12	21.1	13	24.5	12	25.5	25	25.0
	1	1	4.8	0	.	1	2.3	2	6.3	0	.	2	3.5	3	5.7	0	.	3	3.0
	Total	21	100.0	22	100.0	43	100.0	32	100.0	25	100.0	57	100.0	53	100.0	47	100.0	100	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 3	-4	3	15.0	0	.	3	6.8	4	12.9	3	13.6	7	13.2	7	13.7	3	6.5	10	10.3
	-3	3	15.0	7	29.2	10	22.7	6	19.4	1	4.5	7	13.2	9	17.6	8	17.4	17	17.5
	-2	5	25.0	6	25.0	11	25.0	5	16.1	7	31.8	12	22.6	10	19.6	13	28.3	23	23.7
	-1	3	15.0	8	33.3	11	25.0	9	29.0	8	36.4	17	32.1	12	23.5	16	34.8	28	28.9
	0	6	30.0	3	12.5	9	20.5	7	22.6	3	13.6	10	18.9	13	25.5	6	13.0	19	19.6
	Total	20	100.0	24	100.0	44	100.0	31	100.0	22	100.0	53	100.0	51	100.0	46	100.0	97	100.0
Week 4	-4	3	13.0	0	.	3	6.7	3	9.7	2	8.3	5	9.1	6	11.1	2	4.3	8	8.0
	-3	4	17.4	5	22.7	9	20.0	7	22.6	3	12.5	10	18.2	11	20.4	8	17.4	19	19.0
	-2	6	26.1	10	45.5	16	35.6	9	29.0	8	33.3	17	30.9	15	27.8	18	39.1	33	33.0
	-1	5	21.7	3	13.6	8	17.8	7	22.6	7	29.2	14	25.5	12	22.2	10	21.7	22	22.0
	0	5	21.7	3	13.6	8	17.8	4	12.9	3	12.5	7	12.7	9	16.7	6	13.0	15	15.0
	1	0	.	1	4.5	1	2.2	1	3.2	1	4.2	2	3.6	1	1.9	2	4.3	3	3.0
	Total	23	100.0	22	100.0	45	100.0	31	100.0	24	100.0	55	100.0	54	100.0	46	100.0	100	100.0
Week 8	-4	1	5.0	2	10.0	3	7.5	2	7.4	4	20.0	6	12.8	3	6.4	6	15.0	9	10.3
	-3	5	25.0	6	30.0	11	27.5	7	25.9	1	5.0	8	17.0	12	25.5	7	17.5	19	21.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 8	-2	4	20.0	6	30.0	10	25.0	9	33.3	8	40.0	17	36.2	13	27.7	14	35.0	27	31.0
	-1	7	35.0	4	20.0	11	27.5	4	14.8	5	25.0	9	19.1	11	23.4	9	22.5	20	23.0
	0	3	15.0	2	10.0	5	12.5	5	18.5	2	10.0	7	14.9	8	17.0	4	10.0	12	13.8
	Total	20	100.0	20	100.0	40	100.0	27	100.0	20	100.0	47	100.0	47	100.0	40	100.0	87	100.0
Week 12	-4	1	5.9	2	10.5	3	8.3	1	4.5	2	11.1	3	7.5	2	5.1	4	10.8	6	7.9
	-3	3	17.6	4	21.1	7	19.4	4	18.2	6	33.3	10	25.0	7	17.9	10	27.0	17	22.4
	-2	5	29.4	6	31.6	11	30.6	9	40.9	5	27.8	14	35.0	14	35.9	11	29.7	25	32.9
	-1	8	47.1	7	36.8	15	41.7	6	27.3	2	11.1	8	20.0	14	35.9	9	24.3	23	30.3
	0	0	.	0	.	0	.	2	9.1	3	16.7	5	12.5	2	5.1	3	8.1	5	6.6
	Total	17	100.0	19	100.0	36	100.0	22	100.0	18	100.0	40	100.0	39	100.0	37	100.0	76	100.0
Week 16	-4	2	13.3	2	11.1	4	12.1	0	.	3	18.8	3	8.1	2	5.6	5	14.7	7	10.0
	-3	2	13.3	3	16.7	5	15.2	4	19.0	4	25.0	8	21.6	6	16.7	7	20.6	13	18.6
	-2	6	40.0	6	33.3	12	36.4	11	52.4	5	31.3	16	43.2	17	47.2	11	32.4	28	40.0
	-1	5	33.3	4	22.2	9	27.3	3	14.3	2	12.5	5	13.5	8	22.2	6	17.6	14	20.0
	0	0	.	2	11.1	2	6.1	3	14.3	2	12.5	5	13.5	3	8.3	4	11.8	7	10.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 16	1	0	.	1	5.6	1	3.0	0	.	0	.	0	.	0	.	1	2.9	1	1.4
	Total	15	100.0	18	100.0	33	100.0	21	100.0	16	100.0	37	100.0	36	100.0	34	100.0	70	100.0
Week 20	-4	2	15.4	2	14.3	4	14.8	1	5.9	1	7.7	2	6.7	3	10.0	3	11.1	6	10.5
	-3	4	30.8	4	28.6	8	29.6	4	23.5	4	30.8	8	26.7	8	26.7	8	29.6	16	28.1
	-2	5	38.5	4	28.6	9	33.3	7	41.2	5	38.5	12	40.0	12	40.0	9	33.3	21	36.8
	-1	2	15.4	3	21.4	5	18.5	4	23.5	1	7.7	5	16.7	6	20.0	4	14.8	10	17.5
	0	0	.	1	7.1	1	3.7	1	5.9	1	7.7	2	6.7	1	3.3	2	7.4	3	5.3
	1	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	3.7	1	1.8
	Total	13	100.0	14	100.0	27	100.0	17	100.0	13	100.0	30	100.0	30	100.0	27	100.0	57	100.0
Week 24	-5	1	7.7	0	.	1	3.7	0	.	0	.	0	.	1	4.3	0	.	1	2.0
	-4	1	7.7	2	14.3	3	11.1	1	10.0	2	15.4	3	13.0	2	8.7	4	14.8	6	12.0
	-3	4	30.8	4	28.6	8	29.6	1	10.0	4	30.8	5	21.7	5	21.7	8	29.6	13	26.0
	-2	6	46.2	4	28.6	10	37.0	5	50.0	3	23.1	8	34.8	11	47.8	7	25.9	18	36.0
	-1	1	7.7	3	21.4	4	14.8	1	10.0	3	23.1	4	17.4	2	8.7	6	22.2	8	16.0
	0	0	.	1	7.1	1	3.7	2	20.0	1	7.7	3	13.0	2	8.7	2	7.4	4	8.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 50)						Placebo (N = 66)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to	Total																		
Week 24		13	100.0	14	100.0	27	100.0	10	100.0	13	100.0	23	100.0	23	100.0	27	100.0	50	100.0
Week 24 LOCF	-5	1	4.2	0	.	1	2.0	0	.	0	.	0	.	1	1.7	0	.	1	0.9
	-4	1	4.2	3	12.0	4	8.2	4	11.4	3	10.3	7	10.9	5	8.5	6	11.1	11	9.7
	-3	6	25.0	5	20.0	11	22.4	5	14.3	4	13.8	9	14.1	11	18.6	9	16.7	20	17.7
	-2	8	33.3	6	24.0	14	28.6	10	28.6	7	24.1	17	26.6	18	30.5	13	24.1	31	27.4
	-1	6	25.0	6	24.0	12	24.5	6	17.1	6	20.7	12	18.8	12	20.3	12	22.2	24	21.2
	0	2	8.3	3	12.0	5	10.2	10	28.6	7	24.1	17	26.6	12	20.3	10	18.5	22	19.5
	1	0	.	1	4.0	1	2.0	0	.	2	6.9	2	3.1	0	.	3	5.6	3	2.7
	2	0	.	1	4.0	1	2.0	0	.	0	.	0	.	0	.	1	1.9	1	0.9
	Total	24	100.0	25	100.0	49	100.0	35	100.0	29	100.0	64	100.0	59	100.0	54	100.0	113	100.0

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Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 1	-4	1	5.3	0	.	1	2.6	1	3.6	1	4.3	2	3.9	2	4.3	1	2.4	3	3.4
	-3	3	15.8	0	.	3	7.9	3	10.7	0	.	3	5.9	6	12.8	0	.	6	6.7
	-2	3	15.8	5	26.3	8	21.1	3	10.7	1	4.3	4	7.8	6	12.8	6	14.3	12	13.5
	-1	5	26.3	6	31.6	11	28.9	8	28.6	7	30.4	15	29.4	13	27.7	13	31.0	26	29.2
	0	6	31.6	7	36.8	13	34.2	12	42.9	14	60.9	26	51.0	18	38.3	21	50.0	39	43.8
	1	1	5.3	1	5.3	2	5.3	0	.	0	.	0	.	1	2.1	1	2.4	2	2.2
	2	0	.	0	.	0	.	1	3.6	0	.	1	2.0	1	2.1	0	.	1	1.1
	Total	19	100.0	19	100.0	38	100.0	28	100.0	23	100.0	51	100.0	47	100.0	42	100.0	89	100.0
Week 2	-5	0	.	1	6.3	1	3.0	1	3.4	0	.	1	1.9	1	2.2	1	2.5	2	2.3
	-4	0	.	0	.	0	.	2	6.9	1	4.2	3	5.7	2	4.3	1	2.5	3	3.5
	-3	2	11.8	1	6.3	3	9.1	2	6.9	2	8.3	4	7.5	4	8.7	3	7.5	7	8.1
	-2	4	23.5	2	12.5	6	18.2	4	13.8	1	4.2	5	9.4	8	17.4	3	7.5	11	12.8
	-1	5	29.4	7	43.8	12	36.4	10	34.5	9	37.5	19	35.8	15	32.6	16	40.0	31	36.0
	0	6	35.3	5	31.3	11	33.3	9	31.0	11	45.8	20	37.7	15	32.6	16	40.0	31	36.0
	1	0	.	0	.	0	.	1	3.4	0	.	1	1.9	1	2.2	0	.	1	1.2

(CONTINUED)

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Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to	Total																		
Week 2		17	100.0	16	100.0	33	100.0	29	100.0	24	100.0	53	100.0	46	100.0	40	100.0	86	100.0
Week 3	-5	0	.	0	.	0	.	1	3.1	1	4.8	2	3.8	1	2.0	1	2.8	2	2.3
	-4	0	.	1	6.7	1	2.9	1	3.1	1	4.8	2	3.8	1	2.0	2	5.6	3	3.4
	-3	3	15.8	2	13.3	5	14.7	3	9.4	1	4.8	4	7.5	6	11.8	3	8.3	9	10.3
	-2	7	36.8	0	.	7	20.6	6	18.8	4	19.0	10	18.9	13	25.5	4	11.1	17	19.5
	-1	5	26.3	9	60.0	14	41.2	13	40.6	11	52.4	24	45.3	18	35.3	20	55.6	38	43.7
	0	4	21.1	2	13.3	6	17.6	7	21.9	3	14.3	10	18.9	11	21.6	5	13.9	16	18.4
	1	0	.	1	6.7	1	2.9	0	.	0	.	0	.	0	.	1	2.8	1	1.1
	2	0	.	0	.	0	.	1	3.1	0	.	1	1.9	1	2.0	0	.	1	1.1
	Total	19	100.0	15	100.0	34	100.0	32	100.0	21	100.0	53	100.0	51	100.0	36	100.0	87	100.0
Week 4	-5	0	.	1	5.3	1	2.4	2	7.1	0	.	2	3.8	2	3.9	1	2.3	3	3.2
	-4	0	.	1	5.3	1	2.4	2	7.1	2	8.3	4	7.7	2	3.9	3	7.0	5	5.3
	-3	5	21.7	1	5.3	6	14.3	1	3.6	1	4.2	2	3.8	6	11.8	2	4.7	8	8.5
	-2	7	30.4	3	15.8	10	23.8	8	28.6	5	20.8	13	25.0	15	29.4	8	18.6	23	24.5
	-1	6	26.1	9	47.4	15	35.7	11	39.3	9	37.5	20	38.5	17	33.3	18	41.9	35	37.2

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 4	0	4	17.4	4	21.1	8	19.0	3	10.7	7	29.2	10	19.2	7	13.7	11	25.6	18	19.1
	1	1	4.3	0	.	1	2.4	1	3.6	0	.	1	1.9	2	3.9	0	.	2	2.1
	Total	23	100.0	19	100.0	42	100.0	28	100.0	24	100.0	52	100.0	51	100.0	43	100.0	94	100.0
Week 8	-5	0	.	1	5.9	1	2.7	2	9.5	1	6.3	3	8.1	2	4.9	2	6.1	4	5.4
	-4	0	.	2	11.8	2	5.4	1	4.8	1	6.3	2	5.4	1	2.4	3	9.1	4	5.4
	-3	4	20.0	3	17.6	7	18.9	2	9.5	0	.	2	5.4	6	14.6	3	9.1	9	12.2
	-2	7	35.0	2	11.8	9	24.3	6	28.6	7	43.8	13	35.1	13	31.7	9	27.3	22	29.7
	-1	5	25.0	6	35.3	11	29.7	6	28.6	4	25.0	10	27.0	11	26.8	10	30.3	21	28.4
	0	3	15.0	3	17.6	6	16.2	3	14.3	3	18.8	6	16.2	6	14.6	6	18.2	12	16.2
	1	1	5.0	0	.	1	2.7	0	.	0	.	0	.	1	2.4	0	.	1	1.4
	Missing	0	.	0	.	0	.	1	4.8	0	.	1	2.7	1	2.4	0	.	1	1.4
	Total	20	100.0	17	100.0	37	100.0	21	100.0	16	100.0	37	100.0	41	100.0	33	100.0	74	100.0
Week 12	-4	0	.	0	.	0	.	0	.	2	18.2	2	7.4	0	.	2	9.1	2	4.1
	-3	5	45.5	3	27.3	8	36.4	2	12.5	0	.	2	7.4	7	25.9	3	13.6	10	20.4
	-2	3	27.3	3	27.3	6	27.3	7	43.8	5	45.5	12	44.4	10	37.0	8	36.4	18	36.7

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 12	-1	3	27.3	3	27.3	6	27.3	6	37.5	3	27.3	9	33.3	9	33.3	6	27.3	15	30.6
	0	0	.	2	18.2	2	9.1	1	6.3	1	9.1	2	7.4	1	3.7	3	13.6	4	8.2
	Total	11	100.0	11	100.0	22	100.0	16	100.0	11	100.0	27	100.0	27	100.0	22	100.0	49	100.0
Week 16	-4	0	.	0	.	0	.	0	.	2	15.4	2	9.1	0	.	2	8.0	2	4.5
	-3	3	30.0	2	16.7	5	22.7	2	22.2	2	15.4	4	18.2	5	26.3	4	16.0	9	20.5
	-2	5	50.0	4	33.3	9	40.9	4	44.4	4	30.8	8	36.4	9	47.4	8	32.0	17	38.6
	-1	2	20.0	4	33.3	6	27.3	2	22.2	4	30.8	6	27.3	4	21.1	8	32.0	12	27.3
	0	0	.	2	16.7	2	9.1	1	11.1	1	7.7	2	9.1	1	5.3	3	12.0	4	9.1
	Total	10	100.0	12	100.0	22	100.0	9	100.0	13	100.0	22	100.0	19	100.0	25	100.0	44	100.0
Week 20	-4	0	.	0	.	0	.	0	.	1	20.0	1	8.3	0	.	1	12.5	1	4.5
	-3	3	42.9	0	.	3	30.0	2	28.6	2	40.0	4	33.3	5	35.7	2	25.0	7	31.8
	-2	3	42.9	1	33.3	4	40.0	2	28.6	0	.	2	16.7	5	35.7	1	12.5	6	27.3
	-1	1	14.3	2	66.7	3	30.0	3	42.9	0	.	3	25.0	4	28.6	2	25.0	6	27.3
	0	0	.	0	.	0	.	0	.	2	40.0	2	16.7	0	.	2	25.0	2	9.1
	Total	7	100.0	3	100.0	10	100.0	7	100.0	5	100.0	12	100.0	14	100.0	8	100.0	22	100.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 44)						Placebo (N = 61)						Total (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 24	-4	0	.	1	16.7	1	6.7	0	.	1	25.0	1	10.0	0	.	2	20.0	2	8.0
	-3	3	33.3	2	33.3	5	33.3	2	33.3	0	.	2	20.0	5	33.3	2	20.0	7	28.0
	-2	5	55.6	1	16.7	6	40.0	3	50.0	3	75.0	6	60.0	8	53.3	4	40.0	12	48.0
	-1	1	11.1	2	33.3	3	20.0	1	16.7	0	.	1	10.0	2	13.3	2	20.0	4	16.0
	Total	9	100.0	6	100.0	15	100.0	6	100.0	4	100.0	10	100.0	15	100.0	10	100.0	25	100.0
Week 24 LOCF	-5	0	.	1	5.3	1	2.3	2	6.1	1	3.7	3	5.0	2	3.5	2	4.3	4	3.9
	-4	1	4.2	1	5.3	2	4.7	2	6.1	2	7.4	4	6.7	3	5.3	3	6.5	6	5.8
	-3	6	25.0	6	31.6	12	27.9	3	9.1	0	.	3	5.0	9	15.8	6	13.0	15	14.6
	-2	7	29.2	2	10.5	9	20.9	12	36.4	10	37.0	22	36.7	19	33.3	12	26.1	31	30.1
	-1	7	29.2	7	36.8	14	32.6	10	30.3	8	29.6	18	30.0	17	29.8	15	32.6	32	31.1
	0	2	8.3	2	10.5	4	9.3	3	9.1	6	22.2	9	15.0	5	8.8	8	17.4	13	12.6
	1	1	4.2	0	.	1	2.3	0	.	0	.	0	.	1	1.8	0	.	1	1.0
	2	0	.	0	.	0	.	1	3.0	0	.	1	1.7	1	1.8	0	.	1	1.0
	Total	24	100.0	19	100.0	43	100.0	33	100.0	27	100.0	60	100.0	57	100.0	46	100.0	103	100.0

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Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	1	4.8	2	10.0	3	7.3
	0	11	52.4	9	45.0	20	48.8
	1	7	33.3	6	30.0	13	31.7
	2	1	4.8	2	10.0	3	7.3
	3	0	.	1	5.0	1	2.4
	4	1	4.8	0	.	1	2.4
	Total	21	100.0	20	100.0	41	100.0
Week 2	-2	0	.	1	4.5	1	2.3
	-1	3	14.3	4	18.2	7	16.3
	0	10	47.6	10	45.5	20	46.5
	1	5	23.8	5	22.7	10	23.3
	2	2	9.5	2	9.1	4	9.3
	4	1	4.8	0	.	1	2.3
	Total	21	100.0	22	100.0	43	100.0
Week 3	-3	1	5.0	1	4.2	2	4.5
	-2	0	.	1	4.2	1	2.3
	-1	3	15.0	5	20.8	8	18.2
	0	10	50.0	11	45.8	21	47.7
	1	5	25.0	5	20.8	10	22.7
	2	1	5.0	1	4.2	2	4.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	Total	20	100.0	24	100.0	44	100.0
Week 4	-3	1	4.3	0	.	1	2.2
	-2	2	8.7	2	9.1	4	8.9
	-1	1	4.3	3	13.6	4	8.9
	0	13	56.5	12	54.5	25	55.6
	1	4	17.4	4	18.2	8	17.8
	2	1	4.3	1	4.5	2	4.4
	3	1	4.3	0	.	1	2.2
	Total	23	100.0	22	100.0	45	100.0
Week 8	-2	2	10.0	2	10.0	4	10.0
	-1	2	10.0	6	30.0	8	20.0
	0	13	65.0	12	60.0	25	62.5
	1	1	5.0	0	.	1	2.5
	2	1	5.0	0	.	1	2.5
	3	1	5.0	0	.	1	2.5
	Total	20	100.0	20	100.0	40	100.0
Week 12	-2	2	11.8	3	15.8	5	13.9
	-1	1	5.9	3	15.8	4	11.1
	0	9	52.9	9	47.4	18	50.0
	1	3	17.6	4	21.1	7	19.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	2	2	11.8	0	.	2	5.6
	Total	17	100.0	19	100.0	36	100.0
Week 16	-4	0	.	1	5.6	1	3.0
	-2	2	13.3	2	11.1	4	12.1
	-1	3	20.0	3	16.7	6	18.2
	0	7	46.7	6	33.3	13	39.4
	1	1	6.7	3	16.7	4	12.1
	2	2	13.3	3	16.7	5	15.2
	Total	15	100.0	18	100.0	33	100.0
Week 20	-4	0	.	1	7.1	1	3.7
	-2	3	23.1	2	14.3	5	18.5
	-1	3	23.1	4	28.6	7	25.9
	0	4	30.8	5	35.7	9	33.3
	1	3	23.1	2	14.3	5	18.5
	Total	13	100.0	14	100.0	27	100.0
Week 24	-4	1	7.7	0	.	1	3.7
	-3	0	.	1	7.1	1	3.7
	-2	1	7.7	2	14.3	3	11.1
	-1	2	15.4	5	35.7	7	25.9
	0	7	53.8	4	28.6	11	40.7

(CONTINUED)

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Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24	1	2	15.4	2	14.3	4	14.8
	Total	13	100.0	14	100.0	27	100.0
Week 24 LOCF	-4	1	4.2	0	.	1	2.0
	-3	0	.	1	4.0	1	2.0
	-2	2	8.3	2	8.0	4	8.2
	-1	3	12.5	6	24.0	9	18.4
	0	13	54.2	8	32.0	21	42.9
	1	4	16.7	5	20.0	9	18.4
	2	1	4.2	2	8.0	3	6.1
	3	0	.	1	4.0	1	2.0
	Total	24	100.0	25	100.0	49	100.0

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Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	2	10.5	0	.	2	5.3
	0	10	52.6	15	78.9	25	65.8
	1	3	15.8	2	10.5	5	13.2
	2	4	21.1	2	10.5	6	15.8
	Total	19	100.0	19	100.0	38	100.0
Week 2	-3	0	.	1	6.3	1	3.0
	-1	1	5.9	3	18.8	4	12.1
	0	9	52.9	10	62.5	19	57.6
	1	4	23.5	1	6.3	5	15.2
	2	3	17.6	1	6.3	4	12.1
	Total	17	100.0	16	100.0	33	100.0
Week 3	-2	0	.	1	6.7	1	2.9
	-1	3	15.8	4	26.7	7	20.6
	0	12	63.2	6	40.0	18	52.9
	1	4	21.1	4	26.7	8	23.5
	Total	19	100.0	15	100.0	34	100.0
Week 4	-3	0	.	1	5.3	1	2.4
	-2	1	4.3	1	5.3	2	4.8
	-1	2	8.7	3	15.8	5	11.9
	0	17	73.9	12	63.2	29	69.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	1	1	4.3	2	10.5	3	7.1
	2	2	8.7	0	.	2	4.8
	Total	23	100.0	19	100.0	42	100.0
Week 8	-3	0	.	2	11.8	2	5.4
	-2	2	10.0	2	11.8	4	10.8
	-1	1	5.0	3	17.6	4	10.8
	0	11	55.0	8	47.1	19	51.4
	1	4	20.0	2	11.8	6	16.2
	2	2	10.0	0	.	2	5.4
	Total	20	100.0	17	100.0	37	100.0
Week 12	-3	2	18.2	0	.	2	9.1
	-2	0	.	2	18.2	2	9.1
	-1	1	9.1	2	18.2	3	13.6
	0	5	45.5	6	54.5	11	50.0
	1	3	27.3	1	9.1	4	18.2
	Total	11	100.0	11	100.0	22	100.0
Week 16	-3	1	10.0	0	.	1	4.5
	-2	1	10.0	1	8.3	2	9.1
	-1	1	10.0	3	25.0	4	18.2
	0	3	30.0	8	66.7	11	50.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 44)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 16	1	4	40.0	0	.	4	18.2
	Total	10	100.0	12	100.0	22	100.0
Week 20	-2	1	14.3	0	.	1	10.0
	-1	2	28.6	1	33.3	3	30.0
	0	4	57.1	2	66.7	6	60.0
	Total	7	100.0	3	100.0	10	100.0
Week 24	-2	1	11.1	2	33.3	3	20.0
	-1	1	11.1	3	50.0	4	26.7
	0	6	66.7	1	16.7	7	46.7
	1	1	11.1	0	.	1	6.7
	Total	9	100.0	6	100.0	15	100.0
Week 24 LOCF	-3	1	4.2	1	5.3	2	4.7
	-2	2	8.3	3	15.8	5	11.6
	-1	1	4.2	8	42.1	9	20.9
	0	16	66.7	7	36.8	23	53.5
	1	3	12.5	0	.	3	7.0
	2	1	4.2	0	.	1	2.3
	Total	24	100.0	19	100.0	43	100.0

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-2	1	3.0	0	.	1	1.7
	-1	9	27.3	2	7.7	11	18.6
	0	20	60.6	18	69.2	38	64.4
	1	3	9.1	4	15.4	7	11.9
	2	0	.	1	3.8	1	1.7
	Missing	0	.	1	3.8	1	1.7
	Total	33	100.0	26	100.0	59	100.0
Week 2	-3	1	3.1	1	4.0	2	3.5
	-1	12	37.5	5	20.0	17	29.8
	0	15	46.9	13	52.0	28	49.1
	1	4	12.5	4	16.0	8	14.0
	2	0	.	1	4.0	1	1.8
	Missing	0	.	1	4.0	1	1.8
	Total	32	100.0	25	100.0	57	100.0
Week 3	-4	1	3.2	0	.	1	1.9
	-3	1	3.2	0	.	1	1.9
	-2	2	6.5	0	.	2	3.8
	-1	10	32.3	7	31.8	17	32.1
	0	15	48.4	11	50.0	26	49.1
	1	1	3.2	1	4.5	2	3.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	2	1	3.2	2	9.1	3	5.7
	Missing	0	.	1	4.5	1	1.9
	Total	31	100.0	22	100.0	53	100.0
Week 4	-4	1	3.2	0	.	1	1.8
	-3	1	3.2	0	.	1	1.8
	-2	4	12.9	0	.	4	7.3
	-1	9	29.0	7	29.2	16	29.1
	0	13	41.9	12	50.0	25	45.5
	1	1	3.2	4	16.7	5	9.1
	2	2	6.5	0	.	2	3.6
	Missing	0	.	1	4.2	1	1.8
	Total	31	100.0	24	100.0	55	100.0
Week 8	-4	1	3.7	0	.	1	2.1
	-3	2	7.4	0	.	2	4.3
	-2	3	11.1	1	5.0	4	8.5
	-1	5	18.5	10	50.0	15	31.9
	0	14	51.9	7	35.0	21	44.7
	1	1	3.7	0	.	1	2.1
	2	0	.	1	5.0	1	2.1
	3	1	3.7	0	.	1	2.1

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 8	Missing	0	.	1	5.0	1	2.1
	Total	27	100.0	20	100.0	47	100.0
Week 12	-4	1	4.5	0	.	1	2.5
	-3	2	9.1	1	5.6	3	7.5
	-2	3	13.6	2	11.1	5	12.5
	-1	7	31.8	5	27.8	12	30.0
	0	6	27.3	9	50.0	15	37.5
	1	2	9.1	0	.	2	5.0
	3	1	4.5	0	.	1	2.5
	Missing	0	.	1	5.6	1	2.5
	Total	22	100.0	18	100.0	40	100.0
Week 16	-3	1	4.8	0	.	1	2.7
	-2	6	28.6	4	25.0	10	27.0
	-1	4	19.0	4	25.0	8	21.6
	0	9	42.9	6	37.5	15	40.5
	1	1	4.8	0	.	1	2.7
	2	0	.	1	6.3	1	2.7
	Missing	0	.	1	6.3	1	2.7
	Total	21	100.0	16	100.0	37	100.0
Week 20	-3	2	11.8	0	.	2	6.7

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	-2	4	23.5	3	23.1	7	23.3
	-1	6	35.3	2	15.4	8	26.7
	0	5	29.4	4	30.8	9	30.0
	1	0	.	2	15.4	2	6.7
	2	0	.	2	15.4	2	6.7
	Total	17	100.0	13	100.0	30	100.0
Week 24	-4	1	10.0	0	.	1	4.3
	-2	2	20.0	2	15.4	4	17.4
	-1	2	20.0	4	30.8	6	26.1
	0	5	50.0	4	30.8	9	39.1
	1	0	.	1	7.7	1	4.3
	2	0	.	1	7.7	1	4.3
	3	0	.	1	7.7	1	4.3
	Total	10	100.0	13	100.0	23	100.0
Week 24 LOCF	-4	1	2.9	0	.	1	1.6
	-2	5	14.3	2	6.9	7	10.9
	-1	8	22.9	6	20.7	14	21.9
	0	18	51.4	13	44.8	31	48.4
	1	1	2.9	5	17.2	6	9.4
	2	0	.	1	3.4	1	1.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	3	2	5.7	1	3.4	3	4.7
	Missing	0	.	1	3.4	1	1.6
	Total	35	100.0	29	100.0	64	100.0

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	4	14.3	2	8.7	6	11.8
	0	12	42.9	13	56.5	25	49.0
	1	6	21.4	5	21.7	11	21.6
	2	2	7.1	3	13.0	5	9.8
	3	3	10.7	0	.	3	5.9
	Missing	1	3.6	0	.	1	2.0
	Total	28	100.0	23	100.0	51	100.0
Week 2	-2	0	.	1	4.2	1	1.9
	-1	6	20.7	2	8.3	8	15.1
	0	15	51.7	16	66.7	31	58.5
	1	4	13.8	3	12.5	7	13.2
	2	2	6.9	2	8.3	4	7.5
	3	1	3.4	0	.	1	1.9
	Missing	1	3.4	0	.	1	1.9
	Total	29	100.0	24	100.0	53	100.0
Week 3	-2	0	.	2	9.5	2	3.8
	-1	9	28.1	5	23.8	14	26.4
	0	12	37.5	12	57.1	24	45.3
	1	7	21.9	1	4.8	8	15.1
	2	2	6.3	1	4.8	3	5.7

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 61)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	3	1	3.1	0	.	1	1.9
	Missing	1	3.1	0	.	1	1.9
	Total	32	100.0	21	100.0	53	100.0
Week 4	-3	1	3.6	0	.	1	1.9
	-1	8	28.6	8	33.3	16	30.8
	0	13	46.4	14	58.3	27	51.9
	1	4	14.3	1	4.2	5	9.6
	2	1	3.6	1	4.2	2	3.8
	Missing	1	3.6	0	.	1	1.9
	Total	28	100.0	24	100.0	52	100.0
Week 8	-3	1	4.8	0	.	1	2.7
	-2	2	9.5	3	18.8	5	13.5
	-1	5	23.8	5	31.3	10	27.0
	0	8	38.1	6	37.5	14	37.8
	1	3	14.3	2	12.5	5	13.5
	Missing	2	9.5	0	.	2	5.4
	Total	21	100.0	16	100.0	37	100.0
Week 12	-2	3	18.8	2	18.2	5	18.5
	-1	6	37.5	7	63.6	13	48.1
	0	5	31.3	2	18.2	7	25.9

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	1	1	6.3	0	.	1	3.7
	Missing	1	6.3	0	.	1	3.7
	Total	16	100.0	11	100.0	27	100.0
Week 16	-3	0	.	1	7.7	1	4.5
	-2	2	22.2	1	7.7	3	13.6
	-1	2	22.2	9	69.2	11	50.0
	0	4	44.4	2	15.4	6	27.3
	Missing	1	11.1	0	.	1	4.5
	Total	9	100.0	13	100.0	22	100.0
Week 20	-3	0	.	1	20.0	1	8.3
	-2	2	28.6	1	20.0	3	25.0
	-1	2	28.6	0	.	2	16.7
	0	3	42.9	3	60.0	6	50.0
	Total	7	100.0	5	100.0	12	100.0
Week 24	-2	3	50.0	1	25.0	4	40.0
	-1	1	16.7	2	50.0	3	30.0
	0	2	33.3	1	25.0	3	30.0
	Total	6	100.0	4	100.0	10	100.0
Week 24 LOCF	-3	1	3.0	0	.	1	1.7
	-2	5	15.2	3	11.1	8	13.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 61)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	-1	7	21.2	11	40.7	18	30.0
	0	13	39.4	11	40.7	24	40.0
	1	5	15.2	2	7.4	7	11.7
	3	1	3.0	0	.	1	1.7
	Missing	1	3.0	0	.	1	1.7
	Total	33	100.0	27	100.0	60	100.0

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group														
	Paroxetine (N = 25)					Placebo (N = 36)					Total (N = 61)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.3	4.0	4	6	25	4.2	4.0	3	6	36	4.2	4.0	3	6	61
Change from Acute Study Baseline to 716:															
Week 1	-1.3	-1.0	-4	1	21	-1.3	-1.0	-4	1	33	-1.3	-1.0	-4	1	54
Week 2	-1.3	-1.0	-4	1	21	-1.5	-1.0	-5	1	32	-1.4	-1.0	-5	1	53
Week 3	-1.7	-2.0	-4	0	20	-1.7	-1.0	-4	0	31	-1.7	-2.0	-4	0	51
Week 4	-1.8	-2.0	-4	0	23	-1.8	-2.0	-4	1	31	-1.8	-2.0	-4	1	54
Week 8	-1.7	-1.5	-4	0	20	-1.9	-2.0	-4	0	27	-1.8	-2.0	-4	0	47
Week 12	-1.8	-2.0	-4	-1	17	-1.8	-2.0	-4	0	22	-1.8	-2.0	-4	0	39
Week 16	-2.1	-2.0	-4	-1	15	-1.8	-2.0	-3	0	21	-1.9	-2.0	-4	0	36
Week 20	-2.5	-2.0	-4	-1	13	-2.0	-2.0	-4	0	17	-2.2	-2.0	-4	0	30
Week 24	-2.6	-2.0	-5	-1	13	-1.8	-2.0	-4	0	10	-2.3	-2.0	-5	0	23
Week 24 LOCF	-2.0	-2.0	-5	0	24	-1.6	-2.0	-4	0	35	-1.8	-2.0	-5	0	59

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group														
	Paroxetine (N = 25)					Placebo (N = 30)					Total (N = 55)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.2	4.0	3	5	25	4.3	4.0	4	5	30	4.3	4.0	3	5	55
Change from Acute Study Baseline to 716:															
Week 1	-1.0	-1.0	-3	1	20	-1.3	-1.0	-4	0	26	-1.2	-1.0	-4	1	46
Week 2	-1.5	-2.0	-3	0	22	-1.5	-1.0	-4	0	25	-1.5	-1.0	-4	0	47
Week 3	-1.7	-2.0	-3	0	24	-1.7	-1.5	-4	0	22	-1.7	-2.0	-4	0	46
Week 4	-1.7	-2.0	-3	1	22	-1.6	-2.0	-4	1	24	-1.7	-2.0	-4	1	46
Week 8	-2.1	-2.0	-4	0	20	-2.0	-2.0	-4	0	20	-2.1	-2.0	-4	0	40
Week 12	-2.1	-2.0	-4	-1	19	-2.1	-2.0	-4	0	18	-2.1	-2.0	-4	0	37
Week 16	-1.8	-2.0	-4	1	18	-2.3	-2.0	-4	0	16	-2.0	-2.0	-4	1	34
Week 20	-2.2	-2.0	-4	0	14	-2.0	-2.0	-4	1	13	-2.1	-2.0	-4	1	27
Week 24	-2.2	-2.0	-4	0	14	-2.2	-2.0	-4	0	13	-2.2	-2.0	-4	0	27
Week 24 LOCF	-1.7	-2.0	-4	2	25	-1.4	-1.0	-4	1	29	-1.6	-2.0	-4	2	54

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group														
	Paroxetine (N = 50)					Placebo (N = 66)					Total (N = 116)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.3	4.0	3	6	50	4.2	4.0	3	6	66	4.2	4.0	3	6	116
Change from Acute Study Baseline to 716:															
Week 1	-1.1	-1.0	-4	1	41	-1.3	-1.0	-4	1	59	-1.2	-1.0	-4	1	100
Week 2	-1.4	-1.0	-4	1	43	-1.5	-1.0	-5	1	57	-1.5	-1.0	-5	1	100
Week 3	-1.7	-2.0	-4	0	44	-1.7	-1.0	-4	0	53	-1.7	-2.0	-4	0	97
Week 4	-1.7	-2.0	-4	1	45	-1.7	-2.0	-4	1	55	-1.7	-2.0	-4	1	100
Week 8	-1.9	-2.0	-4	0	40	-1.9	-2.0	-4	0	47	-1.9	-2.0	-4	0	87
Week 12	-1.9	-2.0	-4	-1	36	-2.0	-2.0	-4	0	40	-1.9	-2.0	-4	0	76
Week 16	-1.9	-2.0	-4	1	33	-2.0	-2.0	-4	0	37	-1.9	-2.0	-4	1	70
Week 20	-2.3	-2.0	-4	0	27	-2.0	-2.0	-4	1	30	-2.2	-2.0	-4	1	57
Week 24	-2.4	-2.0	-5	0	27	-2.0	-2.0	-4	0	23	-2.2	-2.0	-5	0	50
Week 24 LOCF	-1.9	-2.0	-5	2	49	-1.5	-2.0	-4	1	64	-1.7	-2.0	-5	2	113

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group														
	Paroxetine (N = 24)					Placebo (N = 34)					Total (N = 58)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.5	4.0	4	6	24	4.7	5.0	3	6	34	4.6	4.0	3	6	58
Change from Acute Study Baseline to 716:															
Week 1	-1.2	-1.0	-4	1	19	-0.9	-1.0	-4	2	28	-1.0	-1.0	-4	2	47
Week 2	-1.1	-1.0	-3	0	17	-1.2	-1.0	-5	1	29	-1.2	-1.0	-5	1	46
Week 3	-1.5	-2.0	-3	0	19	-1.3	-1.0	-5	2	32	-1.4	-1.0	-5	2	51
Week 4	-1.5	-2.0	-3	1	23	-1.7	-1.0	-5	1	28	-1.6	-1.0	-5	1	51
Week 8	-1.5	-2.0	-3	1	20	-1.9	-2.0	-5	0	20	-1.7	-2.0	-5	1	40
Week 12	-2.2	-2.0	-3	-1	11	-1.6	-2.0	-3	0	16	-1.9	-2.0	-3	0	27
Week 16	-2.1	-2.0	-3	-1	10	-1.8	-2.0	-3	0	9	-1.9	-2.0	-3	0	19
Week 20	-2.3	-2.0	-3	-1	7	-1.9	-2.0	-3	-1	7	-2.1	-2.0	-3	-1	14
Week 24	-2.2	-2.0	-3	-1	9	-2.2	-2.0	-3	-1	6	-2.2	-2.0	-3	-1	15
Week 24 LOCF	-1.8	-2.0	-4	1	24	-1.8	-2.0	-5	2	33	-1.8	-2.0	-5	2	57

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group														
	Paroxetine (N = 20)					Placebo (N = 27)					Total (N = 47)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.7	5.0	4	6	20	4.7	5.0	3	6	27	4.7	5.0	3	6	47
Change from Acute Study Baseline to 716:															
Week 1	-0.8	-1.0	-2	1	19	-0.6	0.0	-4	0	23	-0.7	0.0	-4	1	42
Week 2	-1.2	-1.0	-5	0	16	-0.9	-1.0	-4	0	24	-1.0	-1.0	-5	0	40
Week 3	-1.2	-1.0	-4	1	15	-1.5	-1.0	-5	0	21	-1.4	-1.0	-5	1	36
Week 4	-1.4	-1.0	-5	0	19	-1.3	-1.0	-4	0	24	-1.3	-1.0	-5	0	43
Week 8	-1.9	-1.0	-5	0	17	-1.7	-2.0	-5	0	16	-1.8	-2.0	-5	0	33
Week 12	-1.6	-2.0	-3	0	11	-1.9	-2.0	-4	0	11	-1.8	-2.0	-4	0	22
Week 16	-1.5	-1.5	-3	0	12	-2.0	-2.0	-4	0	13	-1.8	-2.0	-4	0	25
Week 20	-1.3	-1.0	-2	-1	3	-2.0	-3.0	-4	0	5	-1.8	-1.5	-4	0	8
Week 24	-2.3	-2.5	-4	-1	6	-2.5	-2.0	-4	-2	4	-2.4	-2.0	-4	-1	10
Week 24 LOCF	-2.0	-2.0	-5	0	19	-1.5	-1.0	-5	0	27	-1.7	-1.5	-5	0	46

BRL 29060 - 716
Interim Output
Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group														
	Paroxetine (N = 44)					Placebo (N = 61)					Total (N = 105)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.6	4.5	4	6	44	4.7	5.0	3	6	61	4.6	5.0	3	6	105
Change from Acute Study Baseline to 716:															
Week 1	-1.0	-1.0	-4	1	38	-0.7	0.0	-4	2	51	-0.9	-1.0	-4	2	89
Week 2	-1.2	-1.0	-5	0	33	-1.1	-1.0	-5	1	53	-1.1	-1.0	-5	1	86
Week 3	-1.4	-1.0	-4	1	34	-1.4	-1.0	-5	2	53	-1.4	-1.0	-5	2	87
Week 4	-1.5	-1.0	-5	1	42	-1.5	-1.0	-5	1	52	-1.5	-1.0	-5	1	94
Week 8	-1.7	-2.0	-5	1	37	-1.8	-2.0	-5	0	36	-1.7	-2.0	-5	1	73
Week 12	-1.9	-2.0	-3	0	22	-1.7	-2.0	-4	0	27	-1.8	-2.0	-4	0	49
Week 16	-1.8	-2.0	-3	0	22	-1.9	-2.0	-4	0	22	-1.8	-2.0	-4	0	44
Week 20	-2.0	-2.0	-3	-1	10	-1.9	-2.0	-4	0	12	-2.0	-2.0	-4	0	22
Week 24	-2.3	-2.0	-4	-1	15	-2.3	-2.0	-4	-1	10	-2.3	-2.0	-4	-1	25
Week 24 LOCF	-1.9	-2.0	-5	1	43	-1.7	-2.0	-5	2	60	-1.7	-2.0	-5	2	103

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Paroxetine (N = 25)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.5	2.0	1	5	25
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	4	21
Week 2	0.5	0.0	-1	4	21
Week 3	0.1	0.0	-3	2	20
Week 4	0.0	0.0	-3	3	23
Week 8	0.0	0.0	-2	3	20
Week 12	0.1	0.0	-2	2	17
Week 16	-0.1	0.0	-2	2	15
Week 20	-0.5	0.0	-2	1	13
Week 24	-0.5	0.0	-4	1	13
Week 24 LOCF	-0.2	0.0	-4	2	24

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Paroxetine (N = 25)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.6	3.0	1	5	25
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	3	20
Week 2	0.1	0.0	-2	2	22
Week 3	-0.1	0.0	-3	2	24
Week 4	-0.0	0.0	-2	2	22
Week 8	-0.5	0.0	-2	0	20
Week 12	-0.3	0.0	-2	1	19
Week 16	-0.1	0.0	-4	2	18
Week 20	-0.7	-0.5	-4	1	14
Week 24	-0.7	-1.0	-3	1	14
Week 24 LOCF	-0.0	0.0	-3	3	25

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Paroxetine (N = 50)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.6	2.0	1	5	50
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	4	41
Week 2	0.3	0.0	-2	4	43
Week 3	-0.0	0.0	-3	2	44
Week 4	0.0	0.0	-3	3	45
Week 8	-0.3	0.0	-2	3	40
Week 12	-0.1	0.0	-2	2	36
Week 16	-0.1	0.0	-4	2	33
Week 20	-0.6	0.0	-4	1	27
Week 24	-0.6	0.0	-4	1	27
Week 24 LOCF	-0.1	0.0	-4	3	49

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Paroxetine (N = 24)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.8	3.0	1	5	24
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.5	0.0	-1	2	19
Week 2	0.5	0.0	-1	2	17
Week 3	0.1	0.0	-1	1	19
Week 4	0.0	0.0	-2	2	23
Week 8	0.2	0.0	-2	2	20
Week 12	-0.4	0.0	-3	1	11
Week 16	-0.2	0.0	-3	1	10
Week 20	-0.6	0.0	-2	0	7
Week 24	-0.2	0.0	-2	1	9
Week 24 LOCF	-0.1	0.0	-3	2	24

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Paroxetine (N = 20)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.7	4.0	2	5	20
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.3	0.0	0	2	19
Week 2	-0.2	0.0	-3	2	16
Week 3	-0.1	0.0	-2	1	15
Week 4	-0.3	0.0	-3	1	19
Week 8	-0.6	0.0	-3	1	17
Week 12	-0.5	0.0	-2	1	11
Week 16	-0.4	0.0	-2	0	12
Week 20	-0.3	0.0	-1	0	3
Week 24	-1.2	-1.0	-2	0	6
Week 24 LOCF	-0.9	-1.0	-3	0	19

BRL 29060 - 716
Interim Output
Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Paroxetine (N = 44)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.2	3.0	1	5	44
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.4	0.0	-1	2	38
Week 2	0.2	0.0	-3	2	33
Week 3	-0.0	0.0	-2	1	34
Week 4	-0.1	0.0	-3	2	42
Week 8	-0.2	0.0	-3	2	37
Week 12	-0.4	0.0	-3	1	22
Week 16	-0.3	0.0	-3	1	22
Week 20	-0.5	0.0	-2	0	10
Week 24	-0.6	0.0	-2	1	15
Week 24 LOCF	-0.5	0.0	-3	2	43

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Placebo (N = 36)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.0	3.0	1	5	36
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	-0.2	0.0	-2	1	33
Week 2	-0.3	0.0	-3	1	32
Week 3	-0.6	0.0	-4	2	31
Week 4	-0.6	0.0	-4	2	31
Week 8	-0.6	0.0	-4	3	27
Week 12	-0.8	-1.0	-4	3	22
Week 16	-0.9	-1.0	-3	1	21
Week 20	-1.2	-1.0	-3	0	17
Week 24	-1.0	-0.5	-4	0	10
Week 24 LOCF	-0.4	0.0	-4	3	35

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Placebo (N = 30)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.8	3.0	1	4	29
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.2	0.0	-1	2	25
Week 2	-0.1	0.0	-3	2	24
Week 3	-0.1	0.0	-1	2	21
Week 4	-0.1	0.0	-1	1	23
Week 8	-0.5	-1.0	-2	2	19
Week 12	-0.7	0.0	-3	0	17
Week 16	-0.7	-1.0	-2	2	15
Week 20	-0.2	0.0	-2	2	13
Week 24	-0.2	0.0	-2	3	13
Week 24 LOCF	0.0	0.0	-2	3	28

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Placebo (N = 66)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.9	3.0	1	5	65
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	-0.1	0.0	-2	2	58
Week 2	-0.2	0.0	-3	2	56
Week 3	-0.4	0.0	-4	2	52
Week 4	-0.4	0.0	-4	2	54
Week 8	-0.6	0.0	-4	3	46
Week 12	-0.8	-1.0	-4	3	39
Week 16	-0.8	-1.0	-3	2	36
Week 20	-0.7	-1.0	-3	2	30
Week 24	-0.5	0.0	-4	3	23
Week 24 LOCF	-0.2	0.0	-4	3	63

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Placebo (N = 34)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.3	4.0	1	5	33
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	3	27
Week 2	0.2	0.0	-1	3	28
Week 3	0.2	0.0	-1	3	31
Week 4	-0.2	0.0	-3	2	27
Week 8	-0.5	0.0	-3	1	19
Week 12	-0.7	-1.0	-2	1	15
Week 16	-0.8	-0.5	-2	0	8
Week 20	-0.9	-1.0	-2	0	7
Week 24	-1.2	-1.5	-2	0	6
Week 24 LOCF	-0.4	0.0	-3	3	32

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Placebo (N = 27)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.7	4.0	1	6	27
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.4	0.0	-1	2	23
Week 2	0.1	0.0	-2	2	24
Week 3	-0.3	0.0	-2	2	21
Week 4	-0.2	0.0	-1	2	24
Week 8	-0.6	-0.5	-2	1	16
Week 12	-1.0	-1.0	-2	0	11
Week 16	-1.1	-1.0	-3	0	13
Week 20	-1.0	0.0	-3	0	5
Week 24	-1.0	-1.0	-2	0	4
Week 24 LOCF	-0.6	-1.0	-2	1	27

BRL 29060 - 716
Interim Output
Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Placebo (N = 61)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.5	4.0	1	6	60
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.5	0.0	-1	3	50
Week 2	0.2	0.0	-2	3	52
Week 3	-0.0	0.0	-2	3	52
Week 4	-0.2	0.0	-3	2	51
Week 8	-0.5	0.0	-3	1	35
Week 12	-0.8	-1.0	-2	1	26
Week 16	-1.0	-1.0	-3	0	21
Week 20	-0.9	-0.5	-3	0	12
Week 24	-1.1	-1.0	-2	0	10
Week 24 LOCF	-0.5	0.0	-3	3	59

BRL 29060 - 716
Interim Output
Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 2 (20mg)

		Paroxetine (N=16)			Placebo (N=15)			Total (N=31)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	9	7	16	8	7	15	17	14	31
	MEAN	34.9	27.9	31.8	28.5	29.0	28.7	31.9	28.4	30.3
	MEDIAN	35.0	27.0	30.5	26.0	21.0	24.0	31.0	26.0	28.0
	STDDEV	12.73	8.13	11.22	9.91	11.94	10.50	11.61	9.83	10.81
	MINIMUM	20	19	19	18	18	18	18	18	18
	MAXIMUM	56	42	56	42	46	46	56	46	56
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	8	7	15	8	7	15	16	14	30
	MEAN	39.8	30.3	35.3	32.9	29.1	31.1	36.3	29.7	33.2
	MEDIAN	35.0	30.0	31.0	34.0	24.0	33.0	34.5	28.5	32.0
	STDDEV	16.76	6.26	13.46	16.31	9.94	13.38	16.37	8.00	13.36
	MINIMUM	20	22	20	17	19	17	17	19	17
	MAXIMUM	66	42	66	68	44	68	68	44	68
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	8	7	15	8	7	15	16	14	30
	MEAN	7.1	2.4	4.9	4.4	0.1	2.4	5.8	1.3	3.7
	MEDIAN	2.5	0.0	2.0	0.0	-1.0	0.0	0.0	0.0	0.0
	STDDEV	12.09	4.08	9.28	16.69	3.24	12.19	14.15	3.73	10.72
	MINIMUM	-4	-2	-4	-9	-3	-9	-9	-3	-9
	MAXIMUM	30	8	30	44	6	44	44	8	44
	MISSING	0	0	0	0	0	0	0	0	0

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 3 (30mg)

		Paroxetine (N=18)			Placebo (N=22)			Total (N=40)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	7	11	18	10	12	22	17	23	40
	MEAN	26.3	32.8	30.3	32.3	38.6	35.7	29.8	35.8	33.3
	MEDIAN	24.0	30.0	27.0	28.5	34.0	33.0	25.0	33.0	30.5
	STDDEV	7.11	13.61	11.73	12.55	10.87	11.82	10.81	12.33	11.95
	MINIMUM	21	20	20	19	25	19	19	20	19
	MAXIMUM	42	71	71	51	61	61	51	71	71
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	5	10	15	10	12	22	15	22	37
	MEAN	30.8	31.4	31.2	33.8	40.3	37.4	32.8	36.3	34.9
	MEDIAN	28.0	28.5	28.0	33.0	35.5	35.0	33.0	34.5	33.0
	STDDEV	7.05	10.37	9.14	11.19	11.79	11.73	9.84	11.82	11.05
	MINIMUM	24	20	20	17	28	17	17	20	17
	MAXIMUM	41	48	48	52	56	56	52	56	56
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	10	15	10	12	22	15	22	37
	MEAN	3.4	-1.7	0.0	1.5	1.8	1.6	2.1	0.2	1.0
	MEDIAN	3.0	-2.0	0.0	0.5	2.0	1.5	1.0	0.0	0.0
	STDDEV	11.37	11.94	11.61	7.59	6.20	6.69	8.65	9.18	8.90
	MINIMUM	-14	-24	-24	-10	-7	-10	-14	-24	-24
	MAXIMUM	15	24	24	18	14	18	18	24	24
	MISSING	0	0	0	0	0	0	0	0	0

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 4 (40mg)

		Paroxetine (N=10)			Placebo (N=6)			Total (N=16)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	5	10	2	4	6	7	9	16
	MEAN	43.2	43.6	43.4	42.0	38.5	39.7	42.9	41.3	42.0
	MEDIAN	41.0	48.0	43.5	42.0	39.0	42.0	42.0	42.0	42.0
	STDDEV	13.33	12.42	12.15	0.00	13.30	10.46	10.90	12.28	11.34
	MINIMUM	26	29	26	42	22	22	26	22	22
	MAXIMUM	63	57	63	42	54	54	63	57	63
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	5	5	10	2	3	5	7	8	15
	MEAN	43.2	49.2	46.2	52.5	47.3	49.4	45.9	48.5	47.3
	MEDIAN	42.0	50.0	46.0	52.5	50.0	50.0	44.0	50.0	48.0
	STDDEV	19.41	10.03	14.91	10.61	14.19	11.70	17.04	10.77	13.58
	MINIMUM	27	33	27	45	32	32	27	32	27
	MAXIMUM	75	58	75	60	60	60	75	60	75
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	5	10	2	3	5	7	8	15
	MEAN	0.0	5.6	2.8	10.5	8.0	9.0	3.0	6.5	4.9
	MEDIAN	1.0	4.0	3.0	10.5	10.0	10.0	3.0	5.0	4.0
	STDDEV	9.30	6.23	8.02	10.61	11.14	9.59	10.13	7.69	8.77
	MINIMUM	-13	0	-13	3	-4	-4	-13	-4	-13
	MAXIMUM	12	16	16	18	18	18	18	18	18
	MISSING	0	0	0	0	0	0	0	0	0

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 5 (50mg)

		Paroxetine (N=3)			Placebo (N=12)			Total (N=15)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	1	2	3	6	5	11	7	7	14
	MEAN	29.0	44.5	39.3	42.0	44.0	42.9	40.1	44.1	42.1
	MEDIAN	29.0	44.5	39.0	40.5	41.0	41.0	39.0	41.0	40.0
	STDDEV	.	7.78	10.50	6.00	15.30	10.62	7.36	12.89	10.29
	MINIMUM	29	39	29	35	26	26	29	26	26
	MAXIMUM	29	50	50	51	65	65	51	65	65
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	1	2	3	6	6	12	7	8	15
	MEAN	55.0	43.5	47.3	45.8	51.2	48.5	47.1	49.3	48.3
	MEDIAN	55.0	43.5	48.0	43.5	55.0	47.0	46.0	48.0	48.0
	STDDEV	.	6.36	8.02	9.28	17.95	13.91	9.15	15.76	12.70
	MINIMUM	55	39	39	38	28	28	38	28	28
	MAXIMUM	55	48	55	63	73	73	63	73	73
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	1	2	3	6	5	11	7	7	14
	MEAN	26.0	-1.0	8.0	3.8	10.8	7.0	7.0	7.4	7.2
	MEDIAN	26.0	-1.0	0.0	0.0	8.0	2.0	0.0	2.0	1.0
	STDDEV	.	1.41	15.62	8.93	13.55	11.25	11.69	12.49	11.62
	MINIMUM	26	-2	-2	-3	-5	-5	-3	-5	-5
	MAXIMUM	26	0	26	21	28	28	26	28	28
	MISSING	0	0	0	0	1	1	0	1	1

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 2 (20mg)

		Paroxetine (N=11)			Placebo (N=7)			Total (N=18)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	9	2	11	5	2	7	14	4	18
	MEAN	6.6	17.0	8.5	17.2	20.0	18.0	10.4	18.5	12.2
	MEDIAN	4.0	17.0	10.0	14.0	20.0	16.0	12.5	19.5	13.5
	STDDEV	6.64	4.24	7.41	7.85	1.41	6.58	8.61	3.11	8.40
	MINIMUM	0	14	0	12	19	12	0	14	0
	MAXIMUM	16	20	20	31	21	31	31	21	31
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	9	2	11	5	2	7	14	4	18
	MEAN	9.0	15.0	10.1	21.4	18.0	20.4	13.4	16.5	14.1
	MEDIAN	8.0	15.0	11.0	17.0	18.0	17.0	12.5	16.5	15.0
	STDDEV	8.99	1.41	8.41	9.21	1.41	7.72	10.67	2.08	9.46
	MINIMUM	0	14	0	12	17	12	0	14	0
	MAXIMUM	27	16	27	34	19	34	34	19	34
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	9	2	11	5	2	7	14	4	18
	MEAN	2.4	-2.0	1.6	4.2	-2.0	2.4	3.1	-2.0	1.9
	MEDIAN	1.0	-2.0	1.0	3.0	-2.0	0.0	1.5	-2.0	0.5
	STDDEV	4.50	5.66	4.76	6.22	2.83	6.02	5.01	3.65	5.13
	MINIMUM	-4	-6	-6	0	-4	-4	-4	-6	-6
	MAXIMUM	11	2	11	15	0	15	15	2	15
	MISSING	0	0	0	0	0	0	0	0	0

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 3 (30mg)

		Paroxetine (N=6)			Placebo (N=6)			Total (N=12)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	1	6	2	4	6	7	5	12
	MEAN	15.2	11.0	14.5	18.5	10.5	13.2	16.1	10.6	13.8
	MEDIAN	15.0	11.0	13.0	18.5	11.5	16.0	15.0	11.0	15.0
	STDDEV	6.38	.	5.96	4.95	9.04	8.42	5.81	7.83	6.99
	MINIMUM	8	11	8	15	0	0	8	0	0
	MAXIMUM	23	11	23	22	19	22	23	19	23
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	5	1	6	1	4	5	6	5	11
	MEAN	18.0	11.0	16.8	22.0	17.3	18.2	18.7	16.0	17.5
	MEDIAN	21.0	11.0	16.5	22.0	20.0	21.0	21.5	19.0	21.0
	STDDEV	6.52	.	6.49	.	12.28	10.85	6.06	11.00	8.29
	MINIMUM	10	11	10	22	0	0	10	0	0
	MAXIMUM	24	11	24	22	29	29	24	29	29
	MISSING	0	0	0	1	0	1	1	0	1
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	1	6	1	4	5	6	5	11
	MEAN	2.8	0.0	2.3	0.0	6.8	5.4	2.3	5.4	3.7
	MEDIAN	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0
	STDDEV	6.22	.	5.68	.	11.00	9.99	5.68	9.99	7.66
	MINIMUM	-3	0	-3	0	0	0	-3	0	-3
	MAXIMUM	13	0	13	0	23	23	13	23	23
	MISSING	0	0	0	1	0	1	1	0	1

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 4 (40mg)

		Paroxetine (N=10)			Placebo (N=14)			Total (N=24)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	3	7	10	10	4	14	13	11	24
	MEAN	13.3	17.7	16.4	15.7	19.8	16.9	15.2	18.5	16.7
	MEDIAN	12.0	19.0	19.0	18.0	18.0	18.0	16.0	19.0	19.0
	STDDEV	6.11	5.59	5.80	8.54	12.69	9.55	7.87	8.25	8.05
	MINIMUM	8	9	8	2	7	2	2	7	2
	MAXIMUM	20	24	24	27	36	36	27	36	36
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	2	6	8	10	4	14	12	10	22
	MEAN	20.5	16.7	17.6	17.1	22.8	18.7	17.7	19.1	18.3
	MEDIAN	20.5	17.5	19.5	20.0	21.0	20.0	20.0	18.0	20.0
	STDDEV	0.71	5.28	4.81	7.34	9.39	8.04	6.77	7.40	6.93
	MINIMUM	20	10	10	6	14	6	6	10	6
	MAXIMUM	21	22	22	27	35	35	27	35	35
	MISSING	1	0	1	0	0	0	1	0	1
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	2	6	8	10	4	14	12	10	22
	MEAN	6.5	-0.8	1.0	1.4	3.0	1.9	2.3	0.7	1.5
	MEDIAN	6.5	0.0	0.0	0.0	1.5	0.5	0.0	0.5	0.0
	STDDEV	9.19	2.86	5.42	3.44	4.83	3.76	4.61	4.03	4.33
	MINIMUM	0	-6	-6	-3	-1	-3	-3	-6	-6
	MAXIMUM	13	2	13	9	10	10	13	10	13
	MISSING	1	0	1	0	0	0	1	0	1

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

BRL 29060 - 716
Interim Output
Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 5 (50mg)

		Paroxetine (N=14)			Placebo (N=32)			Total (N=46)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	9	14	14	17	31	19	26	45
	MEAN	20.0	18.7	19.1	18.4	18.6	18.5	18.8	18.7	18.7
	MEDIAN	19.0	17.0	18.0	19.0	19.0	19.0	19.0	19.0	19.0
	STDDEV	8.75	9.03	8.61	7.32	4.87	5.99	7.50	6.42	6.82
	MINIMUM	10	9	9	6	9	6	6	9	6
	MAXIMUM	34	34	34	33	26	33	34	34	34
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	5	9	14	15	17	32	20	26	46
	MEAN	23.6	21.7	22.4	21.3	21.7	21.5	21.9	21.7	21.8
	MEDIAN	22.0	21.0	21.5	23.0	22.0	22.5	22.5	22.0	22.0
	STDDEV	7.16	9.29	8.35	7.26	4.21	5.74	7.11	6.24	6.56
	MINIMUM	16	8	8	7	15	7	7	8	7
	MAXIMUM	35	34	35	31	27	31	35	34	35
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	9	14	14	17	31	19	26	45
	MEAN	3.6	3.0	3.2	2.3	3.1	2.7	2.6	3.0	2.9
	MEDIAN	1.0	0.0	0.5	0.0	3.0	1.0	0.0	2.0	1.0
	STDDEV	6.54	5.22	5.48	7.13	4.19	5.62	6.82	4.47	5.52
	MINIMUM	-1	-1	-1	-9	-4	-9	-9	-4	-9
	MAXIMUM	15	14	15	15	10	15	15	14	15
	MISSING	0	0	0	1	0	1	1	0	1

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.

12 Source Tables: Safety Results

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	TOTAL	6 (12.0%)	8 (12.1%)	14 (12.1%)
Body as a Whole	TOTAL	4 (8.0%)	4 (6.1%)	8 (6.9%)
	HEADACHE	2 (4.0%)	2 (3.0%)	4 (3.4%)
	ABSCESS	1 (2.0%)	0	1 (0.9%)
	INFECTION	1 (2.0%)	0	1 (0.9%)
	ABDOMINAL PAIN	0	1 (1.5%)	1 (0.9%)
	TRAUMA	0	1 (1.5%)	1 (0.9%)
Endocrine System	TOTAL	1 (2.0%)	0	1 (0.9%)
	THYROID DISORDER	1 (2.0%)	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (2.0%)	0	1 (0.9%)
	PURPURA	1 (2.0%)	0	1 (0.9%)
Digestive System	TOTAL	0	2 (3.0%)	2 (1.7%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	NAUSEA	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	SINUSITIS	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ALBUMINURIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	TOTAL	12 (27.3%)	11 (18.0%)	23 (21.9%)
Body as a Whole	TOTAL	8 (18.2%)	4 (6.6%)	12 (11.4%)
	HEADACHE	4 (9.1%)	2 (3.3%)	6 (5.7%)
	TRAUMA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	FEVER	2 (4.5%)	0	2 (1.9%)
	ABDOMINAL PAIN	1 (2.3%)	0	1 (1.0%)
	BACK PAIN	1 (2.3%)	0	1 (1.0%)
	INFECTION	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	3 (6.8%)	3 (4.9%)	6 (5.7%)
	RHINITIS	2 (4.5%)	0	2 (1.9%)
	PHARYNGITIS	1 (2.3%)	1 (1.6%)	2 (1.9%)
	SINUSITIS	0	2 (3.3%)	2 (1.9%)
Digestive System	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	NAUSEA	0	2 (3.3%)	2 (1.9%)
	DIARRHEA	1 (2.3%)	0	1 (1.0%)
	VOMITING	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	0	1 (1.0%)
	PURPURA	1 (2.3%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
Endocrine System	TOTAL	0	1 (1.6%)	1 (1.0%)
	THYROID DISORDER	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	0	1 (1.6%)	1 (1.0%)
	ANXIETY	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	TOTAL	18 (19.1%)	19 (15.0%)	37 (16.7%)
Body as a Whole	TOTAL	12 (12.8%)	8 (6.3%)	20 (9.0%)
	HEADACHE	6 (6.4%)	4 (3.1%)	10 (4.5%)
	TRAUMA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	FEVER	2 (2.1%)	0	2 (0.9%)
	ABDOMINAL PAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	INFECTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	BACK PAIN	1 (1.1%)	0	1 (0.5%)
Respiratory System	TOTAL	3 (3.2%)	4 (3.1%)	7 (3.2%)
	SINUSITIS	0	3 (2.4%)	3 (1.4%)
	RHINITIS	2 (2.1%)	0	2 (0.9%)
	PHARYNGITIS	1 (1.1%)	1 (0.8%)	2 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (2.1%)	0	2 (0.9%)
	PURPURA	2 (2.1%)	0	2 (0.9%)
Digestive System	TOTAL	1 (1.1%)	4 (3.1%)	5 (2.3%)
	NAUSEA	0	3 (2.4%)	3 (1.4%)
	DIARRHEA	1 (1.1%)	0	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	VOMITING	0	1 (0.8%)	1 (0.5%)
Endocrine System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	THYROID DISORDER	1 (1.1%)	1 (0.8%)	2 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	WEIGHT GAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
Nervous System	TOTAL	0	1 (0.8%)	1 (0.5%)
	ANXIETY	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.5%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	0	1 (0.8%)	1 (0.5%)
	ALBUMINURIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.0%)	2 (3.0%)	3 (2.6%)
Urogenital System	TOTAL	1 (2.0%)	0	1 (0.9%)
	KIDNEY FUNCTION ABNORMAL	1 (2.0%)	0	1 (0.9%)
Body as a Whole	TOTAL	0	2 (3.0%)	2 (1.7%)
	ABDOMINAL PAIN	0	1 (1.5%)	1 (0.9%)
	ALLERGIC REACTION	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ASTHMA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (3.3%)	2 (1.9%)
Respiratory System	TOTAL	0	1 (1.6%)	1 (1.0%)
	RHINITIS	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	0	1 (1.6%)	1 (1.0%)
	ECZEMA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.1%)	4 (3.1%)	5 (2.3%)
Urogenital System	TOTAL	1 (1.1%)	0	1 (0.5%)
	KIDNEY FUNCTION ABNORMAL	1 (1.1%)	0	1 (0.5%)
Body as a Whole	TOTAL	0	2 (1.6%)	2 (0.9%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.5%)
	ALLERGIC REACTION	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	0	2 (1.6%)	2 (0.9%)
	ASTHMA	0	1 (0.8%)	1 (0.5%)
	RHINITIS	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.5%)
	ECZEMA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	14 (28.0%)	11 (16.7%)	25 (21.6%)
Body as a Whole	TOTAL	7 (14.0%)	1 (1.5%)	8 (6.9%)
	INFECTION	2 (4.0%)	0	2 (1.7%)
	TRAUMA	2 (4.0%)	0	2 (1.7%)
	ABDOMINAL PAIN	1 (2.0%)	0	1 (0.9%)
	ASTHENIA	1 (2.0%)	0	1 (0.9%)
	PAIN	1 (2.0%)	0	1 (0.9%)
	ALLERGIC REACTION	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	6 (12.0%)	5 (7.6%)	11 (9.5%)
	SOMNOLENCE	3 (6.0%)	3 (4.5%)	6 (5.2%)
	DEPRESSION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.9%)
	MYOCLONUS	1 (2.0%)	0	1 (0.9%)
	NERVOUSNESS	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	HYPERKINESIA	0	1 (1.5%)	1 (0.9%)
	INSOMNIA	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	2 (4.0%)	4 (6.1%)	6 (5.2%)
	RESPIRATORY DISORDER	1 (2.0%)	1 (1.5%)	2 (1.7%)
	RHINITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
	BRONCHITIS	0	1 (1.5%)	1 (0.9%)
	PHARYNGITIS	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (2.0%)	2 (3.0%)	3 (2.6%)
	CARDIAC DISORDERS	1 (2.0%)	0	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
	PALPITATION	0	1 (1.5%)	1 (0.9%)
	TACHYCARDIA	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	1 (2.0%)	0	1 (0.9%)
	OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
Digestive System	TOTAL	0	1 (1.5%)	1 (0.9%)
	DECREASED APPETITE	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.5%)	1 (0.9%)
	SGPT INCREASED	0	1 (1.5%)	1 (0.9%)
	WEIGHT GAIN	0	1 (1.5%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Urogenital System	ALBUMINURIA	0	1 (1.5%)	1 (0.9%)
	HAEMATURIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	1 (4.3%)	0	1 (1.9%)
Urogenital System	TOTAL	1 (4.3%)	0	1 (1.9%)
	MENSTRUAL DISORDER	1 (4.3%)	0	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	TOTAL	14 (31.8%)	13 (21.3%)	27 (25.7%)
Nervous System	TOTAL	6 (13.6%)	5 (8.2%)	11 (10.5%)
	NERVOUSNESS	3 (6.8%)	2 (3.3%)	5 (4.8%)
	INSOMNIA	2 (4.5%)	0	2 (1.9%)
	DEPRESSION	1 (2.3%)	0	1 (1.0%)
	SOMNOLENCE	1 (2.3%)	0	1 (1.0%)
	TREMOR	1 (2.3%)	0	1 (1.0%)
	DIZZINESS	0	1 (1.6%)	1 (1.0%)
	HYPERKINESIA	0	1 (1.6%)	1 (1.0%)
	MANIC REACTION	0	1 (1.6%)	1 (1.0%)
	NYSTAGMUS	0	1 (1.6%)	1 (1.0%)
Body as a Whole	TOTAL	4 (9.1%)	6 (9.8%)	10 (9.5%)
	ALLERGIC REACTION	1 (2.3%)	3 (4.9%)	4 (3.8%)
	ASTHENIA	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ABDOMINAL PAIN	1 (2.3%)	0	1 (1.0%)
	HEADACHE	1 (2.3%)	0	1 (1.0%)
	INFECTION	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	3 (6.8%)	3 (4.9%)	6 (5.7%)
	DECREASED APPETITE	1 (2.3%)	2 (3.3%)	3 (2.9%)
	NAUSEA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	DIARRHEA	1 (2.3%)	0	1 (1.0%)
	FLATULENCE	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	RHINITIS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	COUGH INCREASED	1 (2.3%)	0	1 (1.0%)
	RESPIRATORY DISORDER	1 (2.3%)	0	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	HYPERTENSION	1 (2.3%)	0	1 (1.0%)
	VASODILATATION	0	1 (1.6%)	1 (1.0%)
Endocrine System	TOTAL	1 (2.3%)	0	1 (1.0%)
	THYROID DISORDER	1 (2.3%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	0	1 (1.0%)
	WEIGHT GAIN	1 (2.3%)	0	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.3%)	0	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Musculoskeletal System	MYALGIA	1 (2.3%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ACNE	1 (2.3%)	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (1.0%)
	RASH	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	KERATOCONJUNCTIVITIS	1 (2.3%)	0	1 (1.0%)
	EAR DISORDER	0	1 (1.6%)	1 (1.0%)
	EAR PAIN	0	1 (1.6%)	1 (1.0%)
	OTITIS MEDIA	0	1 (1.6%)	1 (1.0%)
Urogenital System	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	URINARY INCONTINENCE	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.6%)	1 (1.0%)
	LEUKOPENIA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.5%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.5%)	1 (1.6%)
	ABNORMAL EJACULATION	0	1 (2.5%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	28 (29.8%)	24 (18.9%)	52 (23.5%)
Nervous System	TOTAL	12 (12.8%)	10 (7.9%)	22 (10.0%)
	SOMNOLENCE	4 (4.3%)	3 (2.4%)	7 (3.2%)
	NERVOUSNESS	4 (4.3%)	2 (1.6%)	6 (2.7%)
	DEPRESSION	2 (2.1%)	1 (0.8%)	3 (1.4%)
	INSOMNIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	HYPERKINESIA	0	2 (1.6%)	2 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.1%)	0	1 (0.5%)
	MYOCLONUS	1 (1.1%)	0	1 (0.5%)
	TREMOR	1 (1.1%)	0	1 (0.5%)
	ANXIETY	0	1 (0.8%)	1 (0.5%)
	DIZZINESS	0	1 (0.8%)	1 (0.5%)
	MANIC REACTION	0	1 (0.8%)	1 (0.5%)
	NYSTAGMUS	0	1 (0.8%)	1 (0.5%)
Body as a Whole	TOTAL	11 (11.7%)	7 (5.5%)	18 (8.1%)
	ALLERGIC REACTION	1 (1.1%)	4 (3.1%)	5 (2.3%)
	ASTHENIA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	INFECTION	2 (2.1%)	1 (0.8%)	3 (1.4%)
	ABDOMINAL PAIN	2 (2.1%)	0	2 (0.9%)
	TRAUMA	2 (2.1%)	0	2 (0.9%)
	HEADACHE	1 (1.1%)	0	1 (0.5%)
	PAIN	1 (1.1%)	0	1 (0.5%)
Respiratory System	TOTAL	5 (5.3%)	5 (3.9%)	10 (4.5%)
	RHINITIS	3 (3.2%)	2 (1.6%)	5 (2.3%)
	RESPIRATORY DISORDER	2 (2.1%)	1 (0.8%)	3 (1.4%)
	COUGH INCREASED	1 (1.1%)	0	1 (0.5%)
	BRONCHITIS	0	1 (0.8%)	1 (0.5%)
	PHARYNGITIS	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	3 (3.2%)	4 (3.1%)	7 (3.2%)
	DECREASED APPETITE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	NAUSEA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIARRHEA	1 (1.1%)	0	1 (0.5%)
	FLATULENCE	1 (1.1%)	0	1 (0.5%)
	CONSTIPATION	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	2 (2.1%)	3 (2.4%)	5 (2.3%)
	CARDIAC DISORDERS	1 (1.1%)	0	1 (0.5%)
	HYPERTENSION	1 (1.1%)	0	1 (0.5%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
	PALPITATION	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Cardiovascular System	TACHYCARDIA	0	1 (0.8%)	1 (0.5%)
	VASODILATATION	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	2 (2.1%)	2 (1.6%)	4 (1.8%)
	OTITIS MEDIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	KERATOCONJUNCTIVITIS	1 (1.1%)	0	1 (0.5%)
	EAR DISORDER	0	1 (0.8%)	1 (0.5%)
	EAR PAIN	0	1 (0.8%)	1 (0.5%)
Endocrine System	TOTAL	1 (1.1%)	0	1 (0.5%)
	THYROID DISORDER	1 (1.1%)	0	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	WEIGHT GAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	SGPT INCREASED	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	1 (1.1%)	0	1 (0.5%)
	MYALGIA	1 (1.1%)	0	1 (0.5%)
Skin and Appendages	TOTAL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ACNE	1 (1.1%)	0	1 (0.5%)
	FUNGAL DERMATITIS	0	1 (0.8%)	1 (0.5%)
	RASH	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HAEMATURIA	0	2 (1.6%)	2 (0.9%)
	URINARY INCONTINENCE	1 (1.1%)	0	1 (0.5%)
	ALBUMINURIA	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	0	1 (0.8%)	1 (0.5%)
	LEUKOPENIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (1.3%)	1 (0.8%)
Urogenital System	TOTAL	0	1 (1.3%)	1 (0.8%)
	ABNORMAL EJACULATION	0	1 (1.3%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.2%)	0	1 (1.1%)
Urogenital System	TOTAL	1 (2.2%)	0	1 (1.1%)
	MENSTRUAL DISORDER	1 (2.2%)	0	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	20 (80.0%)	25 (69.4%)	45 (73.8%)
Respiratory System	TOTAL	13 (52.0%)	13 (36.1%)	26 (42.6%)
	RESPIRATORY DISORDER	8 (32.0%)	6 (16.7%)	14 (23.0%)
	PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
	RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
	SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
	EPISTAXIS	0	2 (5.6%)	2 (3.3%)
	ASTHMA	0	1 (2.8%)	1 (1.6%)
	BRONCHITIS	0	1 (2.8%)	1 (1.6%)
	PNEUMONIA	0	1 (2.8%)	1 (1.6%)
	YAWN	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	10 (40.0%)	11 (30.6%)	21 (34.4%)
	VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
	DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
	DIARRHEA	2 (8.0%)	1 (2.8%)	3 (4.9%)
	NAUSEA	1 (4.0%)	2 (5.6%)	3 (4.9%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
	STOMATITIS	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	9 (36.0%)	15 (41.7%)	24 (39.3%)
	INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
	HEADACHE	5 (20.0%)	4 (11.1%)	9 (14.8%)
	TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
	ABDOMINAL PAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
	FEVER	4 (16.0%)	2 (5.6%)	6 (9.8%)
	ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
	BACK PAIN	0	3 (8.3%)	3 (4.9%)
	ASTHENIA	0	2 (5.6%)	2 (3.3%)
	FACE EDEMA	1 (4.0%)	0	1 (1.6%)
	PAIN	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	9 (36.0%)	12 (33.3%)	21 (34.4%)
	HOSTILITY	3 (12.0%)	1 (2.8%)	4 (6.6%)
	NERVOUSNESS	3 (12.0%)	0	3 (4.9%)
	DEPRESSION	2 (8.0%)	1 (2.8%)	3 (4.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Nervous System	AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
	INSOMNIA	0	3 (8.3%)	3 (4.9%)
	HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
	VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
	ANXIETY	0	1 (2.8%)	1 (1.6%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	EUPHORIA	0	1 (2.8%)	1 (1.6%)
	PARALYSIS	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	6 (24.0%)	4 (11.1%)	10 (16.4%)
	CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ACNE	2 (8.0%)	0	2 (3.3%)
	HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
	PRURITUS	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	4 (16.0%)	4 (11.1%)	8 (13.1%)
	WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
	DEHYDRATION	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ANEMIA	0	1 (2.8%)	1 (1.6%)
Musculoskeletal System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
	ARTHROSIS	0	1 (2.8%)	1 (1.6%)
	MYALGIA	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	3 (8.3%)	4 (6.6%)
	URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Urogenital System	ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
	CYSTITIS	0	1 (2.8%)	1 (1.6%)
	HAEMATURIA	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.9%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (2.8%)	1 (1.6%)
	MIGRAINE	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	19 (79.2%)	28 (82.4%)	47 (81.0%)
Body as a Whole	TOTAL	13 (54.2%)	15 (44.1%)	28 (48.3%)
	HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
	TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
	ABDOMINAL PAIN	1 (4.2%)	5 (14.7%)	6 (10.3%)
	FEVER	3 (12.5%)	1 (2.9%)	4 (6.9%)
	INFECTION	3 (12.5%)	1 (2.9%)	4 (6.9%)
	PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ABSCESS	1 (4.2%)	0	1 (1.7%)
	BACK PAIN	1 (4.2%)	0	1 (1.7%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	7 (29.2%)	6 (17.6%)	13 (22.4%)
	NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	DIARRHEA	2 (8.3%)	0	2 (3.4%)
	FLATULENCE	0	1 (2.9%)	1 (1.7%)
	GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
	GINGIVITIS	0	1 (2.9%)	1 (1.7%)
	TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
Nervous System	TOTAL	7 (29.2%)	20 (58.8%)	27 (46.6%)
	NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
	HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
	HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
	MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	PSYCHOSIS	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
	VERTIGO	0	1 (2.9%)	1 (1.7%)
Respiratory System	TOTAL	5 (20.8%)	10 (29.4%)	15 (25.9%)
	RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
Respiratory System	RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
	PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
	COUGH INCREASED	2 (8.3%)	1 (2.9%)	3 (5.2%)
	SINUSITIS	2 (8.3%)	1 (2.9%)	3 (5.2%)
	ASTHMA	1 (4.2%)	0	1 (1.7%)
Special Senses	TOTAL	4 (16.7%)	4 (11.8%)	8 (13.8%)
	OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	EAR PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
Cardiovascular System	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
	HAEMATOMA	1 (4.2%)	0	1 (1.7%)
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0	1 (1.7%)
	ANEMIA	1 (4.2%)	0	1 (1.7%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.7%)
	MYALGIA	1 (4.2%)	0	1 (1.7%)
Skin and Appendages	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
	RASH	0	2 (5.9%)	2 (3.4%)
	MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
	HERPES SIMPLEX	0	1 (2.9%)	1 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
Urogenital System	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
	DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	39 (79.6%)	53 (75.7%)	92 (77.3%)
Body as a Whole	TOTAL	22 (44.9%)	30 (42.9%)	52 (43.7%)
	HEADACHE	13 (26.5%)	10 (14.3%)	23 (19.3%)
	INFECTION	7 (14.3%)	10 (14.3%)	17 (14.3%)
	TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
	ABDOMINAL PAIN	5 (10.2%)	8 (11.4%)	13 (10.9%)
	FEVER	7 (14.3%)	3 (4.3%)	10 (8.4%)
	ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
	BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
	PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ASTHENIA	0	2 (2.9%)	2 (1.7%)
	ABSCESS	1 (2.0%)	0	1 (0.8%)
	FACE EDEMA	1 (2.0%)	0	1 (0.8%)
Respiratory System	TOTAL	18 (36.7%)	23 (32.9%)	41 (34.5%)
	RESPIRATORY DISORDER	9 (18.4%)	13 (18.6%)	22 (18.5%)
	PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
	RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
	SINUSITIS	4 (8.2%)	2 (2.9%)	6 (5.0%)
	COUGH INCREASED	3 (6.1%)	2 (2.9%)	5 (4.2%)
	ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	EPISTAXIS	0	2 (2.9%)	2 (1.7%)
	BRONCHITIS	0	1 (1.4%)	1 (0.8%)
	PNEUMONIA	0	1 (1.4%)	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	17 (34.7%)	17 (24.3%)	34 (28.6%)
	DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
	NAUSEA	5 (10.2%)	3 (4.3%)	8 (6.7%)
	VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
	DIARRHEA	4 (8.2%)	1 (1.4%)	5 (4.2%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	STOMATITIS	1 (2.0%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.4%)	1 (0.8%)
	GINGIVITIS	0	1 (1.4%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	16 (32.7%)	32 (45.7%)	48 (40.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Nervous System	NERVOUSNESS	4 (8.2%)	9 (12.9%)	13 (10.9%)
	HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	HOSTILITY	4 (8.2%)	5 (7.1%)	9 (7.6%)
	INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
	AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
	DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
	DEPRESSION	2 (4.1%)	1 (1.4%)	3 (2.5%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	CONCENTRATION IMPAIRED	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	EUPHORIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
	PARALYSIS	0	1 (1.4%)	1 (0.8%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.8%)
	VERTIGO	0	1 (1.4%)	1 (0.8%)
Skin and Appendages	TOTAL	7 (14.3%)	7 (10.0%)	14 (11.8%)
	CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
	RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
	ACNE	2 (4.1%)	0	2 (1.7%)
	MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.8%)
	PRURITUS	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	5 (10.2%)	6 (8.6%)	11 (9.2%)
	OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
	OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
	EAR PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.2%)	5 (7.1%)	9 (7.6%)
	WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	DEHYDRATION	0	1 (1.4%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (4.1%)	2 (2.9%)	4 (3.4%)
	LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Musculoskeletal System	TOTAL	2 (4.1%)	1 (1.4%)	3 (2.5%)
	MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
	ARTHROSIS	0	1 (1.4%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (2.0%)	6 (8.6%)	7 (5.9%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	HAEMATOMA	1 (2.0%)	0	1 (0.8%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.4%)	1 (0.8%)
	MIGRAINE	0	1 (1.4%)	1 (0.8%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	1 (2.0%)	4 (5.7%)	5 (4.2%)
	URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
	CYSTITIS	0	1 (1.4%)	1 (0.8%)
	HAEMATURIA	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
Urogenital System	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
	DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	18 (72.0%)	19 (63.3%)	37 (67.3%)
Body as a Whole	TOTAL	11 (44.0%)	9 (30.0%)	20 (36.4%)
	HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
	TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
	INFECTION	2 (8.0%)	2 (6.7%)	4 (7.3%)
	ASTHENIA	0	3 (10.0%)	3 (5.5%)
	ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
	BACK PAIN	2 (8.0%)	0	2 (3.6%)
	ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
	CHEST PAIN	1 (4.0%)	0	1 (1.8%)
	FEVER	0	1 (3.3%)	1 (1.8%)
	PAIN	0	1 (3.3%)	1 (1.8%)
Nervous System	TOTAL	9 (36.0%)	10 (33.3%)	19 (34.5%)
	SOMNOLENCE	3 (12.0%)	2 (6.7%)	5 (9.1%)
	EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
	NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.8%)
	LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
	VERTIGO	1 (4.0%)	0	1 (1.8%)
	ANXIETY	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
	HOSTILITY	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	6 (24.0%)	7 (23.3%)	13 (23.6%)
	NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
	DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
	VOMITING	2 (8.0%)	0	2 (3.6%)
	DIARRHEA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DRY MOUTH	1 (4.0%)	0	1 (1.8%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.8%)
	TOOTH CARIES	0	1 (3.3%)	1 (1.8%)
Respiratory System	TOTAL	6 (24.0%)	9 (30.0%)	15 (27.3%)
	RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Respiratory System	ASTHMA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
	RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	SINUSITIS	1 (4.0%)	0	1 (1.8%)
	COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
	PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.0%)	3 (10.0%)	5 (9.1%)
	WEIGHT GAIN	1 (4.0%)	3 (10.0%)	4 (7.3%)
	WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	0	1 (1.8%)
	LEUKOPENIA	1 (4.0%)	0	1 (1.8%)
Special Senses	TOTAL	1 (4.0%)	0	1 (1.8%)
	OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HAEMATURIA	0	1 (3.3%)	1 (1.8%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.8%)
	SYNCOPE	0	1 (3.3%)	1 (1.8%)
Skin and Appendages	TOTAL	0	2 (6.7%)	2 (3.6%)
	ACNE	0	1 (3.3%)	1 (1.8%)
	PRURITUS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (13.3%)	2 (8.3%)
Urogenital System	TOTAL	0	2 (13.3%)	2 (8.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	14 (70.0%)	18 (66.7%)	32 (68.1%)
Body as a Whole	TOTAL	11 (55.0%)	11 (40.7%)	22 (46.8%)
	HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
	INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
	ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
	ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
	PAIN	1 (5.0%)	0	1 (2.1%)
	BACK PAIN	0	1 (3.7%)	1 (2.1%)
	FEVER	0	1 (3.7%)	1 (2.1%)
	TRAUMA	0	1 (3.7%)	1 (2.1%)
Nervous System	TOTAL	7 (35.0%)	8 (29.6%)	15 (31.9%)
	INSOMNIA	2 (10.0%)	3 (11.1%)	5 (10.6%)
	HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NEUROSIS	3 (15.0%)	0	3 (6.4%)
	ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	AGITATION	0	2 (7.4%)	2 (4.3%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
	DEPRESSION	0	1 (3.7%)	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	6 (30.0%)	8 (29.6%)	14 (29.8%)
	RESPIRATORY DISORDER	2 (10.0%)	5 (18.5%)	7 (14.9%)
	ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	SINUSITIS	2 (10.0%)	0	2 (4.3%)
	RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EPISTAXIS	0	1 (3.7%)	1 (2.1%)
	PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
	PNEUMONIA	0	1 (3.7%)	1 (2.1%)
Urogenital System	TOTAL	3 (15.0%)	0	3 (6.4%)
	ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
	DYSURIA	1 (5.0%)	0	1 (2.1%)
	HAEMATURIA	1 (5.0%)	0	1 (2.1%)
Digestive System	TOTAL	2 (10.0%)	10 (37.0%)	12 (25.5%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
Digestive System	NAUSEA	0	5 (18.5%)	5 (10.6%)
	DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
	ULCERATIVE STOMATITIS	0	1 (3.7%)	1 (2.1%)
Musculoskeletal System	TOTAL	2 (10.0%)	1 (3.7%)	3 (6.4%)
	ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
Special Senses	TOTAL	2 (10.0%)	2 (7.4%)	4 (8.5%)
	BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
	EYE PAIN	1 (5.0%)	0	1 (2.1%)
	ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
	OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	1 (5.0%)	4 (14.8%)	5 (10.6%)
	ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
	CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
	RASH	0	1 (3.7%)	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
	URTICARIA	0	1 (3.7%)	1 (2.1%)
Cardiovascular System	TOTAL	0	1 (3.7%)	1 (2.1%)
	SYNCOPE	0	1 (3.7%)	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	2 (7.4%)	2 (4.3%)
	EOSINOPHILIA	0	1 (3.7%)	1 (2.1%)
	LEUKOCYTOSIS	0	1 (3.7%)	1 (2.1%)
	MONOCYTOSIS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	0	2 (11.1%)
Urogenital System	TOTAL	2 (22.2%)	0	2 (11.1%)
	DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	32 (71.1%)	37 (64.9%)	69 (67.6%)
Body as a Whole	TOTAL	22 (48.9%)	20 (35.1%)	42 (41.2%)
	HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
	INFECTION	6 (13.3%)	5 (8.8%)	11 (10.8%)
	ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
	ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
	TRAUMA	4 (8.9%)	3 (5.3%)	7 (6.9%)
	ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
	BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
	PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
	FEVER	0	2 (3.5%)	2 (2.0%)
	ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
	CHEST PAIN	1 (2.2%)	0	1 (1.0%)
Nervous System	TOTAL	16 (35.6%)	18 (31.6%)	34 (33.3%)
	INSOMNIA	3 (6.7%)	5 (8.8%)	8 (7.8%)
	EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
	NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
	SOMNOLENCE	4 (8.9%)	2 (3.5%)	6 (5.9%)
	HOSTILITY	1 (2.2%)	4 (7.0%)	5 (4.9%)
	DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
	NEUROSIS	3 (6.7%)	0	3 (2.9%)
	ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
	DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	VERTIGO	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	12 (26.7%)	17 (29.8%)	29 (28.4%)
	RESPIRATORY DISORDER	6 (13.3%)	12 (21.1%)	18 (17.6%)
	ASTHMA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	SINUSITIS	3 (6.7%)	0	3 (2.9%)
	BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	PHARYNGITIS	0	2 (3.5%)	2 (2.0%)
	COUGH INCREASED	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Respiratory System	EPISTAXIS	0	1 (1.8%)	1 (1.0%)
	PNEUMONIA	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	8 (17.8%)	17 (29.8%)	25 (24.5%)
	NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
	DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	DIARRHEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
	VOMITING	2 (4.4%)	0	2 (2.0%)
	INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
	TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	GASTROINTESTINAL DISORDER	0	1 (1.8%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.8%)	1 (1.0%)
Urogenital System	TOTAL	4 (8.9%)	1 (1.8%)	5 (4.9%)
	ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
	HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	DYSURIA	1 (2.2%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	3 (6.7%)	4 (7.0%)	7 (6.9%)
	WEIGHT GAIN	2 (4.4%)	3 (5.3%)	5 (4.9%)
	WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
Special Senses	TOTAL	3 (6.7%)	2 (3.5%)	5 (4.9%)
	OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
	EYE PAIN	1 (2.2%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
Musculoskeletal System	TOTAL	2 (4.4%)	1 (1.8%)	3 (2.9%)
	ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
Hemic and Lymphatic System	TOTAL	1 (2.2%)	2 (3.5%)	3 (2.9%)
	LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
	EOSINOPHILIA	0	1 (1.8%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.8%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.8%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.2%)	6 (10.5%)	7 (6.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Skin and Appendages	ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
	CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
	PRURITUS	0	1 (1.8%)	1 (1.0%)
	RASH	0	1 (1.8%)	1 (1.0%)
	SWEATING	0	1 (1.8%)	1 (1.0%)
	URTICARIA	0	1 (1.8%)	1 (1.0%)
Cardiovascular System	TOTAL	0	2 (3.5%)	2 (2.0%)
	SYNCOPE	0	2 (3.5%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
Urogenital System	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
	DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	38 (76.0%)	44 (66.7%)	82 (70.7%)
Body as a Whole	TOTAL	20 (40.0%)	24 (36.4%)	44 (37.9%)
	HEADACHE	9 (18.0%)	10 (15.2%)	19 (16.4%)
	INFECTION	6 (12.0%)	11 (16.7%)	17 (14.7%)
	TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
	ABDOMINAL PAIN	5 (10.0%)	4 (6.1%)	9 (7.8%)
	FEVER	4 (8.0%)	3 (4.5%)	7 (6.0%)
	ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
	BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ASTHENIA	0	5 (7.6%)	5 (4.3%)
	PAIN	0	2 (3.0%)	2 (1.7%)
	CHEST PAIN	1 (2.0%)	0	1 (0.9%)
	FACE EDEMA	1 (2.0%)	0	1 (0.9%)
Respiratory System	TOTAL	19 (38.0%)	22 (33.3%)	41 (35.3%)
	RESPIRATORY DISORDER	12 (24.0%)	13 (19.7%)	25 (21.6%)
	PHARYNGITIS	4 (8.0%)	5 (7.6%)	9 (7.8%)
	RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
	SINUSITIS	3 (6.0%)	1 (1.5%)	4 (3.4%)
	ASTHMA	1 (2.0%)	3 (4.5%)	4 (3.4%)
	BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
	COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EPISTAXIS	0	2 (3.0%)	2 (1.7%)
	PNEUMONIA	0	1 (1.5%)	1 (0.9%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	18 (36.0%)	22 (33.3%)	40 (34.5%)
	NERVOUSNESS	5 (10.0%)	1 (1.5%)	6 (5.2%)
	EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
	SOMNOLENCE	3 (6.0%)	3 (4.5%)	6 (5.2%)
	INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
	HOSTILITY	3 (6.0%)	2 (3.0%)	5 (4.3%)
	AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
	DEPRESSION	3 (6.0%)	1 (1.5%)	4 (3.4%)
	DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ANXIETY	0	2 (3.0%)	2 (1.7%)
	CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.7%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
	VERTIGO	1 (2.0%)	0	1 (0.9%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Nervous System	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
	EUPHORIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	16 (32.0%)	18 (27.3%)	34 (29.3%)
	NAUSEA	6 (12.0%)	4 (6.1%)	10 (8.6%)
	VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
	DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
	DIARRHEA	3 (6.0%)	2 (3.0%)	5 (4.3%)
	DRY MOUTH	3 (6.0%)	0	3 (2.6%)
	INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	STOMATITIS	1 (2.0%)	0	1 (0.9%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	6 (12.0%)	7 (10.6%)	13 (11.2%)
	WEIGHT GAIN	5 (10.0%)	6 (9.1%)	11 (9.5%)
	WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
	DEHYDRATION	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	6 (12.0%)	6 (9.1%)	12 (10.3%)
	ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
	CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
	RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
	PRURITUS	0	2 (3.0%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	LEUKOPENIA	2 (4.0%)	2 (3.0%)	4 (3.4%)
	ANEMIA	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Urogenital System	TOTAL	2 (4.0%)	4 (6.1%)	6 (5.2%)
	ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HAEMATURIA	0	2 (3.0%)	2 (1.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
	ARTHROSIS	0	1 (1.5%)	1 (0.9%)
	MYALGIA	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	4 (6.1%)	4 (3.4%)
	SYNCOPE	0	2 (3.0%)	2 (1.7%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (6.9%)	2 (3.8%)
Urogenital System	TOTAL	0	2 (6.9%)	2 (3.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	33 (75.0%)	46 (75.4%)	79 (75.2%)
Body as a Whole	TOTAL	24 (54.5%)	26 (42.6%)	50 (47.6%)
	HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
	INFECTION	7 (15.9%)	4 (6.6%)	11 (10.5%)
	ABDOMINAL PAIN	2 (4.5%)	8 (13.1%)	10 (9.5%)
	TRAUMA	4 (9.1%)	4 (6.6%)	8 (7.6%)
	ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
	ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	FEVER	3 (6.8%)	2 (3.3%)	5 (4.8%)
	PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
	ABSCESS	1 (2.3%)	0	1 (1.0%)
Nervous System	TOTAL	14 (31.8%)	28 (45.9%)	42 (40.0%)
	NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
	HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
	INSOMNIA	4 (9.1%)	5 (8.2%)	9 (8.6%)
	HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
	ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
	NEUROSIS	4 (9.1%)	0	4 (3.8%)
	SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
	AGITATION	0	3 (4.9%)	3 (2.9%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	DEPRESSION	0	1 (1.6%)	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
	VERTIGO	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	11 (25.0%)	18 (29.5%)	29 (27.6%)
	RESPIRATORY DISORDER	3 (6.8%)	12 (19.7%)	15 (14.3%)
	RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
	PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)
	SINUSITIS	4 (9.1%)	1 (1.6%)	5 (4.8%)
	ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	COUGH INCREASED	2 (4.5%)	1 (1.6%)	3 (2.9%)
	EPISTAXIS	0	1 (1.6%)	1 (1.0%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Respiratory System	PNEUMONIA	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	9 (20.5%)	16 (26.2%)	25 (23.8%)
	NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DIARRHEA	3 (6.8%)	1 (1.6%)	4 (3.8%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	FLATULENCE	0	2 (3.3%)	2 (1.9%)
	TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
	GINGIVITIS	0	1 (1.6%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	6 (13.6%)	6 (9.8%)	12 (11.4%)
	OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	EAR PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
	EYE PAIN	1 (2.3%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	MYALGIA	1 (2.3%)	0	1 (1.0%)
Urogenital System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
	DYSURIA	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	1 (2.3%)	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	2 (4.5%)	7 (11.5%)	9 (8.6%)
	ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
	CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)
	RASH	0	3 (4.9%)	3 (2.9%)
	MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
	URTICARIA	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	4 (6.6%)	5 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Cardiovascular System	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	HAEMATOMA	1 (2.3%)	0	1 (1.0%)
	SYNCOPE	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ANEMIA	1 (2.3%)	0	1 (1.0%)
	EOSINOPHILIA	0	1 (1.6%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
Urogenital System	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
	DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	TOTAL	71 (75.5%)	90 (70.9%)	161 (72.9%)
Body as a Whole	TOTAL	44 (46.8%)	50 (39.4%)	94 (42.5%)
	HEADACHE	24 (25.5%)	24 (18.9%)	48 (21.7%)
	INFECTION	13 (13.8%)	15 (11.8%)	28 (12.7%)
	TRAUMA	12 (12.8%)	10 (7.9%)	22 (10.0%)
	ABDOMINAL PAIN	7 (7.4%)	12 (9.4%)	19 (8.6%)
	ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
	FEVER	7 (7.4%)	5 (3.9%)	12 (5.4%)
	ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
	BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
	PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
	ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	CHEST PAIN	1 (1.1%)	0	1 (0.5%)
	FACE EDEMA	1 (1.1%)	0	1 (0.5%)
Nervous System	TOTAL	32 (34.0%)	50 (39.4%)	82 (37.1%)
	NERVOUSNESS	7 (7.4%)	13 (10.2%)	20 (9.0%)
	INSOMNIA	5 (5.3%)	10 (7.9%)	15 (6.8%)
	HOSTILITY	5 (5.3%)	9 (7.1%)	14 (6.3%)
	HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
	SOMNOLENCE	5 (5.3%)	4 (3.1%)	9 (4.1%)
	EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
	DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
	AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
	ANXIETY	2 (2.1%)	5 (3.9%)	7 (3.2%)
	DEPRESSION	3 (3.2%)	2 (1.6%)	5 (2.3%)
	NEUROSIS	4 (4.3%)	0	4 (1.8%)
	CONCENTRATION IMPAIRED	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	TREMOR	0	3 (2.4%)	3 (1.4%)
	LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
	HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	EUPHORIA	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	PARALYSIS	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)

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Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Nervous System	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	30 (31.9%)	40 (31.5%)	70 (31.7%)
	RESPIRATORY DISORDER	15 (16.0%)	25 (19.7%)	40 (18.1%)
	RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
	PHARYNGITIS	6 (6.4%)	9 (7.1%)	15 (6.8%)
	SINUSITIS	7 (7.4%)	2 (1.6%)	9 (4.1%)
	ASTHMA	3 (3.2%)	5 (3.9%)	8 (3.6%)
	COUGH INCREASED	3 (3.2%)	3 (2.4%)	6 (2.7%)
	BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EPISTAXIS	0	3 (2.4%)	3 (1.4%)
	PNEUMONIA	0	2 (1.6%)	2 (0.9%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	25 (26.6%)	34 (26.8%)	59 (26.7%)
	NAUSEA	10 (10.6%)	10 (7.9%)	20 (9.0%)
	DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
	VOMITING	6 (6.4%)	4 (3.1%)	10 (4.5%)
	DIARRHEA	6 (6.4%)	3 (2.4%)	9 (4.1%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
	TOOTH CARIES	0	4 (3.1%)	4 (1.8%)
	INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FLATULENCE	0	2 (1.6%)	2 (0.9%)
	GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
	STOMATITIS	1 (1.1%)	0	1 (0.5%)
	TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	GINGIVITIS	0	1 (0.8%)	1 (0.5%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.5%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	8 (8.5%)	13 (10.2%)	21 (9.5%)
	ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
	CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)
	RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
	MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PRURITUS	0	2 (1.6%)	2 (0.9%)
	HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.5%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
	URTICARIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Special Senses	TOTAL	8 (8.5%)	8 (6.3%)	16 (7.2%)
	OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
	OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	EAR PAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
	BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
	EYE PAIN	1 (1.1%)	0	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	7 (7.4%)	9 (7.1%)	16 (7.2%)
	WEIGHT GAIN	6 (6.4%)	7 (5.5%)	13 (5.9%)
	WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEHYDRATION	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	5 (5.3%)	5 (3.9%)	10 (4.5%)
	ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DYSURIA	1 (1.1%)	0	1 (0.5%)
	CYSTITIS	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	4 (4.3%)	2 (1.6%)	6 (2.7%)
	ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
	MYALGIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ARTHROSIS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	3 (3.2%)	4 (3.1%)	7 (3.2%)
	LEUKOPENIA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.5%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.5%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	1 (1.1%)	8 (6.3%)	9 (4.1%)
	SYNCOPE	0	3 (2.4%)	3 (1.4%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	HAEMATOMA	1 (1.1%)	0	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
Urogenital System	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
	DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	20 (80.0%)	25 (69.4%)	45 (73.8%)
RESPIRATORY DISORDER	8 (32.0%)	6 (16.7%)	14 (23.0%)
INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
HEADACHE	5 (20.0%)	4 (11.1%)	9 (14.8%)
PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
ABDOMINAL PAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
FEVER	4 (16.0%)	2 (5.6%)	6 (9.8%)
DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
HOSTILITY	3 (12.0%)	1 (2.8%)	4 (6.6%)
ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
NERVOUSNESS	3 (12.0%)	0	3 (4.9%)
CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
DEPRESSION	2 (8.0%)	1 (2.8%)	3 (4.9%)
DIARRHEA	2 (8.0%)	1 (2.8%)	3 (4.9%)
SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
NAUSEA	1 (4.0%)	2 (5.6%)	3 (4.9%)
RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
BACK PAIN	0	3 (8.3%)	3 (4.9%)
INSOMNIA	0	3 (8.3%)	3 (4.9%)
ACNE	2 (8.0%)	0	2 (3.3%)
DRY MOUTH	2 (8.0%)	0	2 (3.3%)
COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
ASTHENIA	0	2 (5.6%)	2 (3.3%)
EPISTAXIS	0	2 (5.6%)	2 (3.3%)
HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
CONSTIPATION	1 (4.0%)	0	1 (1.6%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
FACE EDEMA	1 (4.0%)	0	1 (1.6%)
HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
STOMATITIS	1 (4.0%)	0	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
ANEMIA	0	1 (2.8%)	1 (1.6%)
ANXIETY	0	1 (2.8%)	1 (1.6%)
ASTHMA	0	1 (2.8%)	1 (1.6%)
BRONCHITIS	0	1 (2.8%)	1 (1.6%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
HAEMATURIA	0	1 (2.8%)	1 (1.6%)
MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
MYALGIA	0	1 (2.8%)	1 (1.6%)
PAIN	0	1 (2.8%)	1 (1.6%)
PNEUMONIA	0	1 (2.8%)	1 (1.6%)
PRURITUS	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
SYNCOPE	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
TOTAL	19 (79.2%)	27 (79.4%)	46 (79.3%)
HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)
TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
ABDOMINAL PAIN	1 (4.2%)	5 (14.7%)	6 (10.3%)
NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
FEVER	3 (12.5%)	1 (2.9%)	4 (6.9%)
INFECTION	3 (12.5%)	1 (2.9%)	4 (6.9%)
DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
COUGH INCREASED	2 (8.3%)	1 (2.9%)	3 (5.2%)
DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
SINUSITIS	2 (8.3%)	1 (2.9%)	3 (5.2%)
ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
VASODILATATION	0	3 (8.8%)	3 (5.2%)
DIARRHEA	2 (8.3%)	0	2 (3.4%)
EAR PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
RASH	0	2 (5.9%)	2 (3.4%)
ABSCESS	1 (4.2%)	0	1 (1.7%)
ANEMIA	1 (4.2%)	0	1 (1.7%)
ASTHMA	1 (4.2%)	0	1 (1.7%)
BACK PAIN	1 (4.2%)	0	1 (1.7%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
HAEMATOMA	1 (4.2%)	0	1 (1.7%)
MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
MYALGIA	1 (4.2%)	0	1 (1.7%)
NEUROSIS	1 (4.2%)	0	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
FLATULENCE	0	1 (2.9%)	1 (1.7%)
GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
MANIC REACTION	0	1 (2.9%)	1 (1.7%)
TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
TREMOR	0	1 (2.9%)	1 (1.7%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)
VERTIGO	0	1 (2.9%)	1 (1.7%)
WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	39 (79.6%)	52 (74.3%)	91 (76.5%)
HEADACHE	13 (26.5%)	10 (14.3%)	23 (19.3%)
RESPIRATORY DISORDER	9 (18.4%)	13 (18.6%)	22 (18.5%)
INFECTION	7 (14.3%)	10 (14.3%)	17 (14.3%)
TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
ABDOMINAL PAIN	5 (10.2%)	8 (11.4%)	13 (10.9%)
NERVOUSNESS	4 (8.2%)	9 (12.9%)	13 (10.9%)
HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
FEVER	7 (14.3%)	3 (4.3%)	10 (8.4%)
DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
HOSTILITY	4 (8.2%)	5 (7.1%)	9 (7.6%)
NAUSEA	5 (10.2%)	3 (4.3%)	8 (6.7%)
VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)
INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
SINUSITIS	4 (8.2%)	2 (2.9%)	6 (5.0%)
OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
DIARRHEA	4 (8.2%)	1 (1.4%)	5 (4.2%)
COUGH INCREASED	3 (6.1%)	2 (2.9%)	5 (4.2%)
ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
DEPRESSION	2 (4.1%)	1 (1.4%)	3 (2.5%)
OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
VASODILATATION	0	3 (4.3%)	3 (2.5%)
ACNE	2 (4.1%)	0	2 (1.7%)
DRY MOUTH	2 (4.1%)	0	2 (1.7%)
ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
CONCENTRATION IMPAIRED	1 (2.0%)	1 (1.4%)	2 (1.7%)
EAR PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHENIA	0	2 (2.9%)	2 (1.7%)
EPISTAXIS	0	2 (2.9%)	2 (1.7%)
GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
TREMOR	0	2 (2.9%)	2 (1.7%)
ABSCESS	1 (2.0%)	0	1 (0.8%)
ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
CONSTIPATION	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
FACE EDEMA	1 (2.0%)	0	1 (0.8%)
HAEMATOMA	1 (2.0%)	0	1 (0.8%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
NEUROSIS	1 (2.0%)	0	1 (0.8%)
STOMATITIS	1 (2.0%)	0	1 (0.8%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
BRONCHITIS	0	1 (1.4%)	1 (0.8%)
FLATULENCE	0	1 (1.4%)	1 (0.8%)
HAEMATURIA	0	1 (1.4%)	1 (0.8%)
LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
MANIC REACTION	0	1 (1.4%)	1 (0.8%)
PNEUMONIA	0	1 (1.4%)	1 (0.8%)
PRURITUS	0	1 (1.4%)	1 (0.8%)
SYNCOPE	0	1 (1.4%)	1 (0.8%)
VERTIGO	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
TOTAL	18 (72.0%)	18 (60.0%)	36 (65.5%)
RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)
HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
SOMNOLENCE	3 (12.0%)	2 (6.7%)	5 (9.1%)
EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
INFECTION	2 (8.0%)	2 (6.7%)	4 (7.3%)
WEIGHT GAIN	1 (4.0%)	3 (10.0%)	4 (7.3%)
DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
ASTHMA	1 (4.0%)	2 (6.7%)	3 (5.5%)
BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
ASTHENIA	0	3 (10.0%)	3 (5.5%)
ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
BACK PAIN	2 (8.0%)	0	2 (3.6%)
VOMITING	2 (8.0%)	0	2 (3.6%)
ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIARRHEA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
CHEST PAIN	1 (4.0%)	0	1 (1.8%)
DEPRESSION	1 (4.0%)	0	1 (1.8%)
DRY MOUTH	1 (4.0%)	0	1 (1.8%)
LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
LEUKOPENIA	1 (4.0%)	0	1 (1.8%)
OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
SINUSITIS	1 (4.0%)	0	1 (1.8%)
VERTIGO	1 (4.0%)	0	1 (1.8%)
WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
ACNE	0	1 (3.3%)	1 (1.8%)
ANXIETY	0	1 (3.3%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
FEVER	0	1 (3.3%)	1 (1.8%)
HAEMATURIA	0	1 (3.3%)	1 (1.8%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
HOSTILITY	0	1 (3.3%)	1 (1.8%)
PAIN	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Preferred Term			
PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
PRURITUS	0	1 (3.3%)	1 (1.8%)
SYNCOPE	0	1 (3.3%)	1 (1.8%)
TOOTH CARIES	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
TOTAL	14 (70.0%)	18 (66.7%)	32 (68.1%)
HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
RESPIRATORY DISORDER	2 (10.0%)	5 (18.5%)	7 (14.9%)
ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
INSOMNIA	2 (10.0%)	3 (11.1%)	5 (10.6%)
NAUSEA	0	5 (18.5%)	5 (10.6%)
ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
NEUROSIS	3 (15.0%)	0	3 (6.4%)
ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
SINUSITIS	2 (10.0%)	0	2 (4.3%)
ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
AGITATION	0	2 (7.4%)	2 (4.3%)
DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
DRY MOUTH	0	2 (7.4%)	2 (4.3%)
DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
DYSURIA	1 (5.0%)	0	1 (2.1%)
EYE PAIN	1 (5.0%)	0	1 (2.1%)
HAEMATURIA	1 (5.0%)	0	1 (2.1%)
MANIC REACTION	1 (5.0%)	0	1 (2.1%)
PAIN	1 (5.0%)	0	1 (2.1%)
SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
BACK PAIN	0	1 (3.7%)	1 (2.1%)
CONSTIPATION	0	1 (3.7%)	1 (2.1%)
CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
DEPRESSION	0	1 (3.7%)	1 (2.1%)
EPISTAXIS	0	1 (3.7%)	1 (2.1%)
FEVER	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Preferred Term			
FLATULENCE	0	1 (3.7%)	1 (2.1%)
OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
PNEUMONIA	0	1 (3.7%)	1 (2.1%)
RASH	0	1 (3.7%)	1 (2.1%)
SYNCOPE	0	1 (3.7%)	1 (2.1%)
TRAUMA	0	1 (3.7%)	1 (2.1%)
TREMOR	0	1 (3.7%)	1 (2.1%)
WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	2 (22.2%)	0	2 (11.1%)
DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	32 (71.1%)	36 (63.2%)	68 (66.7%)
HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
RESPIRATORY DISORDER	6 (13.3%)	12 (21.1%)	18 (17.6%)
NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
INFECTION	6 (13.3%)	5 (8.8%)	11 (10.8%)
ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
INSOMNIA	3 (6.7%)	5 (8.8%)	8 (7.8%)
TRAUMA	4 (8.9%)	3 (5.3%)	7 (6.9%)
EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
SOMNOLENCE	4 (8.9%)	2 (3.5%)	6 (5.9%)
ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
ASTHMA	2 (4.4%)	4 (7.0%)	6 (5.9%)
DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
WEIGHT GAIN	2 (4.4%)	3 (5.3%)	5 (4.9%)
HOSTILITY	1 (2.2%)	4 (7.0%)	5 (4.9%)
ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
DIARRHEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
NEUROSIS	3 (6.7%)	0	3 (2.9%)
SINUSITIS	3 (6.7%)	0	3 (2.9%)
ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
VOMITING	2 (4.4%)	0	2 (2.0%)
DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
FEVER	0	2 (3.5%)	2 (2.0%)
INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
PHARYNGITIS	0	2 (3.5%)	2 (2.0%)
SYNCOPE	0	2 (3.5%)	2 (2.0%)
ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
BLEPHARITIS	1 (2.2%)	0	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Preferred Term			
CHEST PAIN	1 (2.2%)	0	1 (1.0%)
DYSURIA	1 (2.2%)	0	1 (1.0%)
EYE PAIN	1 (2.2%)	0	1 (1.0%)
LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
MANIC REACTION	1 (2.2%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
VERTIGO	1 (2.2%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
CONSTIPATION	0	1 (1.8%)	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
EPISTAXIS	0	1 (1.8%)	1 (1.0%)
FLATULENCE	0	1 (1.8%)	1 (1.0%)
HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
PNEUMONIA	0	1 (1.8%)	1 (1.0%)
PRURITUS	0	1 (1.8%)	1 (1.0%)
RASH	0	1 (1.8%)	1 (1.0%)
TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
TREMOR	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	2 (11.1%)	0	2 (4.8%)
DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	38 (76.0%)	43 (65.2%)	81 (69.8%)
RESPIRATORY DISORDER	12 (24.0%)	13 (19.7%)	25 (21.6%)
HEADACHE	9 (18.0%)	10 (15.2%)	19 (16.4%)
INFECTION	6 (12.0%)	11 (16.7%)	17 (14.7%)
TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
WEIGHT GAIN	5 (10.0%)	6 (9.1%)	11 (9.5%)
NAUSEA	6 (12.0%)	4 (6.1%)	10 (8.6%)
VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
ABDOMINAL PAIN	5 (10.0%)	4 (6.1%)	9 (7.8%)
DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
PHARYNGITIS	4 (8.0%)	5 (7.6%)	9 (7.8%)
FEVER	4 (8.0%)	3 (4.5%)	7 (6.0%)
RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
NERVOUSNESS	5 (10.0%)	1 (1.5%)	6 (5.2%)
ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
SOMNOLENCE	3 (6.0%)	3 (4.5%)	6 (5.2%)
INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
DIARRHEA	3 (6.0%)	2 (3.0%)	5 (4.3%)
HOSTILITY	3 (6.0%)	2 (3.0%)	5 (4.3%)
AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
ASTHENIA	0	5 (7.6%)	5 (4.3%)
DEPRESSION	3 (6.0%)	1 (1.5%)	4 (3.4%)
SINUSITIS	3 (6.0%)	1 (1.5%)	4 (3.4%)
LEUKOPENIA	2 (4.0%)	2 (3.0%)	4 (3.4%)
ASTHMA	1 (2.0%)	3 (4.5%)	4 (3.4%)
BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
DRY MOUTH	3 (6.0%)	0	3 (2.6%)
ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)
DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
ANXIETY	0	2 (3.0%)	2 (1.7%)
CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
EPISTAXIS	0	2 (3.0%)	2 (1.7%)
HAEMATURIA	0	2 (3.0%)	2 (1.7%)
HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
PAIN	0	2 (3.0%)	2 (1.7%)
PRURITUS	0	2 (3.0%)	2 (1.7%)
SYNCOPE	0	2 (3.0%)	2 (1.7%)
ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
CHEST PAIN	1 (2.0%)	0	1 (0.9%)
CONSTIPATION	1 (2.0%)	0	1 (0.9%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
FACE EDEMA	1 (2.0%)	0	1 (0.9%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
STOMATITIS	1 (2.0%)	0	1 (0.9%)
VERTIGO	1 (2.0%)	0	1 (0.9%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
ANEMIA	0	1 (1.5%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
MYALGIA	0	1 (1.5%)	1 (0.9%)
PNEUMONIA	0	1 (1.5%)	1 (0.9%)
TREMOR	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	33 (75.0%)	45 (73.8%)	78 (74.3%)
HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
RESPIRATORY DISORDER	3 (6.8%)	12 (19.7%)	15 (14.3%)
NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
INFECTION	7 (15.9%)	4 (6.6%)	11 (10.5%)
HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
ABDOMINAL PAIN	2 (4.5%)	8 (13.1%)	10 (9.5%)
INSOMNIA	4 (9.1%)	5 (8.2%)	9 (8.6%)
HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
TRAUMA	4 (9.1%)	4 (6.6%)	8 (7.6%)
ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)
SINUSITIS	4 (9.1%)	1 (1.6%)	5 (4.8%)
FEVER	3 (6.8%)	2 (3.3%)	5 (4.8%)
ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
NEUROSIS	4 (9.1%)	0	4 (3.8%)
DIARRHEA	3 (6.8%)	1 (1.6%)	4 (3.8%)
ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
COUGH INCREASED	2 (4.5%)	1 (1.6%)	3 (2.9%)
OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
AGITATION	0	3 (4.9%)	3 (2.9%)
CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)
RASH	0	3 (4.9%)	3 (2.9%)
VASODILATATION	0	3 (4.9%)	3 (2.9%)
ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
EAR PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
DRY MOUTH	0	2 (3.3%)	2 (1.9%)
FLATULENCE	0	2 (3.3%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TREMOR	0	2 (3.3%)	2 (1.9%)
ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
ABSCESS	1 (2.3%)	0	1 (1.0%)
ANEMIA	1 (2.3%)	0	1 (1.0%)
BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
DYSURIA	1 (2.3%)	0	1 (1.0%)
EYE PAIN	1 (2.3%)	0	1 (1.0%)
HAEMATOMA	1 (2.3%)	0	1 (1.0%)
HAEMATURIA	1 (2.3%)	0	1 (1.0%)
MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
MYALGIA	1 (2.3%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
CONSTIPATION	0	1 (1.6%)	1 (1.0%)
DEPRESSION	0	1 (1.6%)	1 (1.0%)
EPISTAXIS	0	1 (1.6%)	1 (1.0%)
GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
PNEUMONIA	0	1 (1.6%)	1 (1.0%)
SYNCOPE	0	1 (1.6%)	1 (1.0%)
TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
VERTIGO	0	1 (1.6%)	1 (1.0%)
WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Preferred Term			
TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	71 (75.5%)	88 (69.3%)	159 (71.9%)
HEADACHE	24 (25.5%)	24 (18.9%)	48 (21.7%)
RESPIRATORY DISORDER	15 (16.0%)	25 (19.7%)	40 (18.1%)
INFECTION	13 (13.8%)	15 (11.8%)	28 (12.7%)
TRAUMA	12 (12.8%)	10 (7.9%)	22 (10.0%)
NAUSEA	10 (10.6%)	10 (7.9%)	20 (9.0%)
NERVOUSNESS	7 (7.4%)	13 (10.2%)	20 (9.0%)
ABDOMINAL PAIN	7 (7.4%)	12 (9.4%)	19 (8.6%)
RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
PHARYNGITIS	6 (6.4%)	9 (7.1%)	15 (6.8%)
INSOMNIA	5 (5.3%)	10 (7.9%)	15 (6.8%)
DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
HOSTILITY	5 (5.3%)	9 (7.1%)	14 (6.3%)
ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
WEIGHT GAIN	6 (6.4%)	7 (5.5%)	13 (5.9%)
FEVER	7 (7.4%)	5 (3.9%)	12 (5.4%)
ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
VOMITING	6 (6.4%)	4 (3.1%)	10 (4.5%)
SINUSITIS	7 (7.4%)	2 (1.6%)	9 (4.1%)
DIARRHEA	6 (6.4%)	3 (2.4%)	9 (4.1%)
SOMNOLENCE	5 (5.3%)	4 (3.1%)	9 (4.1%)
DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
ASTHMA	3 (3.2%)	5 (3.9%)	8 (3.6%)
DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
ANXIETY	2 (2.1%)	5 (3.9%)	7 (3.2%)
ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
COUGH INCREASED	3 (3.2%)	3 (2.4%)	6 (2.7%)
CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)
RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
DEPRESSION	3 (3.2%)	2 (1.6%)	5 (2.3%)
DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
NEUROSIS	4 (4.3%)	0	4 (1.8%)
ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
LEUKOPENIA	2 (2.1%)	2 (1.6%)	4 (1.8%)
BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
TOOTH CARIES	0	4 (3.1%)	4 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
CONCENTRATION IMPAIRED	1 (1.1%)	2 (1.6%)	3 (1.4%)
HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
EPISTAXIS	0	3 (2.4%)	3 (1.4%)
SYNCOPE	0	3 (2.4%)	3 (1.4%)
TREMOR	0	3 (2.4%)	3 (1.4%)
VASODILATATION	0	3 (2.4%)	3 (1.4%)
ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
EAR PAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MYALGIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
FLATULENCE	0	2 (1.6%)	2 (0.9%)
GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
PNEUMONIA	0	2 (1.6%)	2 (0.9%)
PRURITUS	0	2 (1.6%)	2 (0.9%)
ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
ABSCESS	1 (1.1%)	0	1 (0.5%)
BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
CHEST PAIN	1 (1.1%)	0	1 (0.5%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
DYSURIA	1 (1.1%)	0	1 (0.5%)
EYE PAIN	1 (1.1%)	0	1 (0.5%)
FACE EDEMA	1 (1.1%)	0	1 (0.5%)
HAEMATOMA	1 (1.1%)	0	1 (0.5%)
HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
STOMATITIS	1 (1.1%)	0	1 (0.5%)
TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	3 (6.7%)	1 (2.0%)	4 (4.2%)
DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	3 (37.5%)	5 (38.5%)	8 (38.1%)
Nervous System	TOTAL	2 (25.0%)	2 (15.4%)	4 (19.0%)
	DEPRESSION	2 (25.0%)	1 (7.7%)	3 (14.3%)
	HYSTERIA	0	1 (7.7%)	1 (4.8%)
Body as a Whole	TOTAL	1 (12.5%)	0	1 (4.8%)
	FEVER	1 (12.5%)	0	1 (4.8%)
Respiratory System	TOTAL	1 (12.5%)	0	1 (4.8%)
	RESPIRATORY DISORDER	1 (12.5%)	0	1 (4.8%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.8%)
	SYNCOPE	0	1 (7.7%)	1 (4.8%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.8%)
	NAUSEA	0	1 (7.7%)	1 (4.8%)
Special Searches	TOTAL	0	1 (7.7%)	1 (4.8%)
	PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	2 (66.7%)	1 (20.0%)	3 (37.5%)
Body as a Whole	TOTAL	1 (33.3%)	1 (20.0%)	2 (25.0%)
	ABDOMINAL PAIN	1 (33.3%)	0	1 (12.5%)
	HEADACHE	1 (33.3%)	0	1 (12.5%)
	INFECTION	0	1 (20.0%)	1 (12.5%)
Respiratory System	TOTAL	1 (33.3%)	0	1 (12.5%)
	SINUSITIS	1 (33.3%)	0	1 (12.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (20.0%)	1 (12.5%)
	WEIGHT GAIN	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	TOTAL	5 (45.5%)	6 (33.3%)	11 (37.9%)
Body as a Whole	TOTAL	2 (18.2%)	1 (5.6%)	3 (10.3%)
	ABDOMINAL PAIN	1 (9.1%)	0	1 (3.4%)
	FEVER	1 (9.1%)	0	1 (3.4%)
	HEADACHE	1 (9.1%)	0	1 (3.4%)
	INFECTION	0	1 (5.6%)	1 (3.4%)
Nervous System	TOTAL	2 (18.2%)	2 (11.1%)	4 (13.8%)
	DEPRESSION	2 (18.2%)	1 (5.6%)	3 (10.3%)
	HYSTERIA	0	1 (5.6%)	1 (3.4%)
Respiratory System	TOTAL	2 (18.2%)	0	2 (6.9%)
	RESPIRATORY DISORDER	1 (9.1%)	0	1 (3.4%)
	SINUSITIS	1 (9.1%)	0	1 (3.4%)
Cardiovascular System	TOTAL	0	1 (5.6%)	1 (3.4%)
	SYNCOPE	0	1 (5.6%)	1 (3.4%)
Digestive System	TOTAL	0	1 (5.6%)	1 (3.4%)
	NAUSEA	0	1 (5.6%)	1 (3.4%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.6%)	1 (3.4%)
	WEIGHT GAIN	0	1 (5.6%)	1 (3.4%)
Special Searches	TOTAL	0	1 (5.6%)	1 (3.4%)
	PUNCTURE SITE PAIN	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	3 (33.3%)	2 (22.2%)	5 (27.8%)
Hemic and Lymphatic System	TOTAL	1 (11.1%)	0	1 (5.6%)
	LEUKOPENIA	1 (11.1%)	0	1 (5.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (11.1%)	0	1 (5.6%)
	WEIGHT GAIN	1 (11.1%)	0	1 (5.6%)
Nervous System	TOTAL	1 (11.1%)	2 (22.2%)	3 (16.7%)
	HOSTILITY	1 (11.1%)	0	1 (5.6%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.6%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.6%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.6%)
	MYALGIA	0	1 (11.1%)	1 (5.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	1 (50.0%)	1 (33.3%)	2 (40.0%)
Cardiovascular System	TOTAL	1 (50.0%)	0	1 (20.0%)
	BRADYCARDIA	1 (50.0%)	0	1 (20.0%)
Nervous System	TOTAL	0	1 (33.3%)	1 (20.0%)
	ABNORMAL DREAMS	0	1 (33.3%)	1 (20.0%)
	INSOMNIA	0	1 (33.3%)	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	4 (36.4%)	3 (25.0%)	7 (30.4%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.3%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.3%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (4.3%)
	LEUKOPENIA	1 (9.1%)	0	1 (4.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (4.3%)
	WEIGHT GAIN	1 (9.1%)	0	1 (4.3%)
Nervous System	TOTAL	1 (9.1%)	3 (25.0%)	4 (17.4%)
	HOSTILITY	1 (9.1%)	0	1 (4.3%)
	ABNORMAL DREAMS	0	1 (8.3%)	1 (4.3%)
	INSOMNIA	0	1 (8.3%)	1 (4.3%)
	SOMNOLENCE	0	1 (8.3%)	1 (4.3%)
	WITHDRAWAL SYNDROME	0	1 (8.3%)	1 (4.3%)
Musculoskeletal System	TOTAL	0	1 (8.3%)	1 (4.3%)
	MYALGIA	0	1 (8.3%)	1 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	6 (35.3%)	7 (31.8%)	13 (33.3%)
Nervous System	TOTAL	3 (17.6%)	4 (18.2%)	7 (17.9%)
	DEPRESSION	2 (11.8%)	1 (4.5%)	3 (7.7%)
	HOSTILITY	1 (5.9%)	0	1 (2.6%)
	HYSTERIA	0	1 (4.5%)	1 (2.6%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.6%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.6%)
Body as a Whole	TOTAL	1 (5.9%)	0	1 (2.6%)
	FEVER	1 (5.9%)	0	1 (2.6%)
Hemic and Lymphatic System	TOTAL	1 (5.9%)	0	1 (2.6%)
	LEUKOPENIA	1 (5.9%)	0	1 (2.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.9%)	0	1 (2.6%)
	WEIGHT GAIN	1 (5.9%)	0	1 (2.6%)
Respiratory System	TOTAL	1 (5.9%)	0	1 (2.6%)
	RESPIRATORY DISORDER	1 (5.9%)	0	1 (2.6%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.6%)
	SYNCOPE	0	1 (4.5%)	1 (2.6%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.6%)
	NAUSEA	0	1 (4.5%)	1 (2.6%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.6%)
	MYALGIA	0	1 (4.5%)	1 (2.6%)
Special Searches	TOTAL	0	1 (4.5%)	1 (2.6%)
	PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	3 (60.0%)	2 (25.0%)	5 (38.5%)
Body as a Whole	TOTAL	1 (20.0%)	1 (12.5%)	2 (15.4%)
	ABDOMINAL PAIN	1 (20.0%)	0	1 (7.7%)
	HEADACHE	1 (20.0%)	0	1 (7.7%)
	INFECTION	0	1 (12.5%)	1 (7.7%)
Cardiovascular System	TOTAL	1 (20.0%)	0	1 (7.7%)
	BRADYCARDIA	1 (20.0%)	0	1 (7.7%)
Respiratory System	TOTAL	1 (20.0%)	0	1 (7.7%)
	SINUSITIS	1 (20.0%)	0	1 (7.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (7.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (7.7%)
Nervous System	TOTAL	0	1 (12.5%)	1 (7.7%)
	ABNORMAL DREAMS	0	1 (12.5%)	1 (7.7%)
	INSOMNIA	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
TOTAL	TOTAL	9 (40.9%)	9 (30.0%)	18 (34.6%)
Nervous System	TOTAL	3 (13.6%)	5 (16.7%)	8 (15.4%)
	DEPRESSION	2 (9.1%)	1 (3.3%)	3 (5.8%)
	HOSTILITY	1 (4.5%)	0	1 (1.9%)
	ABNORMAL DREAMS	0	1 (3.3%)	1 (1.9%)
	HYSTERIA	0	1 (3.3%)	1 (1.9%)
	INSOMNIA	0	1 (3.3%)	1 (1.9%)
	SOMNOLENCE	0	1 (3.3%)	1 (1.9%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.9%)
Body as a Whole	TOTAL	2 (9.1%)	1 (3.3%)	3 (5.8%)
	ABDOMINAL PAIN	1 (4.5%)	0	1 (1.9%)
	FEVER	1 (4.5%)	0	1 (1.9%)
	HEADACHE	1 (4.5%)	0	1 (1.9%)
	INFECTION	0	1 (3.3%)	1 (1.9%)
Respiratory System	TOTAL	2 (9.1%)	0	2 (3.8%)
	RESPIRATORY DISORDER	1 (4.5%)	0	1 (1.9%)
	SINUSITIS	1 (4.5%)	0	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	BRADYCARDIA	1 (4.5%)	0	1 (1.9%)
	SYNCOPE	0	1 (3.3%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	1 (4.5%)	0	1 (1.9%)
	LEUKOPENIA	1 (4.5%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	WEIGHT GAIN	1 (4.5%)	1 (3.3%)	2 (3.8%)
Digestive System	TOTAL	0	1 (3.3%)	1 (1.9%)
	NAUSEA	0	1 (3.3%)	1 (1.9%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.9%)
	MYALGIA	0	1 (3.3%)	1 (1.9%)
Special Searches	TOTAL	0	1 (3.3%)	1 (1.9%)
	PUNCTURE SITE PAIN	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
TOTAL	3 (37.5%)	5 (38.5%)	8 (38.1%)
DEPRESSION	2 (25.0%)	1 (7.7%)	3 (14.3%)
FEVER	1 (12.5%)	0	1 (4.8%)
RESPIRATORY DISORDER	1 (12.5%)	0	1 (4.8%)
HYSTERIA	0	1 (7.7%)	1 (4.8%)
NAUSEA	0	1 (7.7%)	1 (4.8%)
PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.8%)
SYNCOPE	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Preferred Term			
TOTAL	2 (66.7%)	1 (20.0%)	3 (37.5%)
ABDOMINAL PAIN	1 (33.3%)	0	1 (12.5%)
HEADACHE	1 (33.3%)	0	1 (12.5%)
SINUSITIS	1 (33.3%)	0	1 (12.5%)
INFECTION	0	1 (20.0%)	1 (12.5%)
WEIGHT GAIN	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	5 (45.5%)	6 (33.3%)	11 (37.9%)
DEPRESSION	2 (18.2%)	1 (5.6%)	3 (10.3%)
ABDOMINAL PAIN	1 (9.1%)	0	1 (3.4%)
FEVER	1 (9.1%)	0	1 (3.4%)
HEADACHE	1 (9.1%)	0	1 (3.4%)
RESPIRATORY DISORDER	1 (9.1%)	0	1 (3.4%)
SINUSITIS	1 (9.1%)	0	1 (3.4%)
HYSTERIA	0	1 (5.6%)	1 (3.4%)
INFECTION	0	1 (5.6%)	1 (3.4%)
NAUSEA	0	1 (5.6%)	1 (3.4%)
PUNCTURE SITE PAIN	0	1 (5.6%)	1 (3.4%)
SYNCOPE	0	1 (5.6%)	1 (3.4%)
WEIGHT GAIN	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=9)	 Placebo (N=9)	 Total (N=18)
TOTAL	3 (33.3%)	2 (22.2%)	5 (27.8%)
HOSTILITY	1 (11.1%)	0	1 (5.6%)
LEUKOPENIA	1 (11.1%)	0	1 (5.6%)
WEIGHT GAIN	1 (11.1%)	0	1 (5.6%)
MYALGIA	0	1 (11.1%)	1 (5.6%)
SOMNOLENCE	0	1 (11.1%)	1 (5.6%)
WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Preferred Term			
TOTAL	1 (50.0%)	1 (33.3%)	2 (40.0%)
BRADYCARDIA	1 (50.0%)	0	1 (20.0%)
ABNORMAL DREAMS	0	1 (33.3%)	1 (20.0%)
INSOMNIA	0	1 (33.3%)	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
TOTAL	4 (36.4%)	3 (25.0%)	7 (30.4%)
BRADYCARDIA	1 (9.1%)	0	1 (4.3%)
HOSTILITY	1 (9.1%)	0	1 (4.3%)
LEUKOPENIA	1 (9.1%)	0	1 (4.3%)
WEIGHT GAIN	1 (9.1%)	0	1 (4.3%)
ABNORMAL DREAMS	0	1 (8.3%)	1 (4.3%)
INSOMNIA	0	1 (8.3%)	1 (4.3%)
MYALGIA	0	1 (8.3%)	1 (4.3%)
SOMNOLENCE	0	1 (8.3%)	1 (4.3%)
WITHDRAWAL SYNDROME	0	1 (8.3%)	1 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
TOTAL	6 (35.3%)	7 (31.8%)	13 (33.3%)
DEPRESSION	2 (11.8%)	1 (4.5%)	3 (7.7%)
FEVER	1 (5.9%)	0	1 (2.6%)
HOSTILITY	1 (5.9%)	0	1 (2.6%)
LEUKOPENIA	1 (5.9%)	0	1 (2.6%)
RESPIRATORY DISORDER	1 (5.9%)	0	1 (2.6%)
WEIGHT GAIN	1 (5.9%)	0	1 (2.6%)
HYSTERIA	0	1 (4.5%)	1 (2.6%)
MYALGIA	0	1 (4.5%)	1 (2.6%)
NAUSEA	0	1 (4.5%)	1 (2.6%)
PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.6%)
SOMNOLENCE	0	1 (4.5%)	1 (2.6%)
SYNCOPE	0	1 (4.5%)	1 (2.6%)
WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Preferred Term			
TOTAL	3 (60.0%)	2 (25.0%)	5 (38.5%)
ABDOMINAL PAIN	1 (20.0%)	0	1 (7.7%)
BRADYCARDIA	1 (20.0%)	0	1 (7.7%)
HEADACHE	1 (20.0%)	0	1 (7.7%)
SINUSITIS	1 (20.0%)	0	1 (7.7%)
ABNORMAL DREAMS	0	1 (12.5%)	1 (7.7%)
INFECTION	0	1 (12.5%)	1 (7.7%)
INSOMNIA	0	1 (12.5%)	1 (7.7%)
WEIGHT GAIN	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
TOTAL	9 (40.9%)	9 (30.0%)	18 (34.6%)
DEPRESSION	2 (9.1%)	1 (3.3%)	3 (5.8%)
WEIGHT GAIN	1 (4.5%)	1 (3.3%)	2 (3.8%)
ABDOMINAL PAIN	1 (4.5%)	0	1 (1.9%)
BRADYCARDIA	1 (4.5%)	0	1 (1.9%)
FEVER	1 (4.5%)	0	1 (1.9%)
HEADACHE	1 (4.5%)	0	1 (1.9%)
HOSTILITY	1 (4.5%)	0	1 (1.9%)
LEUKOPENIA	1 (4.5%)	0	1 (1.9%)
RESPIRATORY DISORDER	1 (4.5%)	0	1 (1.9%)
SINUSITIS	1 (4.5%)	0	1 (1.9%)
ABNORMAL DREAMS	0	1 (3.3%)	1 (1.9%)
HYSTERIA	0	1 (3.3%)	1 (1.9%)
INFECTION	0	1 (3.3%)	1 (1.9%)
INSOMNIA	0	1 (3.3%)	1 (1.9%)
MYALGIA	0	1 (3.3%)	1 (1.9%)
NAUSEA	0	1 (3.3%)	1 (1.9%)
PUNCTURE SITE PAIN	0	1 (3.3%)	1 (1.9%)
SOMNOLENCE	0	1 (3.3%)	1 (1.9%)
SYNCOPE	0	1 (3.3%)	1 (1.9%)
WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	20 (80.0%)	25 (69.4%)	45 (73.8%)
Respiratory System	TOTAL	13 (52.0%)	13 (36.1%)	26 (42.6%)
	RESPIRATORY DISORDER	9 (36.0%)	6 (16.7%)	15 (24.6%)
	PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
	RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
	SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
	EPISTAXIS	0	2 (5.6%)	2 (3.3%)
	ASTHMA	0	1 (2.8%)	1 (1.6%)
	BRONCHITIS	0	1 (2.8%)	1 (1.6%)
	PNEUMONIA	0	1 (2.8%)	1 (1.6%)
	YAWN	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	10 (40.0%)	15 (41.7%)	25 (41.0%)
	INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
	HEADACHE	5 (20.0%)	4 (11.1%)	9 (14.8%)
	TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
	FEVER	5 (20.0%)	2 (5.6%)	7 (11.5%)
	ABDOMINAL PAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
	ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
	BACK PAIN	0	3 (8.3%)	3 (4.9%)
	ASTHENIA	0	2 (5.6%)	2 (3.3%)
	FACE EDEMA	1 (4.0%)	0	1 (1.6%)
	PAIN	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	10 (40.0%)	12 (33.3%)	22 (36.1%)
	VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
	DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
	NAUSEA	1 (4.0%)	3 (8.3%)	4 (6.6%)
	DIARRHEA	2 (8.0%)	1 (2.8%)	3 (4.9%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
	STOMATITIS	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	10 (40.0%)	12 (33.3%)	22 (36.1%)
	DEPRESSION	3 (12.0%)	1 (2.8%)	4 (6.6%)
	HOSTILITY	3 (12.0%)	1 (2.8%)	4 (6.6%)
	NERVOUSNESS	3 (12.0%)	0	3 (4.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Nervous System	AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
	INSOMNIA	0	3 (8.3%)	3 (4.9%)
	HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
	VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
	ANXIETY	0	1 (2.8%)	1 (1.6%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	EUPHORIA	0	1 (2.8%)	1 (1.6%)
	HYSTERIA	0	1 (2.8%)	1 (1.6%)
	PARALYSIS	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	6 (24.0%)	4 (11.1%)	10 (16.4%)
	CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ACNE	2 (8.0%)	0	2 (3.3%)
	HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
	PRURITUS	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	4 (16.0%)	4 (11.1%)	8 (13.1%)
	WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
	DEHYDRATION	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ANEMIA	0	1 (2.8%)	1 (1.6%)
Musculoskeletal System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
	ARTHROSIS	0	1 (2.8%)	1 (1.6%)
	MYALGIA	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	3 (8.3%)	4 (6.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Urogenital System	URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
	CYSTITIS	0	1 (2.8%)	1 (1.6%)
	HAEMATURIA	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.9%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (2.8%)	1 (1.6%)
	MIGRAINE	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.6%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	19 (79.2%)	28 (82.4%)	47 (81.0%)
Body as a Whole	TOTAL	13 (54.2%)	16 (47.1%)	29 (50.0%)
	HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
	TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
	ABDOMINAL PAIN	2 (8.3%)	5 (14.7%)	7 (12.1%)
	INFECTION	3 (12.5%)	2 (5.9%)	5 (8.6%)
	FEVER	3 (12.5%)	1 (2.9%)	4 (6.9%)
	PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ABSCESS	1 (4.2%)	0	1 (1.7%)
	BACK PAIN	1 (4.2%)	0	1 (1.7%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	7 (29.2%)	6 (17.6%)	13 (22.4%)
	NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	DIARRHEA	2 (8.3%)	0	2 (3.4%)
	FLATULENCE	0	1 (2.9%)	1 (1.7%)
	GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
	GINGIVITIS	0	1 (2.9%)	1 (1.7%)
	TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
Nervous System	TOTAL	7 (29.2%)	20 (58.8%)	27 (46.6%)
	NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
	HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
	HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
	MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	PSYCHOSIS	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
	VERTIGO	0	1 (2.9%)	1 (1.7%)
Respiratory System	TOTAL	5 (20.8%)	10 (29.4%)	15 (25.9%)
	RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
Respiratory System	RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
	PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
	SINUSITIS	3 (12.5%)	1 (2.9%)	4 (6.9%)
	COUGH INCREASED	2 (8.3%)	1 (2.9%)	3 (5.2%)
	ASTHMA	1 (4.2%)	0	1 (1.7%)
Special Senses	TOTAL	4 (16.7%)	4 (11.8%)	8 (13.8%)
	OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	EAR PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
Cardiovascular System	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
	HAEMATOMA	1 (4.2%)	0	1 (1.7%)
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0	1 (1.7%)
	ANEMIA	1 (4.2%)	0	1 (1.7%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.7%)
	MYALGIA	1 (4.2%)	0	1 (1.7%)
Skin and Appendages	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
	RASH	0	2 (5.9%)	2 (3.4%)
	MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
	HERPES SIMPLEX	0	1 (2.9%)	1 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
Urogenital System	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
	DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	TOTAL	39 (79.6%)	53 (75.7%)	92 (77.3%)
Body as a Whole	TOTAL	23 (46.9%)	31 (44.3%)	54 (45.4%)
	HEADACHE	13 (26.5%)	10 (14.3%)	23 (19.3%)
	INFECTION	7 (14.3%)	11 (15.7%)	18 (15.1%)
	TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
	ABDOMINAL PAIN	6 (12.2%)	8 (11.4%)	14 (11.8%)
	FEVER	8 (16.3%)	3 (4.3%)	11 (9.2%)
	ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
	BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
	PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ASTHENIA	0	2 (2.9%)	2 (1.7%)
	ABSCESS	1 (2.0%)	0	1 (0.8%)
	FACE EDEMA	1 (2.0%)	0	1 (0.8%)
Respiratory System	TOTAL	18 (36.7%)	23 (32.9%)	41 (34.5%)
	RESPIRATORY DISORDER	10 (20.4%)	13 (18.6%)	23 (19.3%)
	PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
	RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
	SINUSITIS	5 (10.2%)	2 (2.9%)	7 (5.9%)
	COUGH INCREASED	3 (6.1%)	2 (2.9%)	5 (4.2%)
	ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	EPISTAXIS	0	2 (2.9%)	2 (1.7%)
	BRONCHITIS	0	1 (1.4%)	1 (0.8%)
	PNEUMONIA	0	1 (1.4%)	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	17 (34.7%)	18 (25.7%)	35 (29.4%)
	DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
	NAUSEA	5 (10.2%)	4 (5.7%)	9 (7.6%)
	VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
	DIARRHEA	4 (8.2%)	1 (1.4%)	5 (4.2%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	STOMATITIS	1 (2.0%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.4%)	1 (0.8%)
	GINGIVITIS	0	1 (1.4%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	17 (34.7%)	32 (45.7%)	49 (41.2%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Nervous System	NERVOUSNESS	4 (8.2%)	9 (12.9%)	13 (10.9%)
	HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	HOSTILITY	4 (8.2%)	5 (7.1%)	9 (7.6%)
	INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
	DEPRESSION	3 (6.1%)	1 (1.4%)	4 (3.4%)
	AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
	DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	CONCENTRATION IMPAIRED	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	EUPHORIA	0	1 (1.4%)	1 (0.8%)
	HYSTERIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
	PARALYSIS	0	1 (1.4%)	1 (0.8%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.8%)
	VERTIGO	0	1 (1.4%)	1 (0.8%)
Skin and Appendages	TOTAL	7 (14.3%)	7 (10.0%)	14 (11.8%)
	CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
	RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
	ACNE	2 (4.1%)	0	2 (1.7%)
	MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.8%)
	PRURITUS	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	5 (10.2%)	6 (8.6%)	11 (9.2%)
	OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
	OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
	EAR PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.2%)	5 (7.1%)	9 (7.6%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)
	DEHYDRATION	0	1 (1.4%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (4.1%)	2 (2.9%)	4 (3.4%)
	LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Musculoskeletal System	TOTAL	2 (4.1%)	1 (1.4%)	3 (2.5%)
	MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
	ARTHROSIS	0	1 (1.4%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (2.0%)	6 (8.6%)	7 (5.9%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	HAEMATOMA	1 (2.0%)	0	1 (0.8%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.4%)	1 (0.8%)
	MIGRAINE	0	1 (1.4%)	1 (0.8%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	1 (2.0%)	4 (5.7%)	5 (4.2%)
	URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
	CYSTITIS	0	1 (1.4%)	1 (0.8%)
	HAEMATURIA	0	1 (1.4%)	1 (0.8%)
Special Searches	TOTAL	0	1 (1.4%)	1 (0.8%)
	PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
Urogenital System	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
	DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	18 (72.0%)	19 (63.3%)	37 (67.3%)
Body as a Whole	TOTAL	11 (44.0%)	9 (30.0%)	20 (36.4%)
	HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
	TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
	INFECTION	2 (8.0%)	2 (6.7%)	4 (7.3%)
	ASTHENIA	0	3 (10.0%)	3 (5.5%)
	ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
	BACK PAIN	2 (8.0%)	0	2 (3.6%)
	ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
	CHEST PAIN	1 (4.0%)	0	1 (1.8%)
	FEVER	0	1 (3.3%)	1 (1.8%)
	PAIN	0	1 (3.3%)	1 (1.8%)
Nervous System	TOTAL	9 (36.0%)	11 (36.7%)	20 (36.4%)
	SOMNOLENCE	3 (12.0%)	3 (10.0%)	6 (10.9%)
	EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
	NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HOSTILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (3.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.8%)
	LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
	VERTIGO	1 (4.0%)	0	1 (1.8%)
	ANXIETY	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	6 (24.0%)	7 (23.3%)	13 (23.6%)
	NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
	DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
	VOMITING	2 (8.0%)	0	2 (3.6%)
	DIARRHEA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DRY MOUTH	1 (4.0%)	0	1 (1.8%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.8%)
	TOOTH CARIES	0	1 (3.3%)	1 (1.8%)
Respiratory System	TOTAL	6 (24.0%)	9 (30.0%)	15 (27.3%)
	RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
Respiratory System	ASTHMA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
	RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	SINUSITIS	1 (4.0%)	0	1 (1.8%)
	COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
	PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	3 (12.0%)	3 (10.0%)	6 (10.9%)
	WEIGHT GAIN	2 (8.0%)	3 (10.0%)	5 (9.1%)
	WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	2 (8.0%)	0	2 (3.6%)
	LEUKOPENIA	2 (8.0%)	0	2 (3.6%)
Special Senses	TOTAL	1 (4.0%)	0	1 (1.8%)
	OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HAEMATURIA	0	1 (3.3%)	1 (1.8%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.8%)
	SYNCOPE	0	1 (3.3%)	1 (1.8%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.8%)
	MYALGIA	0	1 (3.3%)	1 (1.8%)
Skin and Appendages	TOTAL	0	2 (6.7%)	2 (3.6%)
	ACNE	0	1 (3.3%)	1 (1.8%)
	PRURITUS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (13.3%)	2 (8.3%)
Urogenital System	TOTAL	0	2 (13.3%)	2 (8.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	14 (70.0%)	18 (66.7%)	32 (68.1%)
Body as a Whole	TOTAL	11 (55.0%)	11 (40.7%)	22 (46.8%)
	HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
	INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
	ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
	ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
	PAIN	1 (5.0%)	0	1 (2.1%)
	BACK PAIN	0	1 (3.7%)	1 (2.1%)
	FEVER	0	1 (3.7%)	1 (2.1%)
	TRAUMA	0	1 (3.7%)	1 (2.1%)
Nervous System	TOTAL	7 (35.0%)	9 (33.3%)	16 (34.0%)
	INSOMNIA	2 (10.0%)	4 (14.8%)	6 (12.8%)
	HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NEUROSIS	3 (15.0%)	0	3 (6.4%)
	ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	AGITATION	0	2 (7.4%)	2 (4.3%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
	ABNORMAL DREAMS	0	1 (3.7%)	1 (2.1%)
	DEPRESSION	0	1 (3.7%)	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	6 (30.0%)	8 (29.6%)	14 (29.8%)
	RESPIRATORY DISORDER	2 (10.0%)	5 (18.5%)	7 (14.9%)
	ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	SINUSITIS	2 (10.0%)	0	2 (4.3%)
	RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EPISTAXIS	0	1 (3.7%)	1 (2.1%)
	PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
	PNEUMONIA	0	1 (3.7%)	1 (2.1%)
Urogenital System	TOTAL	3 (15.0%)	0	3 (6.4%)
	ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
	DYSURIA	1 (5.0%)	0	1 (2.1%)
	HAEMATURIA	1 (5.0%)	0	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Digestive System	TOTAL	2 (10.0%)	10 (37.0%)	12 (25.5%)
	NAUSEA	0	5 (18.5%)	5 (10.6%)
	DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
	ULCERATIVE STOMATITIS	0	1 (3.7%)	1 (2.1%)
Musculoskeletal System	TOTAL	2 (10.0%)	1 (3.7%)	3 (6.4%)
	ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
Special Senses	TOTAL	2 (10.0%)	2 (7.4%)	4 (8.5%)
	BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
	EYE PAIN	1 (5.0%)	0	1 (2.1%)
	ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
	OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
Cardiovascular System	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	BRADYCARDIA	1 (5.0%)	0	1 (2.1%)
	SYNCOPE	0	1 (3.7%)	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	1 (5.0%)	4 (14.8%)	5 (10.6%)
	ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
	CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
	RASH	0	1 (3.7%)	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
	URTICARIA	0	1 (3.7%)	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	2 (7.4%)	2 (4.3%)
	EOSINOPHILIA	0	1 (3.7%)	1 (2.1%)
	LEUKOCYTOSIS	0	1 (3.7%)	1 (2.1%)
	MONOCYTOSIS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	0	2 (11.1%)
Urogenital System	TOTAL	2 (22.2%)	0	2 (11.1%)
	DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	32 (71.1%)	37 (64.9%)	69 (67.6%)
Body as a Whole	TOTAL	22 (48.9%)	20 (35.1%)	42 (41.2%)
	HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
	INFECTION	6 (13.3%)	5 (8.8%)	11 (10.8%)
	ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
	ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
	TRAUMA	4 (8.9%)	3 (5.3%)	7 (6.9%)
	ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
	BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
	PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
	FEVER	0	2 (3.5%)	2 (2.0%)
	ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
	CHEST PAIN	1 (2.2%)	0	1 (1.0%)
Nervous System	TOTAL	16 (35.6%)	20 (35.1%)	36 (35.3%)
	INSOMNIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
	SOMNOLENCE	4 (8.9%)	3 (5.3%)	7 (6.9%)
	EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
	NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
	HOSTILITY	2 (4.4%)	4 (7.0%)	6 (5.9%)
	DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
	NEUROSIS	3 (6.7%)	0	3 (2.9%)
	ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
	DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	WITHDRAWAL SYNDROME	0	2 (3.5%)	2 (2.0%)
	LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	VERTIGO	1 (2.2%)	0	1 (1.0%)
	ABNORMAL DREAMS	0	1 (1.8%)	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	12 (26.7%)	17 (29.8%)	29 (28.4%)
	RESPIRATORY DISORDER	6 (13.3%)	12 (21.1%)	18 (17.6%)
	ASTHMA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	SINUSITIS	3 (6.7%)	0	3 (2.9%)
	BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	PHARYNGITIS	0	2 (3.5%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Respiratory System	COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
	EPISTAXIS	0	1 (1.8%)	1 (1.0%)
	PNEUMONIA	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	8 (17.8%)	17 (29.8%)	25 (24.5%)
	NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
	DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	DIARRHEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
	VOMITING	2 (4.4%)	0	2 (2.0%)
	INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
	TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	GASTROINTESTINAL DISORDER	0	1 (1.8%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.8%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.9%)	4 (7.0%)	8 (7.8%)
	WEIGHT GAIN	3 (6.7%)	3 (5.3%)	6 (5.9%)
	WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
Urogenital System	TOTAL	4 (8.9%)	1 (1.8%)	5 (4.9%)
	ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
	HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	DYSURIA	1 (2.2%)	0	1 (1.0%)
Special Senses	TOTAL	3 (6.7%)	2 (3.5%)	5 (4.9%)
	OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
	EYE PAIN	1 (2.2%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	2 (4.4%)	2 (3.5%)	4 (3.9%)
	LEUKOPENIA	2 (4.4%)	0	2 (2.0%)
	EOSINOPHILIA	0	1 (1.8%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.8%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.8%)	1 (1.0%)
Musculoskeletal System	TOTAL	2 (4.4%)	2 (3.5%)	4 (3.9%)
	ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
	MYALGIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Cardiovascular System	TOTAL	1 (2.2%)	2 (3.5%)	3 (2.9%)
	SYNCOPE	0	2 (3.5%)	2 (2.0%)
	BRADYCARDIA	1 (2.2%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.2%)	6 (10.5%)	7 (6.9%)
	ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
	CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
	PRURITUS	0	1 (1.8%)	1 (1.0%)
	RASH	0	1 (1.8%)	1 (1.0%)
	SWEATING	0	1 (1.8%)	1 (1.0%)
	URTICARIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
Urogenital System	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
	DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	38 (76.0%)	44 (66.7%)	82 (70.7%)
Body as a Whole	TOTAL	21 (42.0%)	24 (36.4%)	45 (38.8%)
	HEADACHE	9 (18.0%)	10 (15.2%)	19 (16.4%)
	INFECTION	6 (12.0%)	11 (16.7%)	17 (14.7%)
	TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
	ABDOMINAL PAIN	5 (10.0%)	4 (6.1%)	9 (7.8%)
	FEVER	5 (10.0%)	3 (4.5%)	8 (6.9%)
	ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
	BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ASTHENIA	0	5 (7.6%)	5 (4.3%)
	PAIN	0	2 (3.0%)	2 (1.7%)
	CHEST PAIN	1 (2.0%)	0	1 (0.9%)
	FACE EDEMA	1 (2.0%)	0	1 (0.9%)
Nervous System	TOTAL	19 (38.0%)	23 (34.8%)	42 (36.2%)
	SOMNOLENCE	3 (6.0%)	4 (6.1%)	7 (6.0%)
	NERVOUSNESS	5 (10.0%)	1 (1.5%)	6 (5.2%)
	HOSTILITY	4 (8.0%)	2 (3.0%)	6 (5.2%)
	EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
	INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
	DEPRESSION	4 (8.0%)	1 (1.5%)	5 (4.3%)
	AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
	DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ANXIETY	0	2 (3.0%)	2 (1.7%)
	CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.7%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
	WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
	VERTIGO	1 (2.0%)	0	1 (0.9%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
	EUPHORIA	0	1 (1.5%)	1 (0.9%)
	HYSTERIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	19 (38.0%)	22 (33.3%)	41 (35.3%)
	RESPIRATORY DISORDER	13 (26.0%)	13 (19.7%)	26 (22.4%)
	PHARYNGITIS	4 (8.0%)	5 (7.6%)	9 (7.8%)
	RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Respiratory System	SINUSITIS	3 (6.0%)	1 (1.5%)	4 (3.4%)
	ASTHMA	1 (2.0%)	3 (4.5%)	4 (3.4%)
	BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
	COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EPISTAXIS	0	2 (3.0%)	2 (1.7%)
	PNEUMONIA	0	1 (1.5%)	1 (0.9%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	16 (32.0%)	19 (28.8%)	35 (30.2%)
	NAUSEA	6 (12.0%)	5 (7.6%)	11 (9.5%)
	VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
	DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
	DIARRHEA	3 (6.0%)	2 (3.0%)	5 (4.3%)
	DRY MOUTH	3 (6.0%)	0	3 (2.6%)
	INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	STOMATITIS	1 (2.0%)	0	1 (0.9%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	7 (14.0%)	7 (10.6%)	14 (12.1%)
	WEIGHT GAIN	6 (12.0%)	6 (9.1%)	12 (10.3%)
	WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
	DEHYDRATION	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	6 (12.0%)	6 (9.1%)	12 (10.3%)
	ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
	CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
	RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
	PRURITUS	0	2 (3.0%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	3 (6.0%)	2 (3.0%)	5 (4.3%)
	LEUKOPENIA	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ANEMIA	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Urogenital System	TOTAL	2 (4.0%)	4 (6.1%)	6 (5.2%)
	ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HAEMATURIA	0	2 (3.0%)	2 (1.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (2.0%)	2 (3.0%)	3 (2.6%)
	MYALGIA	0	2 (3.0%)	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
	ARTHROSIS	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	4 (6.1%)	4 (3.4%)
	SYNCOPE	0	2 (3.0%)	2 (1.7%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.9%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (6.9%)	2 (3.8%)
Urogenital System	TOTAL	0	2 (6.9%)	2 (3.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	33 (75.0%)	46 (75.4%)	79 (75.2%)
Body as a Whole	TOTAL	24 (54.5%)	27 (44.3%)	51 (48.6%)
	HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
	INFECTION	7 (15.9%)	5 (8.2%)	12 (11.4%)
	ABDOMINAL PAIN	3 (6.8%)	8 (13.1%)	11 (10.5%)
	TRAUMA	4 (9.1%)	4 (6.6%)	8 (7.6%)
	ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
	ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	FEVER	3 (6.8%)	2 (3.3%)	5 (4.8%)
	PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
	ABSCESS	1 (2.3%)	0	1 (1.0%)
Nervous System	TOTAL	14 (31.8%)	29 (47.5%)	43 (41.0%)
	NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
	HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
	INSOMNIA	4 (9.1%)	6 (9.8%)	10 (9.5%)
	HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
	ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
	NEUROSIS	4 (9.1%)	0	4 (3.8%)
	SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
	AGITATION	0	3 (4.9%)	3 (2.9%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	ABNORMAL DREAMS	0	1 (1.6%)	1 (1.0%)
	DEPRESSION	0	1 (1.6%)	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
	VERTIGO	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	11 (25.0%)	18 (29.5%)	29 (27.6%)
	RESPIRATORY DISORDER	3 (6.8%)	12 (19.7%)	15 (14.3%)
	RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
	SINUSITIS	5 (11.4%)	1 (1.6%)	6 (5.7%)
	PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)
	ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	COUGH INCREASED	2 (4.5%)	1 (1.6%)	3 (2.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Respiratory System	EPISTAXIS	0	1 (1.6%)	1 (1.0%)
	PNEUMONIA	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	9 (20.5%)	16 (26.2%)	25 (23.8%)
	NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DIARRHEA	3 (6.8%)	1 (1.6%)	4 (3.8%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	FLATULENCE	0	2 (3.3%)	2 (1.9%)
	TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
	GINGIVITIS	0	1 (1.6%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	6 (13.6%)	6 (9.8%)	12 (11.4%)
	OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	EAR PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
	EYE PAIN	1 (2.3%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	MYALGIA	1 (2.3%)	0	1 (1.0%)
Urogenital System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
	DYSURIA	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	1 (2.3%)	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	2 (4.5%)	4 (6.6%)	6 (5.7%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
	HAEMATOMA	1 (2.3%)	0	1 (1.0%)
	SYNCOPE	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	2 (4.5%)	7 (11.5%)	9 (8.6%)
	ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
	CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Skin and Appendages	RASH	0	3 (4.9%)	3 (2.9%)
	MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
	URTICARIA	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ANEMIA	1 (2.3%)	0	1 (1.0%)
	EOSINOPHILIA	0	1 (1.6%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
Urogenital System	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
	DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	71 (75.5%)	90 (70.9%)	161 (72.9%)
Body as a Whole	TOTAL	45 (47.9%)	51 (40.2%)	96 (43.4%)
	HEADACHE	24 (25.5%)	24 (18.9%)	48 (21.7%)
	INFECTION	13 (13.8%)	16 (12.6%)	29 (13.1%)
	TRAUMA	12 (12.8%)	10 (7.9%)	22 (10.0%)
	ABDOMINAL PAIN	8 (8.5%)	12 (9.4%)	20 (9.0%)
	FEVER	8 (8.5%)	5 (3.9%)	13 (5.9%)
	ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
	ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
	BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
	PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
	ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	CHEST PAIN	1 (1.1%)	0	1 (0.5%)
	FACE EDEMA	1 (1.1%)	0	1 (0.5%)
Nervous System	TOTAL	33 (35.1%)	52 (40.9%)	85 (38.5%)
	NERVOUSNESS	7 (7.4%)	13 (10.2%)	20 (9.0%)
	INSOMNIA	5 (5.3%)	11 (8.7%)	16 (7.2%)
	HOSTILITY	6 (6.4%)	9 (7.1%)	15 (6.8%)
	HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
	SOMNOLENCE	5 (5.3%)	5 (3.9%)	10 (4.5%)
	EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
	DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
	AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
	ANXIETY	2 (2.1%)	5 (3.9%)	7 (3.2%)
	DEPRESSION	4 (4.3%)	2 (1.6%)	6 (2.7%)
	NEUROSIS	4 (4.3%)	0	4 (1.8%)
	CONCENTRATION IMPAIRED	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	TREMOR	0	3 (2.4%)	3 (1.4%)
	LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
	HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
	WITHDRAWAL SYNDROME	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
	ABNORMAL DREAMS	0	1 (0.8%)	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	EUPHORIA	0	1 (0.8%)	1 (0.5%)
	HYSTERIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Nervous System	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	PARALYSIS	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	30 (31.9%)	40 (31.5%)	70 (31.7%)
	RESPIRATORY DISORDER	16 (17.0%)	25 (19.7%)	41 (18.6%)
	RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
	PHARYNGITIS	6 (6.4%)	9 (7.1%)	15 (6.8%)
	SINUSITIS	8 (8.5%)	2 (1.6%)	10 (4.5%)
	ASTHMA	3 (3.2%)	5 (3.9%)	8 (3.6%)
	COUGH INCREASED	3 (3.2%)	3 (2.4%)	6 (2.7%)
	BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EPISTAXIS	0	3 (2.4%)	3 (1.4%)
	PNEUMONIA	0	2 (1.6%)	2 (0.9%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	25 (26.6%)	35 (27.6%)	60 (27.1%)
	NAUSEA	10 (10.6%)	11 (8.7%)	21 (9.5%)
	DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
	VOMITING	6 (6.4%)	4 (3.1%)	10 (4.5%)
	DIARRHEA	6 (6.4%)	3 (2.4%)	9 (4.1%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
	TOOTH CARIES	0	4 (3.1%)	4 (1.8%)
	INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FLATULENCE	0	2 (1.6%)	2 (0.9%)
	GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
	STOMATITIS	1 (1.1%)	0	1 (0.5%)
	TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	GINGIVITIS	0	1 (0.8%)	1 (0.5%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.5%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	8 (8.5%)	9 (7.1%)	17 (7.7%)
	WEIGHT GAIN	7 (7.4%)	7 (5.5%)	14 (6.3%)
	WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEHYDRATION	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	8 (8.5%)	13 (10.2%)	21 (9.5%)
	ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
	CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Skin and Appendages	RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
	MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PRURITUS	0	2 (1.6%)	2 (0.9%)
	HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.5%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
	URTICARIA	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	8 (8.5%)	8 (6.3%)	16 (7.2%)
	OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
	OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	EAR PAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
	BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
	EYE PAIN	1 (1.1%)	0	1 (0.5%)
Urogenital System	TOTAL	5 (5.3%)	5 (3.9%)	10 (4.5%)
	ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
	HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DYSURIA	1 (1.1%)	0	1 (0.5%)
	CYSTITIS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	4 (4.3%)	4 (3.1%)	8 (3.6%)
	LEUKOPENIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.5%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.5%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	4 (4.3%)	3 (2.4%)	7 (3.2%)
	ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
	MYALGIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ARTHROSIS	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	2 (2.1%)	8 (6.3%)	10 (4.5%)
	SYNCOPE	0	3 (2.4%)	3 (1.4%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
	HAEMATOMA	1 (1.1%)	0	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.5%)

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Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Special Searches	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
Urogenital System	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
	DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	20 (80.0%)	25 (69.4%)	45 (73.8%)
RESPIRATORY DISORDER	9 (36.0%)	6 (16.7%)	15 (24.6%)
INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
HEADACHE	5 (20.0%)	4 (11.1%)	9 (14.8%)
PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
FEVER	5 (20.0%)	2 (5.6%)	7 (11.5%)
ABDOMINAL PAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
DEPRESSION	3 (12.0%)	1 (2.8%)	4 (6.6%)
HOSTILITY	3 (12.0%)	1 (2.8%)	4 (6.6%)
ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
NAUSEA	1 (4.0%)	3 (8.3%)	4 (6.6%)
NERVOUSNESS	3 (12.0%)	0	3 (4.9%)
CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
DIARRHEA	2 (8.0%)	1 (2.8%)	3 (4.9%)
SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
BACK PAIN	0	3 (8.3%)	3 (4.9%)
INSOMNIA	0	3 (8.3%)	3 (4.9%)
ACNE	2 (8.0%)	0	2 (3.3%)
DRY MOUTH	2 (8.0%)	0	2 (3.3%)
COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
ASTHENIA	0	2 (5.6%)	2 (3.3%)
EPISTAXIS	0	2 (5.6%)	2 (3.3%)
HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
CONSTIPATION	1 (4.0%)	0	1 (1.6%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
FACE EDEMA	1 (4.0%)	0	1 (1.6%)
HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
STOMATITIS	1 (4.0%)	0	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Preferred Term			
VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
ANEMIA	0	1 (2.8%)	1 (1.6%)
ANXIETY	0	1 (2.8%)	1 (1.6%)
ASTHMA	0	1 (2.8%)	1 (1.6%)
BRONCHITIS	0	1 (2.8%)	1 (1.6%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
HAEMATURIA	0	1 (2.8%)	1 (1.6%)
MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
MYALGIA	0	1 (2.8%)	1 (1.6%)
PAIN	0	1 (2.8%)	1 (1.6%)
PNEUMONIA	0	1 (2.8%)	1 (1.6%)
PRURITUS	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
SYNCOPE	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
TOTAL	19 (79.2%)	27 (79.4%)	46 (79.3%)
HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)
TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
ABDOMINAL PAIN	2 (8.3%)	5 (14.7%)	7 (12.1%)
RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
INFECTION	3 (12.5%)	2 (5.9%)	5 (8.6%)
PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
FEVER	3 (12.5%)	1 (2.9%)	4 (6.9%)
SINUSITIS	3 (12.5%)	1 (2.9%)	4 (6.9%)
DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
COUGH INCREASED	2 (8.3%)	1 (2.9%)	3 (5.2%)
DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
VASODILATATION	0	3 (8.8%)	3 (5.2%)
DIARRHEA	2 (8.3%)	0	2 (3.4%)
EAR PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
RASH	0	2 (5.9%)	2 (3.4%)
ABSCESS	1 (4.2%)	0	1 (1.7%)
ANEMIA	1 (4.2%)	0	1 (1.7%)
ASTHMA	1 (4.2%)	0	1 (1.7%)
BACK PAIN	1 (4.2%)	0	1 (1.7%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
HAEMATOMA	1 (4.2%)	0	1 (1.7%)
MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
MYALGIA	1 (4.2%)	0	1 (1.7%)
NEUROSIS	1 (4.2%)	0	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
FLATULENCE	0	1 (2.9%)	1 (1.7%)
GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
MANIC REACTION	0	1 (2.9%)	1 (1.7%)
TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
TREMOR	0	1 (2.9%)	1 (1.7%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)
VERTIGO	0	1 (2.9%)	1 (1.7%)
WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	39 (79.6%)	52 (74.3%)	91 (76.5%)
HEADACHE	13 (26.5%)	10 (14.3%)	23 (19.3%)
RESPIRATORY DISORDER	10 (20.4%)	13 (18.6%)	23 (19.3%)
INFECTION	7 (14.3%)	11 (15.7%)	18 (15.1%)
TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
ABDOMINAL PAIN	6 (12.2%)	8 (11.4%)	14 (11.8%)
PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
NERVOUSNESS	4 (8.2%)	9 (12.9%)	13 (10.9%)
FEVER	8 (16.3%)	3 (4.3%)	11 (9.2%)
HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
NAUSEA	5 (10.2%)	4 (5.7%)	9 (7.6%)
HOSTILITY	4 (8.2%)	5 (7.1%)	9 (7.6%)
VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)
SINUSITIS	5 (10.2%)	2 (2.9%)	7 (5.9%)
INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
DIARRHEA	4 (8.2%)	1 (1.4%)	5 (4.2%)
COUGH INCREASED	3 (6.1%)	2 (2.9%)	5 (4.2%)
ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
DEPRESSION	3 (6.1%)	1 (1.4%)	4 (3.4%)
AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
VASODILATATION	0	3 (4.3%)	3 (2.5%)
ACNE	2 (4.1%)	0	2 (1.7%)
DRY MOUTH	2 (4.1%)	0	2 (1.7%)
ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
CONCENTRATION IMPAIRED	1 (2.0%)	1 (1.4%)	2 (1.7%)
EAR PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHENIA	0	2 (2.9%)	2 (1.7%)
EPISTAXIS	0	2 (2.9%)	2 (1.7%)
GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
TREMOR	0	2 (2.9%)	2 (1.7%)
ABSCESS	1 (2.0%)	0	1 (0.8%)
ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
CONSTIPATION	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
FACE EDEMA	1 (2.0%)	0	1 (0.8%)
HAEMATOMA	1 (2.0%)	0	1 (0.8%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
NEUROSIS	1 (2.0%)	0	1 (0.8%)
STOMATITIS	1 (2.0%)	0	1 (0.8%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
BRONCHITIS	0	1 (1.4%)	1 (0.8%)
FLATULENCE	0	1 (1.4%)	1 (0.8%)
HAEMATURIA	0	1 (1.4%)	1 (0.8%)
LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
MANIC REACTION	0	1 (1.4%)	1 (0.8%)
PNEUMONIA	0	1 (1.4%)	1 (0.8%)
PRURITUS	0	1 (1.4%)	1 (0.8%)
SYNCOPE	0	1 (1.4%)	1 (0.8%)
VERTIGO	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Preferred Term			
TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
TOTAL	18 (72.0%)	18 (60.0%)	36 (65.5%)
RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)
HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
SOMNOLENCE	3 (12.0%)	3 (10.0%)	6 (10.9%)
EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
WEIGHT GAIN	2 (8.0%)	3 (10.0%)	5 (9.1%)
INFECTION	2 (8.0%)	2 (6.7%)	4 (7.3%)
DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
ASTHMA	1 (4.0%)	2 (6.7%)	3 (5.5%)
BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
ASTHENIA	0	3 (10.0%)	3 (5.5%)
ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
BACK PAIN	2 (8.0%)	0	2 (3.6%)
LEUKOPENIA	2 (8.0%)	0	2 (3.6%)
VOMITING	2 (8.0%)	0	2 (3.6%)
ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIARRHEA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
HOSTILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (3.6%)
CHEST PAIN	1 (4.0%)	0	1 (1.8%)
DEPRESSION	1 (4.0%)	0	1 (1.8%)
DRY MOUTH	1 (4.0%)	0	1 (1.8%)
LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
SINUSITIS	1 (4.0%)	0	1 (1.8%)
VERTIGO	1 (4.0%)	0	1 (1.8%)
WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
ACNE	0	1 (3.3%)	1 (1.8%)
ANXIETY	0	1 (3.3%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
FEVER	0	1 (3.3%)	1 (1.8%)
HAEMATURIA	0	1 (3.3%)	1 (1.8%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
MYALGIA	0	1 (3.3%)	1 (1.8%)
PAIN	0	1 (3.3%)	1 (1.8%)
PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
PRURITUS	0	1 (3.3%)	1 (1.8%)
SYNCOPE	0	1 (3.3%)	1 (1.8%)
TOOTH CARIES	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
TOTAL	14 (70.0%)	18 (66.7%)	32 (68.1%)
HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
RESPIRATORY DISORDER	2 (10.0%)	5 (18.5%)	7 (14.9%)
ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
INSOMNIA	2 (10.0%)	4 (14.8%)	6 (12.8%)
NAUSEA	0	5 (18.5%)	5 (10.6%)
ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
NEUROSIS	3 (15.0%)	0	3 (6.4%)
ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
SINUSITIS	2 (10.0%)	0	2 (4.3%)
ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
AGITATION	0	2 (7.4%)	2 (4.3%)
DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
DRY MOUTH	0	2 (7.4%)	2 (4.3%)
DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
BRADYCARDIA	1 (5.0%)	0	1 (2.1%)
DYSURIA	1 (5.0%)	0	1 (2.1%)
EYE PAIN	1 (5.0%)	0	1 (2.1%)
HAEMATURIA	1 (5.0%)	0	1 (2.1%)
MANIC REACTION	1 (5.0%)	0	1 (2.1%)
PAIN	1 (5.0%)	0	1 (2.1%)
SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
BACK PAIN	0	1 (3.7%)	1 (2.1%)
CONSTIPATION	0	1 (3.7%)	1 (2.1%)
CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
DEPRESSION	0	1 (3.7%)	1 (2.1%)
EPISTAXIS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Preferred Term			
FEVER	0	1 (3.7%)	1 (2.1%)
FLATULENCE	0	1 (3.7%)	1 (2.1%)
OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
PNEUMONIA	0	1 (3.7%)	1 (2.1%)
RASH	0	1 (3.7%)	1 (2.1%)
SYNCOPE	0	1 (3.7%)	1 (2.1%)
TRAUMA	0	1 (3.7%)	1 (2.1%)
TREMOR	0	1 (3.7%)	1 (2.1%)
WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	2 (22.2%)	0	2 (11.1%)
DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	32 (71.1%)	36 (63.2%)	68 (66.7%)
HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
RESPIRATORY DISORDER	6 (13.3%)	12 (21.1%)	18 (17.6%)
NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
INFECTION	6 (13.3%)	5 (8.8%)	11 (10.8%)
ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
INSOMNIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
SOMNOLENCE	4 (8.9%)	3 (5.3%)	7 (6.9%)
TRAUMA	4 (8.9%)	3 (5.3%)	7 (6.9%)
EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
WEIGHT GAIN	3 (6.7%)	3 (5.3%)	6 (5.9%)
ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
ASTHMA	2 (4.4%)	4 (7.0%)	6 (5.9%)
HOSTILITY	2 (4.4%)	4 (7.0%)	6 (5.9%)
DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
DIARRHEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
NEUROSIS	3 (6.7%)	0	3 (2.9%)
SINUSITIS	3 (6.7%)	0	3 (2.9%)
ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
LEUKOPENIA	2 (4.4%)	0	2 (2.0%)
VOMITING	2 (4.4%)	0	2 (2.0%)
DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
FEVER	0	2 (3.5%)	2 (2.0%)
INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
PHARYNGITIS	0	2 (3.5%)	2 (2.0%)
SYNCOPE	0	2 (3.5%)	2 (2.0%)
WITHDRAWAL SYNDROME	0	2 (3.5%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
BRADYCARDIA	1 (2.2%)	0	1 (1.0%)
CHEST PAIN	1 (2.2%)	0	1 (1.0%)
DYSURIA	1 (2.2%)	0	1 (1.0%)
EYE PAIN	1 (2.2%)	0	1 (1.0%)
LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
MANIC REACTION	1 (2.2%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
VERTIGO	1 (2.2%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
CONSTIPATION	0	1 (1.8%)	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
EPISTAXIS	0	1 (1.8%)	1 (1.0%)
FLATULENCE	0	1 (1.8%)	1 (1.0%)
HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
MYALGIA	0	1 (1.8%)	1 (1.0%)
PNEUMONIA	0	1 (1.8%)	1 (1.0%)
PRURITUS	0	1 (1.8%)	1 (1.0%)
RASH	0	1 (1.8%)	1 (1.0%)
TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
TREMOR	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Preferred Term			
TOTAL	2 (11.1%)	0	2 (4.8%)
DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	38 (76.0%)	43 (65.2%)	81 (69.8%)
RESPIRATORY DISORDER	13 (26.0%)	13 (19.7%)	26 (22.4%)
HEADACHE	9 (18.0%)	10 (15.2%)	19 (16.4%)
INFECTION	6 (12.0%)	11 (16.7%)	17 (14.7%)
TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
WEIGHT GAIN	6 (12.0%)	6 (9.1%)	12 (10.3%)
NAUSEA	6 (12.0%)	5 (7.6%)	11 (9.5%)
VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
ABDOMINAL PAIN	5 (10.0%)	4 (6.1%)	9 (7.8%)
DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
PHARYNGITIS	4 (8.0%)	5 (7.6%)	9 (7.8%)
FEVER	5 (10.0%)	3 (4.5%)	8 (6.9%)
RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
SOMNOLENCE	3 (6.0%)	4 (6.1%)	7 (6.0%)
NERVOUSNESS	5 (10.0%)	1 (1.5%)	6 (5.2%)
ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
HOSTILITY	4 (8.0%)	2 (3.0%)	6 (5.2%)
EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
DEPRESSION	4 (8.0%)	1 (1.5%)	5 (4.3%)
DIARRHEA	3 (6.0%)	2 (3.0%)	5 (4.3%)
LEUKOPENIA	3 (6.0%)	2 (3.0%)	5 (4.3%)
AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
ASTHENIA	0	5 (7.6%)	5 (4.3%)
SINUSITIS	3 (6.0%)	1 (1.5%)	4 (3.4%)
ASTHMA	1 (2.0%)	3 (4.5%)	4 (3.4%)
BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
DRY MOUTH	3 (6.0%)	0	3 (2.6%)
ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)
DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
ANXIETY	0	2 (3.0%)	2 (1.7%)
CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
EPISTAXIS	0	2 (3.0%)	2 (1.7%)
HAEMATURIA	0	2 (3.0%)	2 (1.7%)
HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
MYALGIA	0	2 (3.0%)	2 (1.7%)
PAIN	0	2 (3.0%)	2 (1.7%)
PRURITUS	0	2 (3.0%)	2 (1.7%)
SYNCOPE	0	2 (3.0%)	2 (1.7%)
WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.7%)
ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
CHEST PAIN	1 (2.0%)	0	1 (0.9%)
CONSTIPATION	1 (2.0%)	0	1 (0.9%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
FACE EDEMA	1 (2.0%)	0	1 (0.9%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
STOMATITIS	1 (2.0%)	0	1 (0.9%)
VERTIGO	1 (2.0%)	0	1 (0.9%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
ANEMIA	0	1 (1.5%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
PNEUMONIA	0	1 (1.5%)	1 (0.9%)
TREMOR	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	33 (75.0%)	45 (73.8%)	78 (74.3%)
HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
RESPIRATORY DISORDER	3 (6.8%)	12 (19.7%)	15 (14.3%)
NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
INFECTION	7 (15.9%)	5 (8.2%)	12 (11.4%)
HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
ABDOMINAL PAIN	3 (6.8%)	8 (13.1%)	11 (10.5%)
INSOMNIA	4 (9.1%)	6 (9.8%)	10 (9.5%)
NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
TRAUMA	4 (9.1%)	4 (6.6%)	8 (7.6%)
ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
SINUSITIS	5 (11.4%)	1 (1.6%)	6 (5.7%)
ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)
FEVER	3 (6.8%)	2 (3.3%)	5 (4.8%)
ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
NEUROSIS	4 (9.1%)	0	4 (3.8%)
DIARRHEA	3 (6.8%)	1 (1.6%)	4 (3.8%)
ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
COUGH INCREASED	2 (4.5%)	1 (1.6%)	3 (2.9%)
OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
AGITATION	0	3 (4.9%)	3 (2.9%)
CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)
RASH	0	3 (4.9%)	3 (2.9%)
VASODILATATION	0	3 (4.9%)	3 (2.9%)
ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
EAR PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
DRY MOUTH	0	2 (3.3%)	2 (1.9%)
FLATULENCE	0	2 (3.3%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TREMOR	0	2 (3.3%)	2 (1.9%)
ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
ABSCESS	1 (2.3%)	0	1 (1.0%)
ANEMIA	1 (2.3%)	0	1 (1.0%)
BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
DYSURIA	1 (2.3%)	0	1 (1.0%)
EYE PAIN	1 (2.3%)	0	1 (1.0%)
HAEMATOMA	1 (2.3%)	0	1 (1.0%)
HAEMATURIA	1 (2.3%)	0	1 (1.0%)
MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
MYALGIA	1 (2.3%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
CONSTIPATION	0	1 (1.6%)	1 (1.0%)
DEPRESSION	0	1 (1.6%)	1 (1.0%)
EPISTAXIS	0	1 (1.6%)	1 (1.0%)
GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
PNEUMONIA	0	1 (1.6%)	1 (1.0%)
SYNCOPE	0	1 (1.6%)	1 (1.0%)
TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
VERTIGO	0	1 (1.6%)	1 (1.0%)
WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	71 (75.5%)	88 (69.3%)	159 (71.9%)
HEADACHE	24 (25.5%)	24 (18.9%)	48 (21.7%)
RESPIRATORY DISORDER	16 (17.0%)	25 (19.7%)	41 (18.6%)
INFECTION	13 (13.8%)	16 (12.6%)	29 (13.1%)
TRAUMA	12 (12.8%)	10 (7.9%)	22 (10.0%)
NAUSEA	10 (10.6%)	11 (8.7%)	21 (9.5%)
ABDOMINAL PAIN	8 (8.5%)	12 (9.4%)	20 (9.0%)
NERVOUSNESS	7 (7.4%)	13 (10.2%)	20 (9.0%)
INSOMNIA	5 (5.3%)	11 (8.7%)	16 (7.2%)
RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
HOSTILITY	6 (6.4%)	9 (7.1%)	15 (6.8%)
PHARYNGITIS	6 (6.4%)	9 (7.1%)	15 (6.8%)
DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
WEIGHT GAIN	7 (7.4%)	7 (5.5%)	14 (6.3%)
FEVER	8 (8.5%)	5 (3.9%)	13 (5.9%)
ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
SINUSITIS	8 (8.5%)	2 (1.6%)	10 (4.5%)
VOMITING	6 (6.4%)	4 (3.1%)	10 (4.5%)
SOMNOLENCE	5 (5.3%)	5 (3.9%)	10 (4.5%)
DIARRHEA	6 (6.4%)	3 (2.4%)	9 (4.1%)
DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
ASTHMA	3 (3.2%)	5 (3.9%)	8 (3.6%)
DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
ANXIETY	2 (2.1%)	5 (3.9%)	7 (3.2%)
DEPRESSION	4 (4.3%)	2 (1.6%)	6 (2.7%)
ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
COUGH INCREASED	3 (3.2%)	3 (2.4%)	6 (2.7%)
CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)
RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
LEUKOPENIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
NEUROSIS	4 (4.3%)	0	4 (1.8%)
ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
TOOTH CARIES	0	4 (3.1%)	4 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
CONCENTRATION IMPAIRED	1 (1.1%)	2 (1.6%)	3 (1.4%)
HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
MYALGIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
EPISTAXIS	0	3 (2.4%)	3 (1.4%)
SYNCOPE	0	3 (2.4%)	3 (1.4%)
TREMOR	0	3 (2.4%)	3 (1.4%)
VASODILATATION	0	3 (2.4%)	3 (1.4%)
ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
EAR PAIN	1 (1.1%)	1 (0.8%)	2 (0.9%)
LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
FLATULENCE	0	2 (1.6%)	2 (0.9%)
GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
PNEUMONIA	0	2 (1.6%)	2 (0.9%)
PRURITUS	0	2 (1.6%)	2 (0.9%)
WITHDRAWAL SYNDROME	0	2 (1.6%)	2 (0.9%)
ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
ABSCESS	1 (1.1%)	0	1 (0.5%)
BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
CHEST PAIN	1 (1.1%)	0	1 (0.5%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
DYSURIA	1 (1.1%)	0	1 (0.5%)
EYE PAIN	1 (1.1%)	0	1 (0.5%)
FACE EDEMA	1 (1.1%)	0	1 (0.5%)
HAEMATOMA	1 (1.1%)	0	1 (0.5%)
HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
STOMATITIS	1 (1.1%)	0	1 (0.5%)
TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Preferred Term			
TOTAL	3 (6.7%)	1 (2.0%)	4 (4.2%)
DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=18)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	5 (33.3%)	5 (27.8%)	10 (30.3%)
Body as a Whole	TOTAL	3 (20.0%)	1 (5.6%)	4 (12.1%)
	ABDOMINAL PAIN	3 (20.0%)	0	3 (9.1%)
	HEADACHE	2 (13.3%)	0	2 (6.1%)
	ALLERGIC REACTION	0	1 (5.6%)	1 (3.0%)
Nervous System	TOTAL	3 (20.0%)	2 (11.1%)	5 (15.2%)
	ANXIETY	1 (6.7%)	0	1 (3.0%)
	DEPRESSION	1 (6.7%)	0	1 (3.0%)
	INSOMNIA	1 (6.7%)	0	1 (3.0%)
	NERVOUSNESS	1 (6.7%)	0	1 (3.0%)
	WITHDRAWAL SYNDROME	1 (6.7%)	0	1 (3.0%)
	CONCENTRATION IMPAIRED	0	1 (5.6%)	1 (3.0%)
	HOSTILITY	0	1 (5.6%)	1 (3.0%)
Digestive System	TOTAL	1 (6.7%)	2 (11.1%)	3 (9.1%)
	NAUSEA	1 (6.7%)	1 (5.6%)	2 (6.1%)
	INCREASED APPETITE	1 (6.7%)	0	1 (3.0%)
	DIARRHEA	0	1 (5.6%)	1 (3.0%)
	FECAL INCONTINENCE	0	1 (5.6%)	1 (3.0%)
Musculoskeletal System	TOTAL	1 (6.7%)	0	1 (3.0%)
	MYALGIA	1 (6.7%)	0	1 (3.0%)
Respiratory System	TOTAL	1 (6.7%)	2 (11.1%)	3 (9.1%)
	RESPIRATORY DISORDER	1 (6.7%)	2 (11.1%)	3 (9.1%)
Hemic and Lymphatic System	TOTAL	0	1 (5.6%)	1 (3.0%)
	LYMPHOCYTOSIS	0	1 (5.6%)	1 (3.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.6%)	1 (3.0%)
	SGOT INCREASED	0	1 (5.6%)	1 (3.0%)
Urogenital System	TOTAL	0	1 (5.6%)	1 (3.0%)
	URINARY INCONTINENCE	0	1 (5.6%)	1 (3.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=10)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=15)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	3 (42.9%)	4 (26.7%)	7 (31.8%)
Body as a Whole	TOTAL	3 (42.9%)	2 (13.3%)	5 (22.7%)
	HEADACHE	1 (14.3%)	1 (6.7%)	2 (9.1%)
	FEVER	1 (14.3%)	0	1 (4.5%)
	PAIN	1 (14.3%)	0	1 (4.5%)
	INFECTION	0	1 (6.7%)	1 (4.5%)
Special Senses	TOTAL	1 (14.3%)	0	1 (4.5%)
	EAR PAIN	1 (14.3%)	0	1 (4.5%)
Respiratory System	TOTAL	0	1 (6.7%)	1 (4.5%)
	COUGH INCREASED	0	1 (6.7%)	1 (4.5%)
Skin and Appendages	TOTAL	0	1 (6.7%)	1 (4.5%)
	FUNGAL DERMATITIS	0	1 (6.7%)	1 (4.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=12)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=33)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	8 (36.4%)	9 (27.3%)	17 (30.9%)
Body as a Whole	TOTAL	6 (27.3%)	3 (9.1%)	9 (16.4%)
	HEADACHE	3 (13.6%)	1 (3.0%)	4 (7.3%)
	ABDOMINAL PAIN	3 (13.6%)	0	3 (5.5%)
	FEVER	1 (4.5%)	0	1 (1.8%)
	PAIN	1 (4.5%)	0	1 (1.8%)
	ALLERGIC REACTION	0	1 (3.0%)	1 (1.8%)
	INFECTION	0	1 (3.0%)	1 (1.8%)
Nervous System	TOTAL	3 (13.6%)	2 (6.1%)	5 (9.1%)
	ANXIETY	1 (4.5%)	0	1 (1.8%)
	DEPRESSION	1 (4.5%)	0	1 (1.8%)
	INSOMNIA	1 (4.5%)	0	1 (1.8%)
	NERVOUSNESS	1 (4.5%)	0	1 (1.8%)
	WITHDRAWAL SYNDROME	1 (4.5%)	0	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.0%)	1 (1.8%)
	HOSTILITY	0	1 (3.0%)	1 (1.8%)
Digestive System	TOTAL	1 (4.5%)	2 (6.1%)	3 (5.5%)
	NAUSEA	1 (4.5%)	1 (3.0%)	2 (3.6%)
	INCREASED APPETITE	1 (4.5%)	0	1 (1.8%)
	DIARRHEA	0	1 (3.0%)	1 (1.8%)
	FECAL INCONTINENCE	0	1 (3.0%)	1 (1.8%)
Musculoskeletal System	TOTAL	1 (4.5%)	0	1 (1.8%)
	MYALGIA	1 (4.5%)	0	1 (1.8%)
Respiratory System	TOTAL	1 (4.5%)	3 (9.1%)	4 (7.3%)
	RESPIRATORY DISORDER	1 (4.5%)	2 (6.1%)	3 (5.5%)
	COUGH INCREASED	0	1 (3.0%)	1 (1.8%)
Special Senses	TOTAL	1 (4.5%)	0	1 (1.8%)
	EAR PAIN	1 (4.5%)	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	0	1 (3.0%)	1 (1.8%)
	LYMPHOCYTOSIS	0	1 (3.0%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (3.0%)	1 (1.8%)
	SGOT INCREASED	0	1 (3.0%)	1 (1.8%)
Skin and Appendages	TOTAL	0	1 (3.0%)	1 (1.8%)
	FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=33)	Total (N=55)
Body System	Preferred Term			
Urogenital System	TOTAL	0	1 (3.0%)	1 (1.8%)
	URINARY INCONTINENCE	0	1 (3.0%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=11)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=16)	Total (N=34)
Body System	Preferred Term			
TOTAL	TOTAL	4 (22.2%)	2 (12.5%)	6 (17.6%)
Respiratory System	TOTAL	3 (16.7%)	1 (6.3%)	4 (11.8%)
	ASTHMA	1 (5.6%)	0	1 (2.9%)
	PHARYNGITIS	1 (5.6%)	0	1 (2.9%)
	SINUSITIS	1 (5.6%)	0	1 (2.9%)
	RESPIRATORY DISORDER	0	1 (6.3%)	1 (2.9%)
Digestive System	TOTAL	1 (5.6%)	0	1 (2.9%)
	DIARRHEA	1 (5.6%)	0	1 (2.9%)
Body as a Whole	TOTAL	0	1 (6.3%)	1 (2.9%)
	INFECTION	0	1 (6.3%)	1 (2.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=8)	Total (N=19)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=10)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	3 (60.0%)	2 (20.0%)	5 (33.3%)
Respiratory System	TOTAL	2 (40.0%)	0	2 (13.3%)
	RESPIRATORY DISORDER	1 (20.0%)	0	1 (6.7%)
	SINUSITIS	1 (20.0%)	0	1 (6.7%)
Nervous System	TOTAL	1 (20.0%)	0	1 (6.7%)
	PARESTHESIA	1 (20.0%)	0	1 (6.7%)
	THINKING ABNORMAL	1 (20.0%)	0	1 (6.7%)
Body as a Whole	TOTAL	0	1 (10.0%)	1 (6.7%)
	TRAUMA	0	1 (10.0%)	1 (6.7%)
Digestive System	TOTAL	0	1 (10.0%)	1 (6.7%)
	DIARRHEA	0	1 (10.0%)	1 (6.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (10.0%)	1 (6.7%)
	NAUSEA	0	1 (10.0%)	1 (6.7%)
	VOMITING	0	1 (10.0%)	1 (6.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=26)	Total (N=49)
Body System	Preferred Term			
TOTAL	TOTAL	7 (30.4%)	4 (15.4%)	11 (22.4%)
Respiratory System	TOTAL	5 (21.7%)	1 (3.8%)	6 (12.2%)
	SINUSITIS	2 (8.7%)	0	2 (4.1%)
	RESPIRATORY DISORDER	1 (4.3%)	1 (3.8%)	2 (4.1%)
	ASTHMA	1 (4.3%)	0	1 (2.0%)
	PHARYNGITIS	1 (4.3%)	0	1 (2.0%)
Digestive System	TOTAL	1 (4.3%)	1 (3.8%)	2 (4.1%)
	DIARRHEA	1 (4.3%)	1 (3.8%)	2 (4.1%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.8%)	1 (2.0%)
	NAUSEA	0	1 (3.8%)	1 (2.0%)
	VOMITING	0	1 (3.8%)	1 (2.0%)
Nervous System	TOTAL	1 (4.3%)	0	1 (2.0%)
	PARESTHESIA	1 (4.3%)	0	1 (2.0%)
	THINKING ABNORMAL	1 (4.3%)	0	1 (2.0%)
Body as a Whole	TOTAL	0	2 (7.7%)	2 (4.1%)
	INFECTION	0	1 (3.8%)	1 (2.0%)
	TRAUMA	0	1 (3.8%)	1 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	9 (27.3%)	7 (20.6%)	16 (23.9%)
Respiratory System	TOTAL	4 (12.1%)	3 (8.8%)	7 (10.4%)
	RESPIRATORY DISORDER	1 (3.0%)	3 (8.8%)	4 (6.0%)
	ASTHMA	1 (3.0%)	0	1 (1.5%)
	PHARYNGITIS	1 (3.0%)	0	1 (1.5%)
	SINUSITIS	1 (3.0%)	0	1 (1.5%)
Body as a Whole	TOTAL	3 (9.1%)	2 (5.9%)	5 (7.5%)
	ABDOMINAL PAIN	3 (9.1%)	0	3 (4.5%)
	HEADACHE	2 (6.1%)	0	2 (3.0%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.5%)
	INFECTION	0	1 (2.9%)	1 (1.5%)
Nervous System	TOTAL	3 (9.1%)	2 (5.9%)	5 (7.5%)
	ANXIETY	1 (3.0%)	0	1 (1.5%)
	DEPRESSION	1 (3.0%)	0	1 (1.5%)
	INSOMNIA	1 (3.0%)	0	1 (1.5%)
	NERVOUSNESS	1 (3.0%)	0	1 (1.5%)
	WITHDRAWAL SYNDROME	1 (3.0%)	0	1 (1.5%)
	CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.5%)
	HOSTILITY	0	1 (2.9%)	1 (1.5%)
Digestive System	TOTAL	2 (6.1%)	2 (5.9%)	4 (6.0%)
	DIARRHEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
	NAUSEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
	INCREASED APPETITE	1 (3.0%)	0	1 (1.5%)
	FECAL INCONTINENCE	0	1 (2.9%)	1 (1.5%)
Musculoskeletal System	TOTAL	1 (3.0%)	0	1 (1.5%)
	MYALGIA	1 (3.0%)	0	1 (1.5%)
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.5%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.5%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.5%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.5%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	6 (50.0%)	6 (24.0%)	12 (32.4%)
Body as a Whole	TOTAL	3 (25.0%)	3 (12.0%)	6 (16.2%)
	HEADACHE	1 (8.3%)	1 (4.0%)	2 (5.4%)
	FEVER	1 (8.3%)	0	1 (2.7%)
	PAIN	1 (8.3%)	0	1 (2.7%)
	INFECTION	0	1 (4.0%)	1 (2.7%)
	TRAUMA	0	1 (4.0%)	1 (2.7%)
Respiratory System	TOTAL	2 (16.7%)	1 (4.0%)	3 (8.1%)
	RESPIRATORY DISORDER	1 (8.3%)	0	1 (2.7%)
	SINUSITIS	1 (8.3%)	0	1 (2.7%)
	COUGH INCREASED	0	1 (4.0%)	1 (2.7%)
Nervous System	TOTAL	1 (8.3%)	0	1 (2.7%)
	PARESTHESIA	1 (8.3%)	0	1 (2.7%)
	THINKING ABNORMAL	1 (8.3%)	0	1 (2.7%)
Special Senses	TOTAL	1 (8.3%)	0	1 (2.7%)
	EAR PAIN	1 (8.3%)	0	1 (2.7%)
Digestive System	TOTAL	0	1 (4.0%)	1 (2.7%)
	DIARRHEA	0	1 (4.0%)	1 (2.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (4.0%)	1 (2.7%)
	NAUSEA	0	1 (4.0%)	1 (2.7%)
	VOMITING	0	1 (4.0%)	1 (2.7%)
Skin and Appendages	TOTAL	0	1 (4.0%)	1 (2.7%)
	FUNGAL DERMATITIS	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
TOTAL	TOTAL	15 (33.3%)	13 (22.0%)	28 (26.9%)
Body as a Whole	TOTAL	6 (13.3%)	5 (8.5%)	11 (10.6%)
	HEADACHE	3 (6.7%)	1 (1.7%)	4 (3.8%)
	ABDOMINAL PAIN	3 (6.7%)	0	3 (2.9%)
	INFECTION	0	2 (3.4%)	2 (1.9%)
	FEVER	1 (2.2%)	0	1 (1.0%)
	PAIN	1 (2.2%)	0	1 (1.0%)
	ALLERGIC REACTION	0	1 (1.7%)	1 (1.0%)
	TRAUMA	0	1 (1.7%)	1 (1.0%)
Respiratory System	TOTAL	6 (13.3%)	4 (6.8%)	10 (9.6%)
	RESPIRATORY DISORDER	2 (4.4%)	3 (5.1%)	5 (4.8%)
	SINUSITIS	2 (4.4%)	0	2 (1.9%)
	ASTHMA	1 (2.2%)	0	1 (1.0%)
	PHARYNGITIS	1 (2.2%)	0	1 (1.0%)
	COUGH INCREASED	0	1 (1.7%)	1 (1.0%)
Nervous System	TOTAL	4 (8.9%)	2 (3.4%)	6 (5.8%)
	ANXIETY	1 (2.2%)	0	1 (1.0%)
	DEPRESSION	1 (2.2%)	0	1 (1.0%)
	INSOMNIA	1 (2.2%)	0	1 (1.0%)
	NERVOUSNESS	1 (2.2%)	0	1 (1.0%)
	PARESTHESIA	1 (2.2%)	0	1 (1.0%)
	THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
	WITHDRAWAL SYNDROME	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (1.0%)
	HOSTILITY	0	1 (1.7%)	1 (1.0%)
Digestive System	TOTAL	2 (4.4%)	3 (5.1%)	5 (4.8%)
	DIARRHEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
	NAUSEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
	INCREASED APPETITE	1 (2.2%)	0	1 (1.0%)
	FECAL INCONTINENCE	0	1 (1.7%)	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (1.0%)
	VOMITING	0	1 (1.7%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.2%)	0	1 (1.0%)
	MYALGIA	1 (2.2%)	0	1 (1.0%)
Special Senses	TOTAL	1 (2.2%)	0	1 (1.0%)
	EAR PAIN	1 (2.2%)	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
Hemic and Lymphatic System	LYMPHOCYTOSIS	0	1 (1.7%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.7%)	1 (1.0%)
	SGOT INCREASED	0	1 (1.7%)	1 (1.0%)
Skin and Appendages	TOTAL	0	1 (1.7%)	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.7%)	1 (1.0%)
Urogenital System	TOTAL	0	1 (1.7%)	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=15)	Placebo (N=18)	Total (N=33)
TOTAL	5 (33.3%)	5 (27.8%)	10 (30.3%)
ABDOMINAL PAIN	3 (20.0%)	0	3 (9.1%)
RESPIRATORY DISORDER	1 (6.7%)	2 (11.1%)	3 (9.1%)
HEADACHE	2 (13.3%)	0	2 (6.1%)
NAUSEA	1 (6.7%)	1 (5.6%)	2 (6.1%)
ANXIETY	1 (6.7%)	0	1 (3.0%)
DEPRESSION	1 (6.7%)	0	1 (3.0%)
INCREASED APPETITE	1 (6.7%)	0	1 (3.0%)
INSOMNIA	1 (6.7%)	0	1 (3.0%)
MYALGIA	1 (6.7%)	0	1 (3.0%)
NERVOUSNESS	1 (6.7%)	0	1 (3.0%)
WITHDRAWAL SYNDROME	1 (6.7%)	0	1 (3.0%)
ALLERGIC REACTION	0	1 (5.6%)	1 (3.0%)
CONCENTRATION IMPAIRED	0	1 (5.6%)	1 (3.0%)
DIARRHEA	0	1 (5.6%)	1 (3.0%)
FECAL INCONTINENCE	0	1 (5.6%)	1 (3.0%)
HOSTILITY	0	1 (5.6%)	1 (3.0%)
LYMPHOCYTOSIS	0	1 (5.6%)	1 (3.0%)
SGOT INCREASED	0	1 (5.6%)	1 (3.0%)
URINARY INCONTINENCE	0	1 (5.6%)	1 (3.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=10)	Total (N=18)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=15)	Total (N=22)
TOTAL	3 (42.9%)	4 (26.7%)	7 (31.8%)
HEADACHE	1 (14.3%)	1 (6.7%)	2 (9.1%)
EAR PAIN	1 (14.3%)	0	1 (4.5%)
FEVER	1 (14.3%)	0	1 (4.5%)
PAIN	1 (14.3%)	0	1 (4.5%)
COUGH INCREASED	0	1 (6.7%)	1 (4.5%)
FUNGAL DERMATITIS	0	1 (6.7%)	1 (4.5%)
INFECTION	0	1 (6.7%)	1 (4.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=12)	Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=33)	Total (N=55)
Preferred Term			
TOTAL	8 (36.4%)	9 (27.3%)	17 (30.9%)
HEADACHE	3 (13.6%)	1 (3.0%)	4 (7.3%)
ABDOMINAL PAIN	3 (13.6%)	0	3 (5.5%)
RESPIRATORY DISORDER	1 (4.5%)	2 (6.1%)	3 (5.5%)
NAUSEA	1 (4.5%)	1 (3.0%)	2 (3.6%)
ANXIETY	1 (4.5%)	0	1 (1.8%)
DEPRESSION	1 (4.5%)	0	1 (1.8%)
EAR PAIN	1 (4.5%)	0	1 (1.8%)
FEVER	1 (4.5%)	0	1 (1.8%)
INCREASED APPETITE	1 (4.5%)	0	1 (1.8%)
INSOMNIA	1 (4.5%)	0	1 (1.8%)
MYALGIA	1 (4.5%)	0	1 (1.8%)
NERVOUSNESS	1 (4.5%)	0	1 (1.8%)
PAIN	1 (4.5%)	0	1 (1.8%)
WITHDRAWAL SYNDROME	1 (4.5%)	0	1 (1.8%)
ALLERGIC REACTION	0	1 (3.0%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.0%)	1 (1.8%)
COUGH INCREASED	0	1 (3.0%)	1 (1.8%)
DIARRHEA	0	1 (3.0%)	1 (1.8%)
FECAL INCONTINENCE	0	1 (3.0%)	1 (1.8%)
FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)
HOSTILITY	0	1 (3.0%)	1 (1.8%)
INFECTION	0	1 (3.0%)	1 (1.8%)
LYMPHOCYTOSIS	0	1 (3.0%)	1 (1.8%)
SGOT INCREASED	0	1 (3.0%)	1 (1.8%)
URINARY INCONTINENCE	0	1 (3.0%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=11)	Total (N=22)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=18)	 Placebo (N=16)	 Total (N=34)
TOTAL	4 (22.2%)	2 (12.5%)	6 (17.6%)
ASTHMA	1 (5.6%)	0	1 (2.9%)
DIARRHEA	1 (5.6%)	0	1 (2.9%)
PHARYNGITIS	1 (5.6%)	0	1 (2.9%)
SINUSITIS	1 (5.6%)	0	1 (2.9%)
INFECTION	0	1 (6.3%)	1 (2.9%)
RESPIRATORY DISORDER	0	1 (6.3%)	1 (2.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=8)	Total (N=19)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=10)	Total (N=15)
Preferred Term			
TOTAL	3 (60.0%)	2 (20.0%)	5 (33.3%)
PARESTHESIA	1 (20.0%)	0	1 (6.7%)
RESPIRATORY DISORDER	1 (20.0%)	0	1 (6.7%)
SINUSITIS	1 (20.0%)	0	1 (6.7%)
THINKING ABNORMAL	1 (20.0%)	0	1 (6.7%)
DIARRHEA	0	1 (10.0%)	1 (6.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (10.0%)	1 (6.7%)
NAUSEA	0	1 (10.0%)	1 (6.7%)
TRAUMA	0	1 (10.0%)	1 (6.7%)
VOMITING	0	1 (10.0%)	1 (6.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=26)	Total (N=49)
TOTAL	7 (30.4%)	4 (15.4%)	11 (22.4%)
SINUSITIS	2 (8.7%)	0	2 (4.1%)
DIARRHEA	1 (4.3%)	1 (3.8%)	2 (4.1%)
RESPIRATORY DISORDER	1 (4.3%)	1 (3.8%)	2 (4.1%)
ASTHMA	1 (4.3%)	0	1 (2.0%)
PARESTHESIA	1 (4.3%)	0	1 (2.0%)
PHARYNGITIS	1 (4.3%)	0	1 (2.0%)
THINKING ABNORMAL	1 (4.3%)	0	1 (2.0%)
INFECTION	0	1 (3.8%)	1 (2.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.8%)	1 (2.0%)
NAUSEA	0	1 (3.8%)	1 (2.0%)
TRAUMA	0	1 (3.8%)	1 (2.0%)
VOMITING	0	1 (3.8%)	1 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
TOTAL	9 (27.3%)	7 (20.6%)	16 (23.9%)
RESPIRATORY DISORDER	1 (3.0%)	3 (8.8%)	4 (6.0%)
ABDOMINAL PAIN	3 (9.1%)	0	3 (4.5%)
HEADACHE	2 (6.1%)	0	2 (3.0%)
DIARRHEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
NAUSEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
ANXIETY	1 (3.0%)	0	1 (1.5%)
ASTHMA	1 (3.0%)	0	1 (1.5%)
DEPRESSION	1 (3.0%)	0	1 (1.5%)
INCREASED APPETITE	1 (3.0%)	0	1 (1.5%)
INSOMNIA	1 (3.0%)	0	1 (1.5%)
MYALGIA	1 (3.0%)	0	1 (1.5%)
NERVOUSNESS	1 (3.0%)	0	1 (1.5%)
PHARYNGITIS	1 (3.0%)	0	1 (1.5%)
SINUSITIS	1 (3.0%)	0	1 (1.5%)
WITHDRAWAL SYNDROME	1 (3.0%)	0	1 (1.5%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.5%)
CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.5%)
FECAL INCONTINENCE	0	1 (2.9%)	1 (1.5%)
HOSTILITY	0	1 (2.9%)	1 (1.5%)
INFECTION	0	1 (2.9%)	1 (1.5%)
LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.5%)
SGOT INCREASED	0	1 (2.9%)	1 (1.5%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
TOTAL	6 (50.0%)	6 (24.0%)	12 (32.4%)
HEADACHE	1 (8.3%)	1 (4.0%)	2 (5.4%)
EAR PAIN	1 (8.3%)	0	1 (2.7%)
FEVER	1 (8.3%)	0	1 (2.7%)
PAIN	1 (8.3%)	0	1 (2.7%)
PARESTHESIA	1 (8.3%)	0	1 (2.7%)
RESPIRATORY DISORDER	1 (8.3%)	0	1 (2.7%)
SINUSITIS	1 (8.3%)	0	1 (2.7%)
THINKING ABNORMAL	1 (8.3%)	0	1 (2.7%)
COUGH INCREASED	0	1 (4.0%)	1 (2.7%)
DIARRHEA	0	1 (4.0%)	1 (2.7%)
FUNGAL DERMATITIS	0	1 (4.0%)	1 (2.7%)
INFECTION	0	1 (4.0%)	1 (2.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (4.0%)	1 (2.7%)
NAUSEA	0	1 (4.0%)	1 (2.7%)
TRAUMA	0	1 (4.0%)	1 (2.7%)
VOMITING	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
TOTAL	15 (33.3%)	13 (22.0%)	28 (26.9%)
RESPIRATORY DISORDER	2 (4.4%)	3 (5.1%)	5 (4.8%)
HEADACHE	3 (6.7%)	1 (1.7%)	4 (3.8%)
ABDOMINAL PAIN	3 (6.7%)	0	3 (2.9%)
DIARRHEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
NAUSEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
SINUSITIS	2 (4.4%)	0	2 (1.9%)
INFECTION	0	2 (3.4%)	2 (1.9%)
ANXIETY	1 (2.2%)	0	1 (1.0%)
ASTHMA	1 (2.2%)	0	1 (1.0%)
DEPRESSION	1 (2.2%)	0	1 (1.0%)
EAR PAIN	1 (2.2%)	0	1 (1.0%)
FEVER	1 (2.2%)	0	1 (1.0%)
INCREASED APPETITE	1 (2.2%)	0	1 (1.0%)
INSOMNIA	1 (2.2%)	0	1 (1.0%)
MYALGIA	1 (2.2%)	0	1 (1.0%)
NERVOUSNESS	1 (2.2%)	0	1 (1.0%)
PAIN	1 (2.2%)	0	1 (1.0%)
PARESTHESIA	1 (2.2%)	0	1 (1.0%)
PHARYNGITIS	1 (2.2%)	0	1 (1.0%)
THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
WITHDRAWAL SYNDROME	1 (2.2%)	0	1 (1.0%)
ALLERGIC REACTION	0	1 (1.7%)	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (1.0%)
COUGH INCREASED	0	1 (1.7%)	1 (1.0%)
FECAL INCONTINENCE	0	1 (1.7%)	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.7%)	1 (1.0%)
HOSTILITY	0	1 (1.7%)	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (1.0%)
LYMPHOCYTOSIS	0	1 (1.7%)	1 (1.0%)
SGOT INCREASED	0	1 (1.7%)	1 (1.0%)
TRAUMA	0	1 (1.7%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.7%)	1 (1.0%)
VOMITING	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	6 (37.5%)	9 (42.9%)	15 (40.5%)
Body as a Whole	TOTAL	4 (25.0%)	1 (4.8%)	5 (13.5%)
	ABDOMINAL PAIN	3 (18.8%)	0	3 (8.1%)
	HEADACHE	2 (12.5%)	0	2 (5.4%)
	FEVER	1 (6.3%)	0	1 (2.7%)
	ALLERGIC REACTION	0	1 (4.8%)	1 (2.7%)
Nervous System	TOTAL	4 (25.0%)	4 (19.0%)	8 (21.6%)
	DEPRESSION	2 (12.5%)	1 (4.8%)	3 (8.1%)
	ANXIETY	1 (6.3%)	0	1 (2.7%)
	INSOMNIA	1 (6.3%)	0	1 (2.7%)
	NERVOUSNESS	1 (6.3%)	0	1 (2.7%)
	WITHDRAWAL SYNDROME	1 (6.3%)	0	1 (2.7%)
	CONCENTRATION IMPAIRED	0	1 (4.8%)	1 (2.7%)
	HOSTILITY	0	1 (4.8%)	1 (2.7%)
	HYSTERIA	0	1 (4.8%)	1 (2.7%)
Respiratory System	TOTAL	2 (12.5%)	2 (9.5%)	4 (10.8%)
	RESPIRATORY DISORDER	2 (12.5%)	2 (9.5%)	4 (10.8%)
Digestive System	TOTAL	1 (6.3%)	3 (14.3%)	4 (10.8%)
	NAUSEA	1 (6.3%)	2 (9.5%)	3 (8.1%)
	INCREASED APPETITE	1 (6.3%)	0	1 (2.7%)
	DIARRHEA	0	1 (4.8%)	1 (2.7%)
	FECAL INCONTINENCE	0	1 (4.8%)	1 (2.7%)
Musculoskeletal System	TOTAL	1 (6.3%)	0	1 (2.7%)
	MYALGIA	1 (6.3%)	0	1 (2.7%)
Cardiovascular System	TOTAL	0	1 (4.8%)	1 (2.7%)
	SYNCOPE	0	1 (4.8%)	1 (2.7%)
Hemic and Lymphatic System	TOTAL	0	1 (4.8%)	1 (2.7%)
	LYMPHOCYTOSIS	0	1 (4.8%)	1 (2.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.8%)	1 (2.7%)
	SGOT INCREASED	0	1 (4.8%)	1 (2.7%)
Special Searches	TOTAL	0	1 (4.8%)	1 (2.7%)
	PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)
Urogenital System	TOTAL	0	1 (4.8%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
Urogenital System	URINARY INCONTINENCE	0	1 (4.8%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=17)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	4 (50.0%)	4 (23.5%)	8 (32.0%)
Body as a Whole	TOTAL	4 (50.0%)	3 (17.6%)	7 (28.0%)
	HEADACHE	2 (25.0%)	1 (5.9%)	3 (12.0%)
	INFECTION	0	2 (11.8%)	2 (8.0%)
	ABDOMINAL PAIN	1 (12.5%)	0	1 (4.0%)
	FEVER	1 (12.5%)	0	1 (4.0%)
	PAIN	1 (12.5%)	0	1 (4.0%)
Respiratory System	TOTAL	1 (12.5%)	1 (5.9%)	2 (8.0%)
	SINUSITIS	1 (12.5%)	0	1 (4.0%)
	COUGH INCREASED	0	1 (5.9%)	1 (4.0%)
Special Senses	TOTAL	1 (12.5%)	0	1 (4.0%)
	EAR PAIN	1 (12.5%)	0	1 (4.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.9%)	1 (4.0%)
	WEIGHT GAIN	0	1 (5.9%)	1 (4.0%)
Skin and Appendages	TOTAL	0	1 (5.9%)	1 (4.0%)
	FUNGAL DERMATITIS	0	1 (5.9%)	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=13)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=38)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	10 (41.7%)	13 (34.2%)	23 (37.1%)
Body as a Whole	TOTAL	8 (33.3%)	4 (10.5%)	12 (19.4%)
	HEADACHE	4 (16.7%)	1 (2.6%)	5 (8.1%)
	ABDOMINAL PAIN	4 (16.7%)	0	4 (6.5%)
	FEVER	2 (8.3%)	0	2 (3.2%)
	INFECTION	0	2 (5.3%)	2 (3.2%)
	PAIN	1 (4.2%)	0	1 (1.6%)
	ALLERGIC REACTION	0	1 (2.6%)	1 (1.6%)
Nervous System	TOTAL	4 (16.7%)	4 (10.5%)	8 (12.9%)
	DEPRESSION	2 (8.3%)	1 (2.6%)	3 (4.8%)
	ANXIETY	1 (4.2%)	0	1 (1.6%)
	INSOMNIA	1 (4.2%)	0	1 (1.6%)
	NERVOUSNESS	1 (4.2%)	0	1 (1.6%)
	WITHDRAWAL SYNDROME	1 (4.2%)	0	1 (1.6%)
	CONCENTRATION IMPAIRED	0	1 (2.6%)	1 (1.6%)
	HOSTILITY	0	1 (2.6%)	1 (1.6%)
	HYSTERIA	0	1 (2.6%)	1 (1.6%)
Respiratory System	TOTAL	3 (12.5%)	3 (7.9%)	6 (9.7%)
	RESPIRATORY DISORDER	2 (8.3%)	2 (5.3%)	4 (6.5%)
	SINUSITIS	1 (4.2%)	0	1 (1.6%)
	COUGH INCREASED	0	1 (2.6%)	1 (1.6%)
Digestive System	TOTAL	1 (4.2%)	3 (7.9%)	4 (6.5%)
	NAUSEA	1 (4.2%)	2 (5.3%)	3 (4.8%)
	INCREASED APPETITE	1 (4.2%)	0	1 (1.6%)
	DIARRHEA	0	1 (2.6%)	1 (1.6%)
	FECAL INCONTINENCE	0	1 (2.6%)	1 (1.6%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.6%)
	MYALGIA	1 (4.2%)	0	1 (1.6%)
Special Senses	TOTAL	1 (4.2%)	0	1 (1.6%)
	EAR PAIN	1 (4.2%)	0	1 (1.6%)
Cardiovascular System	TOTAL	0	1 (2.6%)	1 (1.6%)
	SYNCOPE	0	1 (2.6%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	0	1 (2.6%)	1 (1.6%)
	LYMPHOCYTOSIS	0	1 (2.6%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=38)	Total (N=62)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	0	2 (5.3%)	2 (3.2%)
	SGOT INCREASED	0	1 (2.6%)	1 (1.6%)
	WEIGHT GAIN	0	1 (2.6%)	1 (1.6%)
Skin and Appendages	TOTAL	0	1 (2.6%)	1 (1.6%)
	FUNGAL DERMATITIS	0	1 (2.6%)	1 (1.6%)
Special Searches	TOTAL	0	1 (2.6%)	1 (1.6%)
	PUNCTURE SITE PAIN	0	1 (2.6%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.6%)	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.6%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=26)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=19)	Total (N=38)
Body System	Preferred Term			
TOTAL	TOTAL	6 (31.6%)	3 (15.8%)	9 (23.7%)
Respiratory System	TOTAL	3 (15.8%)	1 (5.3%)	4 (10.5%)
	ASTHMA	1 (5.3%)	0	1 (2.6%)
	PHARYNGITIS	1 (5.3%)	0	1 (2.6%)
	SINUSITIS	1 (5.3%)	0	1 (2.6%)
	RESPIRATORY DISORDER	0	1 (5.3%)	1 (2.6%)
Digestive System	TOTAL	1 (5.3%)	0	1 (2.6%)
	DIARRHEA	1 (5.3%)	0	1 (2.6%)
Hemic and Lymphatic System	TOTAL	1 (5.3%)	0	1 (2.6%)
	LEUKOPENIA	1 (5.3%)	0	1 (2.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.3%)	0	1 (2.6%)
	WEIGHT GAIN	1 (5.3%)	0	1 (2.6%)
Nervous System	TOTAL	1 (5.3%)	2 (10.5%)	3 (7.9%)
	HOSTILITY	1 (5.3%)	0	1 (2.6%)
	SOMNOLENCE	0	1 (5.3%)	1 (2.6%)
	WITHDRAWAL SYNDROME	0	1 (5.3%)	1 (2.6%)
Body as a Whole	TOTAL	0	1 (5.3%)	1 (2.6%)
	INFECTION	0	1 (5.3%)	1 (2.6%)
Musculoskeletal System	TOTAL	0	1 (5.3%)	1 (2.6%)
	MYALGIA	0	1 (5.3%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=11)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=12)	Total (N=19)
Body System	Preferred Term			
TOTAL	TOTAL	4 (57.1%)	3 (25.0%)	7 (36.8%)
Respiratory System	TOTAL	2 (28.6%)	0	2 (10.5%)
	RESPIRATORY DISORDER	1 (14.3%)	0	1 (5.3%)
	SINUSITIS	1 (14.3%)	0	1 (5.3%)
Cardiovascular System	TOTAL	1 (14.3%)	0	1 (5.3%)
	BRADYCARDIA	1 (14.3%)	0	1 (5.3%)
Nervous System	TOTAL	1 (14.3%)	1 (8.3%)	2 (10.5%)
	PARESTHESIA	1 (14.3%)	0	1 (5.3%)
	THINKING ABNORMAL	1 (14.3%)	0	1 (5.3%)
	ABNORMAL DREAMS	0	1 (8.3%)	1 (5.3%)
	INSOMNIA	0	1 (8.3%)	1 (5.3%)
Body as a Whole	TOTAL	0	1 (8.3%)	1 (5.3%)
	TRAUMA	0	1 (8.3%)	1 (5.3%)
Digestive System	TOTAL	0	1 (8.3%)	1 (5.3%)
	DIARRHEA	0	1 (8.3%)	1 (5.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (8.3%)	1 (5.3%)
	NAUSEA	0	1 (8.3%)	1 (5.3%)
	VOMITING	0	1 (8.3%)	1 (5.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=8)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=4)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=31)	Total (N=57)
Body System	Preferred Term			
TOTAL	TOTAL	10 (38.5%)	6 (19.4%)	16 (28.1%)
Respiratory System	TOTAL	5 (19.2%)	1 (3.2%)	6 (10.5%)
	SINUSITIS	2 (7.7%)	0	2 (3.5%)
	RESPIRATORY DISORDER	1 (3.8%)	1 (3.2%)	2 (3.5%)
	ASTHMA	1 (3.8%)	0	1 (1.8%)
	PHARYNGITIS	1 (3.8%)	0	1 (1.8%)
Nervous System	TOTAL	2 (7.7%)	3 (9.7%)	5 (8.8%)
	HOSTILITY	1 (3.8%)	0	1 (1.8%)
	PARESTHESIA	1 (3.8%)	0	1 (1.8%)
	THINKING ABNORMAL	1 (3.8%)	0	1 (1.8%)
	ABNORMAL DREAMS	0	1 (3.2%)	1 (1.8%)
	INSOMNIA	0	1 (3.2%)	1 (1.8%)
	SOMNOLENCE	0	1 (3.2%)	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (3.2%)	1 (1.8%)
Cardiovascular System	TOTAL	1 (3.8%)	0	1 (1.8%)
	BRADYCARDIA	1 (3.8%)	0	1 (1.8%)
Digestive System	TOTAL	1 (3.8%)	1 (3.2%)	2 (3.5%)
	DIARRHEA	1 (3.8%)	1 (3.2%)	2 (3.5%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.2%)	1 (1.8%)
	NAUSEA	0	1 (3.2%)	1 (1.8%)
	VOMITING	0	1 (3.2%)	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (3.8%)	0	1 (1.8%)
	LEUKOPENIA	1 (3.8%)	0	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (3.8%)	0	1 (1.8%)
	WEIGHT GAIN	1 (3.8%)	0	1 (1.8%)
Body as a Whole	TOTAL	0	2 (6.5%)	2 (3.5%)
	INFECTION	0	1 (3.2%)	1 (1.8%)
	TRAUMA	0	1 (3.2%)	1 (1.8%)
Musculoskeletal System	TOTAL	0	1 (3.2%)	1 (1.8%)
	MYALGIA	0	1 (3.2%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=19)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=12)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	12 (34.3%)	12 (30.0%)	24 (32.0%)
Nervous System	TOTAL	5 (14.3%)	6 (15.0%)	11 (14.7%)
	DEPRESSION	2 (5.7%)	1 (2.5%)	3 (4.0%)
	HOSTILITY	1 (2.9%)	1 (2.5%)	2 (2.7%)
	WITHDRAWAL SYNDROME	1 (2.9%)	1 (2.5%)	2 (2.7%)
	ANXIETY	1 (2.9%)	0	1 (1.3%)
	INSOMNIA	1 (2.9%)	0	1 (1.3%)
	NERVOUSNESS	1 (2.9%)	0	1 (1.3%)
	CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.3%)
	HYSTERIA	0	1 (2.5%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.5%)	1 (1.3%)
Respiratory System	TOTAL	5 (14.3%)	3 (7.5%)	8 (10.7%)
	RESPIRATORY DISORDER	2 (5.7%)	3 (7.5%)	5 (6.7%)
	ASTHMA	1 (2.9%)	0	1 (1.3%)
	PHARYNGITIS	1 (2.9%)	0	1 (1.3%)
	SINUSITIS	1 (2.9%)	0	1 (1.3%)
Body as a Whole	TOTAL	4 (11.4%)	2 (5.0%)	6 (8.0%)
	ABDOMINAL PAIN	3 (8.6%)	0	3 (4.0%)
	HEADACHE	2 (5.7%)	0	2 (2.7%)
	FEVER	1 (2.9%)	0	1 (1.3%)
	ALLERGIC REACTION	0	1 (2.5%)	1 (1.3%)
	INFECTION	0	1 (2.5%)	1 (1.3%)
Digestive System	TOTAL	2 (5.7%)	3 (7.5%)	5 (6.7%)
	NAUSEA	1 (2.9%)	2 (5.0%)	3 (4.0%)
	DIARRHEA	1 (2.9%)	1 (2.5%)	2 (2.7%)
	INCREASED APPETITE	1 (2.9%)	0	1 (1.3%)
	FECAL INCONTINENCE	0	1 (2.5%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (2.9%)	1 (2.5%)	2 (2.7%)
	LEUKOPENIA	1 (2.9%)	0	1 (1.3%)
	LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.9%)	1 (2.5%)	2 (2.7%)
	WEIGHT GAIN	1 (2.9%)	0	1 (1.3%)
	SGOT INCREASED	0	1 (2.5%)	1 (1.3%)
Musculoskeletal System	TOTAL	1 (2.9%)	1 (2.5%)	2 (2.7%)
	MYALGIA	1 (2.9%)	1 (2.5%)	2 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
Body System	Preferred Term			
Cardiovascular System	TOTAL	0	1 (2.5%)	1 (1.3%)
	SYNCOPE	0	1 (2.5%)	1 (1.3%)
Special Searches	TOTAL	0	1 (2.5%)	1 (1.3%)
	PUNCTURE SITE PAIN	0	1 (2.5%)	1 (1.3%)
Urogenital System	TOTAL	0	1 (2.5%)	1 (1.3%)
	URINARY INCONTINENCE	0	1 (2.5%)	1 (1.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=21)	Placebo (N=24)	Total (N=45)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=29)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	8 (53.3%)	7 (24.1%)	15 (34.1%)
Body as a Whole	TOTAL	4 (26.7%)	4 (13.8%)	8 (18.2%)
	HEADACHE	2 (13.3%)	1 (3.4%)	3 (6.8%)
	INFECTION	0	2 (6.9%)	2 (4.5%)
	ABDOMINAL PAIN	1 (6.7%)	0	1 (2.3%)
	FEVER	1 (6.7%)	0	1 (2.3%)
	PAIN	1 (6.7%)	0	1 (2.3%)
	TRAUMA	0	1 (3.4%)	1 (2.3%)
Respiratory System	TOTAL	3 (20.0%)	1 (3.4%)	4 (9.1%)
	SINUSITIS	2 (13.3%)	0	2 (4.5%)
	RESPIRATORY DISORDER	1 (6.7%)	0	1 (2.3%)
	COUGH INCREASED	0	1 (3.4%)	1 (2.3%)
Cardiovascular System	TOTAL	1 (6.7%)	0	1 (2.3%)
	BRADYCARDIA	1 (6.7%)	0	1 (2.3%)
Nervous System	TOTAL	1 (6.7%)	1 (3.4%)	2 (4.5%)
	PARESTHESIA	1 (6.7%)	0	1 (2.3%)
	THINKING ABNORMAL	1 (6.7%)	0	1 (2.3%)
	ABNORMAL DREAMS	0	1 (3.4%)	1 (2.3%)
	INSOMNIA	0	1 (3.4%)	1 (2.3%)
Special Senses	TOTAL	1 (6.7%)	0	1 (2.3%)
	EAR PAIN	1 (6.7%)	0	1 (2.3%)
Digestive System	TOTAL	0	1 (3.4%)	1 (2.3%)
	DIARRHEA	0	1 (3.4%)	1 (2.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.4%)	1 (2.3%)
	NAUSEA	0	1 (3.4%)	1 (2.3%)
	VOMITING	0	1 (3.4%)	1 (2.3%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (3.4%)	1 (2.3%)
	WEIGHT GAIN	0	1 (3.4%)	1 (2.3%)
Skin and Appendages	TOTAL	0	1 (3.4%)	1 (2.3%)
	FUNGAL DERMATITIS	0	1 (3.4%)	1 (2.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=21)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	20 (40.0%)	19 (27.5%)	39 (32.8%)
Body as a Whole	TOTAL	8 (16.0%)	6 (8.7%)	14 (11.8%)
	HEADACHE	4 (8.0%)	1 (1.4%)	5 (4.2%)
	ABDOMINAL PAIN	4 (8.0%)	0	4 (3.4%)
	INFECTION	0	3 (4.3%)	3 (2.5%)
	FEVER	2 (4.0%)	0	2 (1.7%)
	PAIN	1 (2.0%)	0	1 (0.8%)
	ALLERGIC REACTION	0	1 (1.4%)	1 (0.8%)
	TRAUMA	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	8 (16.0%)	4 (5.8%)	12 (10.1%)
	RESPIRATORY DISORDER	3 (6.0%)	3 (4.3%)	6 (5.0%)
	SINUSITIS	3 (6.0%)	0	3 (2.5%)
	ASTHMA	1 (2.0%)	0	1 (0.8%)
	PHARYNGITIS	1 (2.0%)	0	1 (0.8%)
	COUGH INCREASED	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	6 (12.0%)	7 (10.1%)	13 (10.9%)
	DEPRESSION	2 (4.0%)	1 (1.4%)	3 (2.5%)
	HOSTILITY	1 (2.0%)	1 (1.4%)	2 (1.7%)
	INSOMNIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	WITHDRAWAL SYNDROME	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ANXIETY	1 (2.0%)	0	1 (0.8%)
	NERVOUSNESS	1 (2.0%)	0	1 (0.8%)
	PARESTHESIA	1 (2.0%)	0	1 (0.8%)
	THINKING ABNORMAL	1 (2.0%)	0	1 (0.8%)
	ABNORMAL DREAMS	0	1 (1.4%)	1 (0.8%)
	CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.8%)
	HYSTERIA	0	1 (1.4%)	1 (0.8%)
	SOMNOLENCE	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	2 (4.0%)	4 (5.8%)	6 (5.0%)
	NAUSEA	1 (2.0%)	3 (4.3%)	4 (3.4%)
	DIARRHEA	1 (2.0%)	2 (2.9%)	3 (2.5%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	FECAL INCONTINENCE	0	1 (1.4%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
	VOMITING	0	1 (1.4%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	BRADYCARDIA	1 (2.0%)	0	1 (0.8%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
Body System	Preferred Term			
Hemic and Lymphatic System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	LEUKOPENIA	1 (2.0%)	0	1 (0.8%)
	LYMPHOCYTOSIS	0	1 (1.4%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.0%)	2 (2.9%)	3 (2.5%)
	WEIGHT GAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
	SGOT INCREASED	0	1 (1.4%)	1 (0.8%)
Musculoskeletal System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Special Senses	TOTAL	1 (2.0%)	0	1 (0.8%)
	EAR PAIN	1 (2.0%)	0	1 (0.8%)
Skin and Appendages	TOTAL	0	1 (1.4%)	1 (0.8%)
	FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.8%)
Special Searches	TOTAL	0	1 (1.4%)	1 (0.8%)
	PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	0	1 (1.4%)	1 (0.8%)
	URINARY INCONTINENCE	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=45)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=21)	Placebo (N=24)	Total (N=45)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	 Placebo (N=21)	 Total (N=37)
TOTAL	6 (37.5%)	9 (42.9%)	15 (40.5%)
RESPIRATORY DISORDER	2 (12.5%)	2 (9.5%)	4 (10.8%)
ABDOMINAL PAIN	3 (18.8%)	0	3 (8.1%)
DEPRESSION	2 (12.5%)	1 (4.8%)	3 (8.1%)
NAUSEA	1 (6.3%)	2 (9.5%)	3 (8.1%)
HEADACHE	2 (12.5%)	0	2 (5.4%)
ANXIETY	1 (6.3%)	0	1 (2.7%)
FEVER	1 (6.3%)	0	1 (2.7%)
INCREASED APPETITE	1 (6.3%)	0	1 (2.7%)
INSOMNIA	1 (6.3%)	0	1 (2.7%)
MYALGIA	1 (6.3%)	0	1 (2.7%)
NERVOUSNESS	1 (6.3%)	0	1 (2.7%)
WITHDRAWAL SYNDROME	1 (6.3%)	0	1 (2.7%)
ALLERGIC REACTION	0	1 (4.8%)	1 (2.7%)
CONCENTRATION IMPAIRED	0	1 (4.8%)	1 (2.7%)
DIARRHEA	0	1 (4.8%)	1 (2.7%)
FECAL INCONTINENCE	0	1 (4.8%)	1 (2.7%)
HOSTILITY	0	1 (4.8%)	1 (2.7%)
HYSTERIA	0	1 (4.8%)	1 (2.7%)
LYMPHOCYTOSIS	0	1 (4.8%)	1 (2.7%)
PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)
SGOT INCREASED	0	1 (4.8%)	1 (2.7%)
SYNCOPE	0	1 (4.8%)	1 (2.7%)
URINARY INCONTINENCE	0	1 (4.8%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=17)	Total (N=25)
TOTAL	4 (50.0%)	4 (23.5%)	8 (32.0%)
HEADACHE	2 (25.0%)	1 (5.9%)	3 (12.0%)
INFECTION	0	2 (11.8%)	2 (8.0%)
ABDOMINAL PAIN	1 (12.5%)	0	1 (4.0%)
EAR PAIN	1 (12.5%)	0	1 (4.0%)
FEVER	1 (12.5%)	0	1 (4.0%)
PAIN	1 (12.5%)	0	1 (4.0%)
SINUSITIS	1 (12.5%)	0	1 (4.0%)
COUGH INCREASED	0	1 (5.9%)	1 (4.0%)
FUNGAL DERMATITIS	0	1 (5.9%)	1 (4.0%)
WEIGHT GAIN	0	1 (5.9%)	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=13)	Total (N=17)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=38)	Total (N=62)
TOTAL	10 (41.7%)	13 (34.2%)	23 (37.1%)
HEADACHE	4 (16.7%)	1 (2.6%)	5 (8.1%)
ABDOMINAL PAIN	4 (16.7%)	0	4 (6.5%)
RESPIRATORY DISORDER	2 (8.3%)	2 (5.3%)	4 (6.5%)
DEPRESSION	2 (8.3%)	1 (2.6%)	3 (4.8%)
NAUSEA	1 (4.2%)	2 (5.3%)	3 (4.8%)
FEVER	2 (8.3%)	0	2 (3.2%)
INFECTION	0	2 (5.3%)	2 (3.2%)
ANXIETY	1 (4.2%)	0	1 (1.6%)
EAR PAIN	1 (4.2%)	0	1 (1.6%)
INCREASED APPETITE	1 (4.2%)	0	1 (1.6%)
INSOMNIA	1 (4.2%)	0	1 (1.6%)
MYALGIA	1 (4.2%)	0	1 (1.6%)
NERVOUSNESS	1 (4.2%)	0	1 (1.6%)
PAIN	1 (4.2%)	0	1 (1.6%)
SINUSITIS	1 (4.2%)	0	1 (1.6%)
WITHDRAWAL SYNDROME	1 (4.2%)	0	1 (1.6%)
ALLERGIC REACTION	0	1 (2.6%)	1 (1.6%)
CONCENTRATION IMPAIRED	0	1 (2.6%)	1 (1.6%)
COUGH INCREASED	0	1 (2.6%)	1 (1.6%)
DIARRHEA	0	1 (2.6%)	1 (1.6%)
FECAL INCONTINENCE	0	1 (2.6%)	1 (1.6%)
FUNGAL DERMATITIS	0	1 (2.6%)	1 (1.6%)
HOSTILITY	0	1 (2.6%)	1 (1.6%)
HYSTERIA	0	1 (2.6%)	1 (1.6%)
LYMPHOCYTOSIS	0	1 (2.6%)	1 (1.6%)
PUNCTURE SITE PAIN	0	1 (2.6%)	1 (1.6%)
SGOT INCREASED	0	1 (2.6%)	1 (1.6%)
SYNCOPE	0	1 (2.6%)	1 (1.6%)
URINARY INCONTINENCE	0	1 (2.6%)	1 (1.6%)
WEIGHT GAIN	0	1 (2.6%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=26)	Total (N=39)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=19)	Total (N=38)
Preferred Term			
TOTAL	6 (31.6%)	3 (15.8%)	9 (23.7%)
ASTHMA	1 (5.3%)	0	1 (2.6%)
DIARRHEA	1 (5.3%)	0	1 (2.6%)
HOSTILITY	1 (5.3%)	0	1 (2.6%)
LEUKOPENIA	1 (5.3%)	0	1 (2.6%)
PHARYNGITIS	1 (5.3%)	0	1 (2.6%)
SINUSITIS	1 (5.3%)	0	1 (2.6%)
WEIGHT GAIN	1 (5.3%)	0	1 (2.6%)
INFECTION	0	1 (5.3%)	1 (2.6%)
MYALGIA	0	1 (5.3%)	1 (2.6%)
RESPIRATORY DISORDER	0	1 (5.3%)	1 (2.6%)
SOMNOLENCE	0	1 (5.3%)	1 (2.6%)
WITHDRAWAL SYNDROME	0	1 (5.3%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=11)	Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=12)	Total (N=19)
Preferred Term			
TOTAL	4 (57.1%)	3 (25.0%)	7 (36.8%)
BRADYCARDIA	1 (14.3%)	0	1 (5.3%)
PARESTHESIA	1 (14.3%)	0	1 (5.3%)
RESPIRATORY DISORDER	1 (14.3%)	0	1 (5.3%)
SINUSITIS	1 (14.3%)	0	1 (5.3%)
THINKING ABNORMAL	1 (14.3%)	0	1 (5.3%)
ABNORMAL DREAMS	0	1 (8.3%)	1 (5.3%)
DIARRHEA	0	1 (8.3%)	1 (5.3%)
INSOMNIA	0	1 (8.3%)	1 (5.3%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (8.3%)	1 (5.3%)
NAUSEA	0	1 (8.3%)	1 (5.3%)
TRAUMA	0	1 (8.3%)	1 (5.3%)
VOMITING	0	1 (8.3%)	1 (5.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=8)	Total (N=12)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=4)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=26)	Placebo (N=31)	Total (N=57)
Preferred Term			
TOTAL	10 (38.5%)	6 (19.4%)	16 (28.1%)
SINUSITIS	2 (7.7%)	0	2 (3.5%)
DIARRHEA	1 (3.8%)	1 (3.2%)	2 (3.5%)
RESPIRATORY DISORDER	1 (3.8%)	1 (3.2%)	2 (3.5%)
ASTHMA	1 (3.8%)	0	1 (1.8%)
BRADYCARDIA	1 (3.8%)	0	1 (1.8%)
HOSTILITY	1 (3.8%)	0	1 (1.8%)
LEUKOPENIA	1 (3.8%)	0	1 (1.8%)
PARESTHESIA	1 (3.8%)	0	1 (1.8%)
PHARYNGITIS	1 (3.8%)	0	1 (1.8%)
THINKING ABNORMAL	1 (3.8%)	0	1 (1.8%)
WEIGHT GAIN	1 (3.8%)	0	1 (1.8%)
ABNORMAL DREAMS	0	1 (3.2%)	1 (1.8%)
INFECTION	0	1 (3.2%)	1 (1.8%)
INSOMNIA	0	1 (3.2%)	1 (1.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.2%)	1 (1.8%)
MYALGIA	0	1 (3.2%)	1 (1.8%)
NAUSEA	0	1 (3.2%)	1 (1.8%)
SOMNOLENCE	0	1 (3.2%)	1 (1.8%)
TRAUMA	0	1 (3.2%)	1 (1.8%)
VOMITING	0	1 (3.2%)	1 (1.8%)
WITHDRAWAL SYNDROME	0	1 (3.2%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=19)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=10)	Placebo (N=12)	Total (N=22)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
TOTAL	12 (34.3%)	12 (30.0%)	24 (32.0%)
RESPIRATORY DISORDER	2 (5.7%)	3 (7.5%)	5 (6.7%)
ABDOMINAL PAIN	3 (8.6%)	0	3 (4.0%)
DEPRESSION	2 (5.7%)	1 (2.5%)	3 (4.0%)
NAUSEA	1 (2.9%)	2 (5.0%)	3 (4.0%)
HEADACHE	2 (5.7%)	0	2 (2.7%)
DIARRHEA	1 (2.9%)	1 (2.5%)	2 (2.7%)
HOSTILITY	1 (2.9%)	1 (2.5%)	2 (2.7%)
MYALGIA	1 (2.9%)	1 (2.5%)	2 (2.7%)
WITHDRAWAL SYNDROME	1 (2.9%)	1 (2.5%)	2 (2.7%)
ANXIETY	1 (2.9%)	0	1 (1.3%)
ASTHMA	1 (2.9%)	0	1 (1.3%)
FEVER	1 (2.9%)	0	1 (1.3%)
INCREASED APPETITE	1 (2.9%)	0	1 (1.3%)
INSOMNIA	1 (2.9%)	0	1 (1.3%)
LEUKOPENIA	1 (2.9%)	0	1 (1.3%)
NERVOUSNESS	1 (2.9%)	0	1 (1.3%)
PHARYNGITIS	1 (2.9%)	0	1 (1.3%)
SINUSITIS	1 (2.9%)	0	1 (1.3%)
WEIGHT GAIN	1 (2.9%)	0	1 (1.3%)
ALLERGIC REACTION	0	1 (2.5%)	1 (1.3%)
CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.3%)
FECAL INCONTINENCE	0	1 (2.5%)	1 (1.3%)
HYSTERIA	0	1 (2.5%)	1 (1.3%)
INFECTION	0	1 (2.5%)	1 (1.3%)
LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.3%)
PUNCTURE SITE PAIN	0	1 (2.5%)	1 (1.3%)
SGOT INCREASED	0	1 (2.5%)	1 (1.3%)
SOMNOLENCE	0	1 (2.5%)	1 (1.3%)
SYNCOPE	0	1 (2.5%)	1 (1.3%)
URINARY INCONTINENCE	0	1 (2.5%)	1 (1.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=21)	Placebo (N=24)	Total (N=45)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=15)	Placebo (N=29)	Total (N=44)
Preferred Term			
TOTAL	8 (53.3%)	7 (24.1%)	15 (34.1%)
HEADACHE	2 (13.3%)	1 (3.4%)	3 (6.8%)
SINUSITIS	2 (13.3%)	0	2 (4.5%)
INFECTION	0	2 (6.9%)	2 (4.5%)
ABDOMINAL PAIN	1 (6.7%)	0	1 (2.3%)
BRADYCARDIA	1 (6.7%)	0	1 (2.3%)
EAR PAIN	1 (6.7%)	0	1 (2.3%)
FEVER	1 (6.7%)	0	1 (2.3%)
PAIN	1 (6.7%)	0	1 (2.3%)
PARESTHESIA	1 (6.7%)	0	1 (2.3%)
RESPIRATORY DISORDER	1 (6.7%)	0	1 (2.3%)
THINKING ABNORMAL	1 (6.7%)	0	1 (2.3%)
ABNORMAL DREAMS	0	1 (3.4%)	1 (2.3%)
COUGH INCREASED	0	1 (3.4%)	1 (2.3%)
DIARRHEA	0	1 (3.4%)	1 (2.3%)
FUNGAL DERMATITIS	0	1 (3.4%)	1 (2.3%)
INSOMNIA	0	1 (3.4%)	1 (2.3%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.4%)	1 (2.3%)
NAUSEA	0	1 (3.4%)	1 (2.3%)
TRAUMA	0	1 (3.4%)	1 (2.3%)
VOMITING	0	1 (3.4%)	1 (2.3%)
WEIGHT GAIN	0	1 (3.4%)	1 (2.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=21)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=69)	Total (N=119)
TOTAL	20 (40.0%)	19 (27.5%)	39 (32.8%)
RESPIRATORY DISORDER	3 (6.0%)	3 (4.3%)	6 (5.0%)
HEADACHE	4 (8.0%)	1 (1.4%)	5 (4.2%)
ABDOMINAL PAIN	4 (8.0%)	0	4 (3.4%)
NAUSEA	1 (2.0%)	3 (4.3%)	4 (3.4%)
SINUSITIS	3 (6.0%)	0	3 (2.5%)
DEPRESSION	2 (4.0%)	1 (1.4%)	3 (2.5%)
DIARRHEA	1 (2.0%)	2 (2.9%)	3 (2.5%)
INFECTION	0	3 (4.3%)	3 (2.5%)
FEVER	2 (4.0%)	0	2 (1.7%)
HOSTILITY	1 (2.0%)	1 (1.4%)	2 (1.7%)
INSOMNIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYALGIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
WEIGHT GAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
WITHDRAWAL SYNDROME	1 (2.0%)	1 (1.4%)	2 (1.7%)
ANXIETY	1 (2.0%)	0	1 (0.8%)
ASTHMA	1 (2.0%)	0	1 (0.8%)
BRADYCARDIA	1 (2.0%)	0	1 (0.8%)
EAR PAIN	1 (2.0%)	0	1 (0.8%)
INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
LEUKOPENIA	1 (2.0%)	0	1 (0.8%)
NERVOUSNESS	1 (2.0%)	0	1 (0.8%)
PAIN	1 (2.0%)	0	1 (0.8%)
PARESTHESIA	1 (2.0%)	0	1 (0.8%)
PHARYNGITIS	1 (2.0%)	0	1 (0.8%)
THINKING ABNORMAL	1 (2.0%)	0	1 (0.8%)
ABNORMAL DREAMS	0	1 (1.4%)	1 (0.8%)
ALLERGIC REACTION	0	1 (1.4%)	1 (0.8%)
CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.8%)
COUGH INCREASED	0	1 (1.4%)	1 (0.8%)
FECAL INCONTINENCE	0	1 (1.4%)	1 (0.8%)
FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.8%)
HYSTERIA	0	1 (1.4%)	1 (0.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
LYMPHOCYTOSIS	0	1 (1.4%)	1 (0.8%)
PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.8%)
SGOT INCREASED	0	1 (1.4%)	1 (0.8%)
SOMNOLENCE	0	1 (1.4%)	1 (0.8%)
SYNCOPE	0	1 (1.4%)	1 (0.8%)
TRAUMA	0	1 (1.4%)	1 (0.8%)
URINARY INCONTINENCE	0	1 (1.4%)	1 (0.8%)
VOMITING	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=29)	Placebo (N=45)	Total (N=74)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=21)	Placebo (N=24)	Total (N=45)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	20 (80.0%)	26 (72.2%)	46 (75.4%)
Respiratory System	TOTAL	13 (52.0%)	13 (36.1%)	26 (42.6%)
	RESPIRATORY DISORDER	9 (36.0%)	6 (16.7%)	15 (24.6%)
	PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
	RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
	SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
	EPISTAXIS	0	2 (5.6%)	2 (3.3%)
	ASTHMA	0	1 (2.8%)	1 (1.6%)
	BRONCHITIS	0	1 (2.8%)	1 (1.6%)
	PNEUMONIA	0	1 (2.8%)	1 (1.6%)
	YAWN	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	12 (48.0%)	15 (41.7%)	27 (44.3%)
	INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
	HEADACHE	7 (28.0%)	4 (11.1%)	11 (18.0%)
	ABDOMINAL PAIN	7 (28.0%)	3 (8.3%)	10 (16.4%)
	TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
	FEVER	5 (20.0%)	2 (5.6%)	7 (11.5%)
	ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
	BACK PAIN	0	3 (8.3%)	3 (4.9%)
	ASTHENIA	0	2 (5.6%)	2 (3.3%)
	FACE EDEMA	1 (4.0%)	0	1 (1.6%)
	PAIN	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	11 (44.0%)	14 (38.9%)	25 (41.0%)
	VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
	DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
	NAUSEA	2 (8.0%)	4 (11.1%)	6 (9.8%)
	DIARRHEA	2 (8.0%)	2 (5.6%)	4 (6.6%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	INCREASED APPETITE	2 (8.0%)	0	2 (3.3%)
	TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	STOMATITIS	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	FECAL INCONTINENCE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	11 (44.0%)	13 (36.1%)	24 (39.3%)
	HOSTILITY	3 (12.0%)	2 (5.6%)	5 (8.2%)
	NERVOUSNESS	4 (16.0%)	0	4 (6.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Nervous System	DEPRESSION	3 (12.0%)	1 (2.8%)	4 (6.6%)
	INSOMNIA	1 (4.0%)	3 (8.3%)	4 (6.6%)
	AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ANXIETY	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONCENTRATION IMPAIRED	0	2 (5.6%)	2 (3.3%)
	HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
	VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
	WITHDRAWAL SYNDROME	1 (4.0%)	0	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	EUPHORIA	0	1 (2.8%)	1 (1.6%)
	HYSTERIA	0	1 (2.8%)	1 (1.6%)
	PARALYSIS	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	6 (24.0%)	4 (11.1%)	10 (16.4%)
	CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
	RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ACNE	2 (8.0%)	0	2 (3.3%)
	HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
	PRURITUS	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	4 (16.0%)	5 (13.9%)	9 (14.8%)
	WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
	DEHYDRATION	0	1 (2.8%)	1 (1.6%)
	SGOT INCREASED	0	1 (2.8%)	1 (1.6%)
Musculoskeletal System	TOTAL	2 (8.0%)	1 (2.8%)	3 (4.9%)
	MYALGIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
	ARTHROSIS	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
	ANEMIA	0	1 (2.8%)	1 (1.6%)
	LYMPHOCYTOSIS	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Special Senses	OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	4 (11.1%)	5 (8.2%)
	URINARY INCONTINENCE	1 (4.0%)	3 (8.3%)	4 (6.6%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
	CYSTITIS	0	1 (2.8%)	1 (1.6%)
	HAEMATURIA	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.9%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (2.8%)	1 (1.6%)
	MIGRAINE	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.6%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	19 (79.2%)	29 (85.3%)	48 (82.8%)
Body as a Whole	TOTAL	13 (54.2%)	16 (47.1%)	29 (50.0%)
	HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
	TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
	ABDOMINAL PAIN	2 (8.3%)	5 (14.7%)	7 (12.1%)
	INFECTION	3 (12.5%)	3 (8.8%)	6 (10.3%)
	FEVER	4 (16.7%)	1 (2.9%)	5 (8.6%)
	PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ABSCESS	1 (4.2%)	0	1 (1.7%)
	BACK PAIN	1 (4.2%)	0	1 (1.7%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	7 (29.2%)	6 (17.6%)	13 (22.4%)
	NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	DIARRHEA	2 (8.3%)	0	2 (3.4%)
	FLATULENCE	0	1 (2.9%)	1 (1.7%)
	GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
	GINGIVITIS	0	1 (2.9%)	1 (1.7%)
	TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
Nervous System	TOTAL	7 (29.2%)	20 (58.8%)	27 (46.6%)
	NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
	HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
	HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
	MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	PSYCHOSIS	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
	VERTIGO	0	1 (2.9%)	1 (1.7%)
Respiratory System	TOTAL	5 (20.8%)	10 (29.4%)	15 (25.9%)
	RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)

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Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
Respiratory System	RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
	PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
	SINUSITIS	3 (12.5%)	1 (2.9%)	4 (6.9%)
	COUGH INCREASED	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ASTHMA	1 (4.2%)	0	1 (1.7%)
Special Senses	TOTAL	5 (20.8%)	4 (11.8%)	9 (15.5%)
	OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	EAR PAIN	2 (8.3%)	1 (2.9%)	3 (5.2%)
	OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
Cardiovascular System	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
	HAEMATOMA	1 (4.2%)	0	1 (1.7%)
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0	1 (1.7%)
	ANEMIA	1 (4.2%)	0	1 (1.7%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.7%)
	MYALGIA	1 (4.2%)	0	1 (1.7%)
Skin and Appendages	TOTAL	1 (4.2%)	4 (11.8%)	5 (8.6%)
	CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
	RASH	0	2 (5.9%)	2 (3.4%)
	MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
	FUNGAL DERMATITIS	0	1 (2.9%)	1 (1.7%)
	HERPES SIMPLEX	0	1 (2.9%)	1 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

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Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
Urogenital System	TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
	DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	39 (79.6%)	55 (78.6%)	94 (79.0%)
Body as a Whole	TOTAL	25 (51.0%)	31 (44.3%)	56 (47.1%)
	HEADACHE	15 (30.6%)	10 (14.3%)	25 (21.0%)
	INFECTION	7 (14.3%)	12 (17.1%)	19 (16.0%)
	ABDOMINAL PAIN	9 (18.4%)	8 (11.4%)	17 (14.3%)
	TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
	FEVER	9 (18.4%)	3 (4.3%)	12 (10.1%)
	ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
	BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
	PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ASTHENIA	0	2 (2.9%)	2 (1.7%)
	ABSCESS	1 (2.0%)	0	1 (0.8%)
	FACE EDEMA	1 (2.0%)	0	1 (0.8%)
Digestive System	TOTAL	18 (36.7%)	20 (28.6%)	38 (31.9%)
	NAUSEA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
	VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
	DIARRHEA	4 (8.2%)	2 (2.9%)	6 (5.0%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	INCREASED APPETITE	2 (4.1%)	0	2 (1.7%)
	GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	STOMATITIS	1 (2.0%)	0	1 (0.8%)
	FECAL INCONTINENCE	0	1 (1.4%)	1 (0.8%)
	FLATULENCE	0	1 (1.4%)	1 (0.8%)
	GINGIVITIS	0	1 (1.4%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	18 (36.7%)	33 (47.1%)	51 (42.9%)
	NERVOUSNESS	5 (10.2%)	9 (12.9%)	14 (11.8%)
	HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	HOSTILITY	4 (8.2%)	6 (8.6%)	10 (8.4%)
	INSOMNIA	3 (6.1%)	5 (7.1%)	8 (6.7%)
	ANXIETY	2 (4.1%)	3 (4.3%)	5 (4.2%)
	DEPRESSION	3 (6.1%)	1 (1.4%)	4 (3.4%)
	AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
	DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
	CONCENTRATION IMPAIRED	1 (2.0%)	2 (2.9%)	3 (2.5%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Nervous System	MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
	WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	EUPHORIA	0	1 (1.4%)	1 (0.8%)
	HYSTERIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
	PARALYSIS	0	1 (1.4%)	1 (0.8%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.8%)
	VERTIGO	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	18 (36.7%)	23 (32.9%)	41 (34.5%)
	RESPIRATORY DISORDER	10 (20.4%)	13 (18.6%)	23 (19.3%)
	PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
	RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
	SINUSITIS	5 (10.2%)	2 (2.9%)	7 (5.9%)
	COUGH INCREASED	3 (6.1%)	3 (4.3%)	6 (5.0%)
	ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	EPISTAXIS	0	2 (2.9%)	2 (1.7%)
	BRONCHITIS	0	1 (1.4%)	1 (0.8%)
	PNEUMONIA	0	1 (1.4%)	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Skin and Appendages	TOTAL	7 (14.3%)	8 (11.4%)	15 (12.6%)
	CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
	RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
	ACNE	2 (4.1%)	0	2 (1.7%)
	MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
	FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.8%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.8%)
	PRURITUS	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	6 (12.2%)	6 (8.6%)	12 (10.1%)
	OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
	EAR PAIN	2 (4.1%)	1 (1.4%)	3 (2.5%)
	OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	4 (8.2%)	6 (8.6%)	10 (8.4%)
	WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)
	DEHYDRATION	0	1 (1.4%)	1 (0.8%)
	SGOT INCREASED	0	1 (1.4%)	1 (0.8%)
Musculoskeletal System	TOTAL	3 (6.1%)	1 (1.4%)	4 (3.4%)
	MYALGIA	2 (4.1%)	1 (1.4%)	3 (2.5%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
	ARTHROSIS	0	1 (1.4%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (4.1%)	2 (2.9%)	4 (3.4%)
	LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	LYMPHOCYTOSIS	0	1 (1.4%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (2.0%)	6 (8.6%)	7 (5.9%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	HAEMATOMA	1 (2.0%)	0	1 (0.8%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.4%)	1 (0.8%)
	MIGRAINE	0	1 (1.4%)	1 (0.8%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	1 (2.0%)	5 (7.1%)	6 (5.0%)
	URINARY INCONTINENCE	1 (2.0%)	4 (5.7%)	5 (4.2%)
	ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
	CYSTITIS	0	1 (1.4%)	1 (0.8%)
	HAEMATURIA	0	1 (1.4%)	1 (0.8%)
Special Searches	TOTAL	0	1 (1.4%)	1 (0.8%)
	PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
Urogenital System	TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
	DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	18 (72.0%)	19 (63.3%)	37 (67.3%)
Body as a Whole	TOTAL	11 (44.0%)	10 (33.3%)	21 (38.2%)
	HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
	TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
	INFECTION	2 (8.0%)	3 (10.0%)	5 (9.1%)
	ASTHENIA	0	3 (10.0%)	3 (5.5%)
	ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
	BACK PAIN	2 (8.0%)	0	2 (3.6%)
	ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
	CHEST PAIN	1 (4.0%)	0	1 (1.8%)
	FEVER	0	1 (3.3%)	1 (1.8%)
	PAIN	0	1 (3.3%)	1 (1.8%)
Nervous System	TOTAL	9 (36.0%)	11 (36.7%)	20 (36.4%)
	SOMNOLENCE	3 (12.0%)	3 (10.0%)	6 (10.9%)
	EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
	NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
	DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HOSTILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (3.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.8%)
	LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
	VERTIGO	1 (4.0%)	0	1 (1.8%)
	ANXIETY	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
Respiratory System	TOTAL	8 (32.0%)	10 (33.3%)	18 (32.7%)
	RESPIRATORY DISORDER	4 (16.0%)	8 (26.7%)	12 (21.8%)
	ASTHMA	2 (8.0%)	2 (6.7%)	4 (7.3%)
	BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
	SINUSITIS	2 (8.0%)	0	2 (3.6%)
	PHARYNGITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	6 (24.0%)	7 (23.3%)	13 (23.6%)
	NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
	DIARRHEA	2 (8.0%)	1 (3.3%)	3 (5.5%)
	DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
Digestive System	VOMITING	2 (8.0%)	0	2 (3.6%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DRY MOUTH	1 (4.0%)	0	1 (1.8%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.8%)
	TOOTH CARIES	0	1 (3.3%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	3 (12.0%)	3 (10.0%)	6 (10.9%)
	WEIGHT GAIN	2 (8.0%)	3 (10.0%)	5 (9.1%)
	WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	2 (8.0%)	0	2 (3.6%)
	LEUKOPENIA	2 (8.0%)	0	2 (3.6%)
Special Senses	TOTAL	1 (4.0%)	0	1 (1.8%)
	OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HAEMATURIA	0	1 (3.3%)	1 (1.8%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.8%)
	SYNCOPE	0	1 (3.3%)	1 (1.8%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.8%)
	MYALGIA	0	1 (3.3%)	1 (1.8%)
Skin and Appendages	TOTAL	0	2 (6.7%)	2 (3.6%)
	ACNE	0	1 (3.3%)	1 (1.8%)
	PRURITUS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (13.3%)	2 (8.3%)
Urogenital System	TOTAL	0	2 (13.3%)	2 (8.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	15 (75.0%)	18 (66.7%)	33 (70.2%)
Body as a Whole	TOTAL	11 (55.0%)	12 (44.4%)	23 (48.9%)
	HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
	INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
	ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
	ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
	TRAUMA	0	2 (7.4%)	2 (4.3%)
	ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
	PAIN	1 (5.0%)	0	1 (2.1%)
	BACK PAIN	0	1 (3.7%)	1 (2.1%)
	FEVER	0	1 (3.7%)	1 (2.1%)
Nervous System	TOTAL	8 (40.0%)	9 (33.3%)	17 (36.2%)
	INSOMNIA	2 (10.0%)	4 (14.8%)	6 (12.8%)
	HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
	NEUROSIS	3 (15.0%)	0	3 (6.4%)
	ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	AGITATION	0	2 (7.4%)	2 (4.3%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	PARESTHESIA	1 (5.0%)	0	1 (2.1%)
	SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
	THINKING ABNORMAL	1 (5.0%)	0	1 (2.1%)
	ABNORMAL DREAMS	0	1 (3.7%)	1 (2.1%)
	DEPRESSION	0	1 (3.7%)	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	8 (40.0%)	8 (29.6%)	16 (34.0%)
	RESPIRATORY DISORDER	3 (15.0%)	5 (18.5%)	8 (17.0%)
	SINUSITIS	3 (15.0%)	0	3 (6.4%)
	ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EPISTAXIS	0	1 (3.7%)	1 (2.1%)
	PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
	PNEUMONIA	0	1 (3.7%)	1 (2.1%)
Urogenital System	TOTAL	3 (15.0%)	0	3 (6.4%)
	ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
	DYSURIA	1 (5.0%)	0	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
Urogenital System	HAEMATURIA	1 (5.0%)	0	1 (2.1%)
Digestive System	TOTAL	2 (10.0%)	10 (37.0%)	12 (25.5%)
	NAUSEA	0	5 (18.5%)	5 (10.6%)
	DIARRHEA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.7%)	1 (2.1%)
	ULCERATIVE STOMATITIS	0	1 (3.7%)	1 (2.1%)
	VOMITING	0	1 (3.7%)	1 (2.1%)
Musculoskeletal System	TOTAL	2 (10.0%)	1 (3.7%)	3 (6.4%)
	ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
Special Senses	TOTAL	2 (10.0%)	2 (7.4%)	4 (8.5%)
	BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
	EYE PAIN	1 (5.0%)	0	1 (2.1%)
	ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
	OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
Cardiovascular System	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	BRADYCARDIA	1 (5.0%)	0	1 (2.1%)
	SYNCOPE	0	1 (3.7%)	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	1 (5.0%)	4 (14.8%)	5 (10.6%)
	ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
	CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
	RASH	0	1 (3.7%)	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
	URTICARIA	0	1 (3.7%)	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	2 (7.4%)	2 (4.3%)
	EOSINOPHILIA	0	1 (3.7%)	1 (2.1%)
	LEUKOCYTOSIS	0	1 (3.7%)	1 (2.1%)
	MONOCYTOSIS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	0	2 (11.1%)
Urogenital System	TOTAL	2 (22.2%)	0	2 (11.1%)
	DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	33 (73.3%)	37 (64.9%)	70 (68.6%)
Body as a Whole	TOTAL	22 (48.9%)	22 (38.6%)	44 (43.1%)
	HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
	INFECTION	6 (13.3%)	6 (10.5%)	12 (11.8%)
	ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
	ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
	TRAUMA	4 (8.9%)	4 (7.0%)	8 (7.8%)
	ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
	BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
	PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
	FEVER	0	2 (3.5%)	2 (2.0%)
	ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
	CHEST PAIN	1 (2.2%)	0	1 (1.0%)
Nervous System	TOTAL	17 (37.8%)	20 (35.1%)	37 (36.3%)
	INSOMNIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
	SOMNOLENCE	4 (8.9%)	3 (5.3%)	7 (6.9%)
	EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
	NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
	HOSTILITY	2 (4.4%)	4 (7.0%)	6 (5.9%)
	DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
	NEUROSIS	3 (6.7%)	0	3 (2.9%)
	ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
	DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	WITHDRAWAL SYNDROME	0	2 (3.5%)	2 (2.0%)
	LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	PARESTHESIA	1 (2.2%)	0	1 (1.0%)
	THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
	VERTIGO	1 (2.2%)	0	1 (1.0%)
	ABNORMAL DREAMS	0	1 (1.8%)	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	16 (35.6%)	18 (31.6%)	34 (33.3%)
	RESPIRATORY DISORDER	7 (15.6%)	13 (22.8%)	20 (19.6%)
	ASTHMA	3 (6.7%)	4 (7.0%)	7 (6.9%)
	SINUSITIS	5 (11.1%)	0	5 (4.9%)
	RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Respiratory System	BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	PHARYNGITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
	EPISTAXIS	0	1 (1.8%)	1 (1.0%)
	PNEUMONIA	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	8 (17.8%)	17 (29.8%)	25 (24.5%)
	NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
	DIARRHEA	3 (6.7%)	3 (5.3%)	6 (5.9%)
	DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	VOMITING	2 (4.4%)	1 (1.8%)	3 (2.9%)
	DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
	INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
	TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	GASTROINTESTINAL DISORDER	0	1 (1.8%)	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.8%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.9%)	4 (7.0%)	8 (7.8%)
	WEIGHT GAIN	3 (6.7%)	3 (5.3%)	6 (5.9%)
	WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
Urogenital System	TOTAL	4 (8.9%)	1 (1.8%)	5 (4.9%)
	ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
	HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	DYSURIA	1 (2.2%)	0	1 (1.0%)
Special Senses	TOTAL	3 (6.7%)	2 (3.5%)	5 (4.9%)
	OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
	EYE PAIN	1 (2.2%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	2 (4.4%)	2 (3.5%)	4 (3.9%)
	LEUKOPENIA	2 (4.4%)	0	2 (2.0%)
	EOSINOPHILIA	0	1 (1.8%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.8%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Musculoskeletal System	TOTAL	2 (4.4%)	2 (3.5%)	4 (3.9%)
	ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
	MYALGIA	0	1 (1.8%)	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.2%)	2 (3.5%)	3 (2.9%)
	SYNCOPE	0	2 (3.5%)	2 (2.0%)
	BRADYCARDIA	1 (2.2%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.2%)	6 (10.5%)	7 (6.9%)
	ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
	CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
	PRURITUS	0	1 (1.8%)	1 (1.0%)
	RASH	0	1 (1.8%)	1 (1.0%)
	SWEATING	0	1 (1.8%)	1 (1.0%)
	URTICARIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
Urogenital System	TOTAL	2 (11.1%)	2 (8.3%)	4 (9.5%)
	DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	38 (76.0%)	45 (68.2%)	83 (71.6%)
Body as a Whole	TOTAL	23 (46.0%)	25 (37.9%)	48 (41.4%)
	HEADACHE	11 (22.0%)	10 (15.2%)	21 (18.1%)
	INFECTION	6 (12.0%)	12 (18.2%)	18 (15.5%)
	TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
	ABDOMINAL PAIN	8 (16.0%)	4 (6.1%)	12 (10.3%)
	FEVER	5 (10.0%)	3 (4.5%)	8 (6.9%)
	ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
	BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ASTHENIA	0	5 (7.6%)	5 (4.3%)
	PAIN	0	2 (3.0%)	2 (1.7%)
	CHEST PAIN	1 (2.0%)	0	1 (0.9%)
	FACE EDEMA	1 (2.0%)	0	1 (0.9%)
Respiratory System	TOTAL	21 (42.0%)	23 (34.8%)	44 (37.9%)
	RESPIRATORY DISORDER	13 (26.0%)	14 (21.2%)	27 (23.3%)
	PHARYNGITIS	5 (10.0%)	5 (7.6%)	10 (8.6%)
	RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
	SINUSITIS	4 (8.0%)	1 (1.5%)	5 (4.3%)
	ASTHMA	2 (4.0%)	3 (4.5%)	5 (4.3%)
	BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
	COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EPISTAXIS	0	2 (3.0%)	2 (1.7%)
	PNEUMONIA	0	1 (1.5%)	1 (0.9%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	20 (40.0%)	24 (36.4%)	44 (37.9%)
	NERVOUSNESS	6 (12.0%)	1 (1.5%)	7 (6.0%)
	HOSTILITY	4 (8.0%)	3 (4.5%)	7 (6.0%)
	SOMNOLENCE	3 (6.0%)	4 (6.1%)	7 (6.0%)
	INSOMNIA	2 (4.0%)	5 (7.6%)	7 (6.0%)
	EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
	DEPRESSION	4 (8.0%)	1 (1.5%)	5 (4.3%)
	AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ANXIETY	1 (2.0%)	2 (3.0%)	3 (2.6%)
	DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	WITHDRAWAL SYNDROME	1 (2.0%)	2 (3.0%)	3 (2.6%)
	CONCENTRATION IMPAIRED	0	3 (4.5%)	3 (2.6%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Nervous System	VERTIGO	1 (2.0%)	0	1 (0.9%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
	EUPHORIA	0	1 (1.5%)	1 (0.9%)
	HYSTERIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	17 (34.0%)	21 (31.8%)	38 (32.8%)
	NAUSEA	7 (14.0%)	6 (9.1%)	13 (11.2%)
	VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
	DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
	DIARRHEA	4 (8.0%)	3 (4.5%)	7 (6.0%)
	INCREASED APPETITE	2 (4.0%)	2 (3.0%)	4 (3.4%)
	DRY MOUTH	3 (6.0%)	0	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	STOMATITIS	1 (2.0%)	0	1 (0.9%)
	FECAL INCONTINENCE	0	1 (1.5%)	1 (0.9%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	7 (14.0%)	8 (12.1%)	15 (12.9%)
	WEIGHT GAIN	6 (12.0%)	6 (9.1%)	12 (10.3%)
	WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
	DEHYDRATION	0	1 (1.5%)	1 (0.9%)
	SGOT INCREASED	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	6 (12.0%)	6 (9.1%)	12 (10.3%)
	ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
	CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
	RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
	PRURITUS	0	2 (3.0%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	3 (6.0%)	2 (3.0%)	5 (4.3%)
	LEUKOPENIA	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ANEMIA	0	1 (1.5%)	1 (0.9%)
	LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Musculoskeletal System	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	MYALGIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
	ARTHROSIS	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
Urogenital System	TOTAL	2 (4.0%)	5 (7.6%)	7 (6.0%)
	URINARY INCONTINENCE	1 (2.0%)	3 (4.5%)	4 (3.4%)
	ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HAEMATURIA	0	2 (3.0%)	2 (1.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	4 (6.1%)	4 (3.4%)
	SYNCOPE	0	2 (3.0%)	2 (1.7%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.9%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (6.9%)	2 (3.8%)
Urogenital System	TOTAL	0	2 (6.9%)	2 (3.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	TOTAL	34 (77.3%)	47 (77.0%)	81 (77.1%)
Body as a Whole	TOTAL	24 (54.5%)	28 (45.9%)	52 (49.5%)
	HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
	INFECTION	7 (15.9%)	6 (9.8%)	13 (12.4%)
	ABDOMINAL PAIN	3 (6.8%)	8 (13.1%)	11 (10.5%)
	TRAUMA	4 (9.1%)	5 (8.2%)	9 (8.6%)
	ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
	FEVER	4 (9.1%)	2 (3.3%)	6 (5.7%)
	ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
	ABSCESS	1 (2.3%)	0	1 (1.0%)
Nervous System	TOTAL	15 (34.1%)	29 (47.5%)	44 (41.9%)
	NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
	HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
	INSOMNIA	4 (9.1%)	6 (9.8%)	10 (9.5%)
	HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
	ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
	NEUROSIS	4 (9.1%)	0	4 (3.8%)
	SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
	AGITATION	0	3 (4.9%)	3 (2.9%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	PARESTHESIA	1 (2.3%)	0	1 (1.0%)
	THINKING ABNORMAL	1 (2.3%)	0	1 (1.0%)
	ABNORMAL DREAMS	0	1 (1.6%)	1 (1.0%)
	DEPRESSION	0	1 (1.6%)	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
	VERTIGO	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	13 (29.5%)	18 (29.5%)	31 (29.5%)
	RESPIRATORY DISORDER	4 (9.1%)	12 (19.7%)	16 (15.2%)
	RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
	SINUSITIS	6 (13.6%)	1 (1.6%)	7 (6.7%)
	PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Respiratory System	ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	COUGH INCREASED	2 (4.5%)	2 (3.3%)	4 (3.8%)
	EPISTAXIS	0	1 (1.6%)	1 (1.0%)
	PNEUMONIA	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	9 (20.5%)	16 (26.2%)	25 (23.8%)
	NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DIARRHEA	3 (6.8%)	2 (3.3%)	5 (4.8%)
	DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	FLATULENCE	0	2 (3.3%)	2 (1.9%)
	TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
	GINGIVITIS	0	1 (1.6%)	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.6%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (1.0%)
	VOMITING	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	7 (15.9%)	6 (9.8%)	13 (12.4%)
	OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
	EAR PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
	EYE PAIN	1 (2.3%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	MYALGIA	1 (2.3%)	0	1 (1.0%)
Urogenital System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
	DYSURIA	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	1 (2.3%)	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	2 (4.5%)	4 (6.6%)	6 (5.7%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
	HAEMATOMA	1 (2.3%)	0	1 (1.0%)
	SYNCOPE	0	1 (1.6%)	1 (1.0%)

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Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Skin and Appendages	TOTAL	2 (4.5%)	8 (13.1%)	10 (9.5%)
	ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
	CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)
	RASH	0	3 (4.9%)	3 (2.9%)
	MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
	URTICARIA	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ANEMIA	1 (2.3%)	0	1 (1.0%)
	EOSINOPHILIA	0	1 (1.6%)	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
Urogenital System	TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
	DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	72 (76.6%)	92 (72.4%)	164 (74.2%)
Body as a Whole	TOTAL	47 (50.0%)	53 (41.7%)	100 (45.2%)
	HEADACHE	26 (27.7%)	24 (18.9%)	50 (22.6%)
	INFECTION	13 (13.8%)	18 (14.2%)	31 (14.0%)
	TRAUMA	12 (12.8%)	11 (8.7%)	23 (10.4%)
	ABDOMINAL PAIN	11 (11.7%)	12 (9.4%)	23 (10.4%)
	FEVER	9 (9.6%)	5 (3.9%)	14 (6.3%)
	ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
	ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
	BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
	PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
	ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	CHEST PAIN	1 (1.1%)	0	1 (0.5%)
	FACE EDEMA	1 (1.1%)	0	1 (0.5%)
Nervous System	TOTAL	35 (37.2%)	53 (41.7%)	88 (39.8%)
	NERVOUSNESS	8 (8.5%)	13 (10.2%)	21 (9.5%)
	INSOMNIA	6 (6.4%)	11 (8.7%)	17 (7.7%)
	HOSTILITY	6 (6.4%)	10 (7.9%)	16 (7.2%)
	HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
	SOMNOLENCE	5 (5.3%)	5 (3.9%)	10 (4.5%)
	EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
	ANXIETY	3 (3.2%)	5 (3.9%)	8 (3.6%)
	DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
	AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
	DEPRESSION	4 (4.3%)	2 (1.6%)	6 (2.7%)
	NEUROSIS	4 (4.3%)	0	4 (1.8%)
	CONCENTRATION IMPAIRED	1 (1.1%)	3 (2.4%)	4 (1.8%)
	HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	WITHDRAWAL SYNDROME	1 (1.1%)	2 (1.6%)	3 (1.4%)
	TREMOR	0	3 (2.4%)	3 (1.4%)
	LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
	HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	PARESTHESIA	1 (1.1%)	0	1 (0.5%)
	THINKING ABNORMAL	1 (1.1%)	0	1 (0.5%)
	VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
	ABNORMAL DREAMS	0	1 (0.8%)	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Nervous System	EUPHORIA	0	1 (0.8%)	1 (0.5%)
	HYSTERIA	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	PARALYSIS	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	34 (36.2%)	41 (32.3%)	75 (33.9%)
	RESPIRATORY DISORDER	17 (18.1%)	26 (20.5%)	43 (19.5%)
	PHARYNGITIS	7 (7.4%)	9 (7.1%)	16 (7.2%)
	RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
	SINUSITIS	10 (10.6%)	2 (1.6%)	12 (5.4%)
	ASTHMA	4 (4.3%)	5 (3.9%)	9 (4.1%)
	COUGH INCREASED	3 (3.2%)	4 (3.1%)	7 (3.2%)
	BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EPISTAXIS	0	3 (2.4%)	3 (1.4%)
	PNEUMONIA	0	2 (1.6%)	2 (0.9%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	26 (27.7%)	37 (29.1%)	63 (28.5%)
	NAUSEA	11 (11.7%)	12 (9.4%)	23 (10.4%)
	DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
	DIARRHEA	7 (7.4%)	5 (3.9%)	12 (5.4%)
	VOMITING	6 (6.4%)	5 (3.9%)	11 (5.0%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
	INCREASED APPETITE	2 (2.1%)	2 (1.6%)	4 (1.8%)
	TOOTH CARIES	0	4 (3.1%)	4 (1.8%)
	CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FLATULENCE	0	2 (1.6%)	2 (0.9%)
	GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	2 (1.6%)	2 (0.9%)
	STOMATITIS	1 (1.1%)	0	1 (0.5%)
	TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
	FECAL INCONTINENCE	0	1 (0.8%)	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	GINGIVITIS	0	1 (0.8%)	1 (0.5%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	9 (9.6%)	8 (6.3%)	17 (7.7%)
	OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
	EAR PAIN	2 (2.1%)	1 (0.8%)	3 (1.4%)
	OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
	BLEPHARITIS	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Special Senses	EYE PAIN	1 (1.1%)	0	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	8 (8.5%)	10 (7.9%)	18 (8.1%)
	WEIGHT GAIN	7 (7.4%)	7 (5.5%)	14 (6.3%)
	WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEHYDRATION	0	1 (0.8%)	1 (0.5%)
	SGOT INCREASED	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	8 (8.5%)	14 (11.0%)	22 (10.0%)
	ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
	CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)
	RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
	MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PRURITUS	0	2 (1.6%)	2 (0.9%)
	HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
	FUNGAL DERMATITIS	0	1 (0.8%)	1 (0.5%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.5%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
	URTICARIA	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	5 (5.3%)	3 (2.4%)	8 (3.6%)
	ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
	MYALGIA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ARTHROSIS	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	5 (5.3%)	6 (4.7%)	11 (5.0%)
	ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	URINARY INCONTINENCE	1 (1.1%)	4 (3.1%)	5 (2.3%)
	HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DYSURIA	1 (1.1%)	0	1 (0.5%)
	CYSTITIS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	4 (4.3%)	4 (3.1%)	8 (3.6%)
	LEUKOPENIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.5%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.5%)
	LYMPHOCYTOSIS	0	1 (0.8%)	1 (0.5%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	2 (2.1%)	8 (6.3%)	10 (4.5%)
	SYNCOPE	0	3 (2.4%)	3 (1.4%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Cardiovascular System	BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
	HAEMATOMA	1 (1.1%)	0	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.5%)
	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
Urogenital System	TOTAL	3 (6.7%)	3 (6.0%)	6 (6.3%)
	DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	20 (80.0%)	26 (72.2%)	46 (75.4%)
RESPIRATORY DISORDER	9 (36.0%)	6 (16.7%)	15 (24.6%)
INFECTION	4 (16.0%)	9 (25.0%)	13 (21.3%)
HEADACHE	7 (28.0%)	4 (11.1%)	11 (18.0%)
ABDOMINAL PAIN	7 (28.0%)	3 (8.3%)	10 (16.4%)
PHARYNGITIS	4 (16.0%)	4 (11.1%)	8 (13.1%)
TRAUMA	4 (16.0%)	4 (11.1%)	8 (13.1%)
VOMITING	4 (16.0%)	4 (11.1%)	8 (13.1%)
FEVER	5 (20.0%)	2 (5.6%)	7 (11.5%)
WEIGHT GAIN	4 (16.0%)	3 (8.3%)	7 (11.5%)
DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
NAUSEA	2 (8.0%)	4 (11.1%)	6 (9.8%)
HOSTILITY	3 (12.0%)	2 (5.6%)	5 (8.2%)
RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
NERVOUSNESS	4 (16.0%)	0	4 (6.6%)
DEPRESSION	3 (12.0%)	1 (2.8%)	4 (6.6%)
ALLERGIC REACTION	2 (8.0%)	2 (5.6%)	4 (6.6%)
DIARRHEA	2 (8.0%)	2 (5.6%)	4 (6.6%)
INSOMNIA	1 (4.0%)	3 (8.3%)	4 (6.6%)
URINARY INCONTINENCE	1 (4.0%)	3 (8.3%)	4 (6.6%)
CONTACT DERMATITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
SINUSITIS	2 (8.0%)	1 (2.8%)	3 (4.9%)
AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
LEUKOPENIA	1 (4.0%)	2 (5.6%)	3 (4.9%)
RASH	1 (4.0%)	2 (5.6%)	3 (4.9%)
BACK PAIN	0	3 (8.3%)	3 (4.9%)
ACNE	2 (8.0%)	0	2 (3.3%)
DRY MOUTH	2 (8.0%)	0	2 (3.3%)
INCREASED APPETITE	2 (8.0%)	0	2 (3.3%)
ANXIETY	1 (4.0%)	1 (2.8%)	2 (3.3%)
COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
HALLUCINATIONS	1 (4.0%)	1 (2.8%)	2 (3.3%)
HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
MYALGIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
OTITIS MEDIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
ASTHENIA	0	2 (5.6%)	2 (3.3%)
CONCENTRATION IMPAIRED	0	2 (5.6%)	2 (3.3%)
EPISTAXIS	0	2 (5.6%)	2 (3.3%)
HYPESTHESIA	0	2 (5.6%)	2 (3.3%)
TOOTH CARIES	0	2 (5.6%)	2 (3.3%)
ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
CONSTIPATION	1 (4.0%)	0	1 (1.6%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
FACE EDEMA	1 (4.0%)	0	1 (1.6%)
HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
STOMATITIS	1 (4.0%)	0	1 (1.6%)
VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
WITHDRAWAL SYNDROME	1 (4.0%)	0	1 (1.6%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
ANEMIA	0	1 (2.8%)	1 (1.6%)
ASTHMA	0	1 (2.8%)	1 (1.6%)
BRONCHITIS	0	1 (2.8%)	1 (1.6%)
DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
HAEMATURIA	0	1 (2.8%)	1 (1.6%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.6%)
MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
PAIN	0	1 (2.8%)	1 (1.6%)
PNEUMONIA	0	1 (2.8%)	1 (1.6%)
PRURITUS	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
SYNCOPE	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
TOTAL	19 (79.2%)	27 (79.4%)	46 (79.3%)
HEADACHE	8 (33.3%)	6 (17.6%)	14 (24.1%)
NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
RESPIRATORY DISORDER	1 (4.2%)	7 (20.6%)	8 (13.8%)
TRAUMA	4 (16.7%)	3 (8.8%)	7 (12.1%)
ABDOMINAL PAIN	2 (8.3%)	5 (14.7%)	7 (12.1%)
INFECTION	3 (12.5%)	3 (8.8%)	6 (10.3%)
RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
FEVER	4 (16.7%)	1 (2.9%)	5 (8.6%)
NAUSEA	4 (16.7%)	1 (2.9%)	5 (8.6%)
PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
HOSTILITY	1 (4.2%)	4 (11.8%)	5 (8.6%)
SINUSITIS	3 (12.5%)	1 (2.9%)	4 (6.9%)
COUGH INCREASED	2 (8.3%)	2 (5.9%)	4 (6.9%)
DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
OTITIS MEDIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
DYSPEPSIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
EAR PAIN	2 (8.3%)	1 (2.9%)	3 (5.2%)
OTITIS EXTERNA	2 (8.3%)	1 (2.9%)	3 (5.2%)
ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
DIZZINESS	1 (4.2%)	2 (5.9%)	3 (5.2%)
VASODILATATION	0	3 (8.8%)	3 (5.2%)
DIARRHEA	2 (8.3%)	0	2 (3.4%)
MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
CONTACT DERMATITIS	0	2 (5.9%)	2 (3.4%)
RASH	0	2 (5.9%)	2 (3.4%)
ABSCESS	1 (4.2%)	0	1 (1.7%)
ANEMIA	1 (4.2%)	0	1 (1.7%)
ASTHMA	1 (4.2%)	0	1 (1.7%)
BACK PAIN	1 (4.2%)	0	1 (1.7%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
HAEMATOMA	1 (4.2%)	0	1 (1.7%)
MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
MYALGIA	1 (4.2%)	0	1 (1.7%)
NEUROSIS	1 (4.2%)	0	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
FLATULENCE	0	1 (2.9%)	1 (1.7%)
GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
MANIC REACTION	0	1 (2.9%)	1 (1.7%)
TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
TREMOR	0	1 (2.9%)	1 (1.7%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)
VERTIGO	0	1 (2.9%)	1 (1.7%)
WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	1 (7.7%)	1 (8.3%)	2 (8.0%)
DYSMENORRHEA	1 (7.7%)	1 (8.3%)	2 (8.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	39 (79.6%)	53 (75.7%)	92 (77.3%)
HEADACHE	15 (30.6%)	10 (14.3%)	25 (21.0%)
RESPIRATORY DISORDER	10 (20.4%)	13 (18.6%)	23 (19.3%)
INFECTION	7 (14.3%)	12 (17.1%)	19 (16.0%)
ABDOMINAL PAIN	9 (18.4%)	8 (11.4%)	17 (14.3%)
TRAUMA	8 (16.3%)	7 (10.0%)	15 (12.6%)
NERVOUSNESS	5 (10.2%)	9 (12.9%)	14 (11.8%)
PHARYNGITIS	6 (12.2%)	7 (10.0%)	13 (10.9%)
FEVER	9 (18.4%)	3 (4.3%)	12 (10.1%)
HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
NAUSEA	6 (12.2%)	5 (7.1%)	11 (9.2%)
RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
HOSTILITY	4 (8.2%)	6 (8.6%)	10 (8.4%)
DYSPEPSIA	5 (10.2%)	4 (5.7%)	9 (7.6%)
VOMITING	4 (8.2%)	4 (5.7%)	8 (6.7%)
WEIGHT GAIN	4 (8.2%)	4 (5.7%)	8 (6.7%)
INSOMNIA	3 (6.1%)	5 (7.1%)	8 (6.7%)
SINUSITIS	5 (10.2%)	2 (2.9%)	7 (5.9%)
DIARRHEA	4 (8.2%)	2 (2.9%)	6 (5.0%)
COUGH INCREASED	3 (6.1%)	3 (4.3%)	6 (5.0%)
OTITIS MEDIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
ALLERGIC REACTION	2 (4.1%)	3 (4.3%)	5 (4.2%)
ANXIETY	2 (4.1%)	3 (4.3%)	5 (4.2%)
CONTACT DERMATITIS	2 (4.1%)	3 (4.3%)	5 (4.2%)
DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
RASH	1 (2.0%)	4 (5.7%)	5 (4.2%)
URINARY INCONTINENCE	1 (2.0%)	4 (5.7%)	5 (4.2%)
DEPRESSION	3 (6.1%)	1 (1.4%)	4 (3.4%)
AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
DIZZINESS	1 (2.0%)	3 (4.3%)	4 (3.4%)
EAR PAIN	2 (4.1%)	1 (1.4%)	3 (2.5%)
MYALGIA	2 (4.1%)	1 (1.4%)	3 (2.5%)
OTITIS EXTERNA	2 (4.1%)	1 (1.4%)	3 (2.5%)
CONCENTRATION IMPAIRED	1 (2.0%)	2 (2.9%)	3 (2.5%)
LEUKOPENIA	1 (2.0%)	2 (2.9%)	3 (2.5%)
PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
TOOTH CARIES	0	3 (4.3%)	3 (2.5%)
VASODILATATION	0	3 (4.3%)	3 (2.5%)
ACNE	2 (4.1%)	0	2 (1.7%)
DRY MOUTH	2 (4.1%)	0	2 (1.7%)
INCREASED APPETITE	2 (4.1%)	0	2 (1.7%)
ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=49)	 Placebo (N=70)	 Total (N=119)
ASTHMA	1 (2.0%)	1 (1.4%)	2 (1.7%)
HALLUCINATIONS	1 (2.0%)	1 (1.4%)	2 (1.7%)
MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHENIA	0	2 (2.9%)	2 (1.7%)
EPISTAXIS	0	2 (2.9%)	2 (1.7%)
GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
HYPESTHESIA	0	2 (2.9%)	2 (1.7%)
TREMOR	0	2 (2.9%)	2 (1.7%)
ABSCESS	1 (2.0%)	0	1 (0.8%)
ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
CONSTIPATION	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
FACE EDEMA	1 (2.0%)	0	1 (0.8%)
HAEMATOMA	1 (2.0%)	0	1 (0.8%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
NEUROSIS	1 (2.0%)	0	1 (0.8%)
STOMATITIS	1 (2.0%)	0	1 (0.8%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
BRONCHITIS	0	1 (1.4%)	1 (0.8%)
FLATULENCE	0	1 (1.4%)	1 (0.8%)
HAEMATURIA	0	1 (1.4%)	1 (0.8%)
LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
MANIC REACTION	0	1 (1.4%)	1 (0.8%)
PNEUMONIA	0	1 (1.4%)	1 (0.8%)
PRURITUS	0	1 (1.4%)	1 (0.8%)
SYNCOPE	0	1 (1.4%)	1 (0.8%)
VERTIGO	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
TOTAL	1 (3.7%)	1 (3.8%)	2 (3.8%)
DYSMENORRHEA	1 (3.7%)	1 (3.8%)	2 (3.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
TOTAL	18 (72.0%)	18 (60.0%)	36 (65.5%)
RESPIRATORY DISORDER	4 (16.0%)	8 (26.7%)	12 (21.8%)
HEADACHE	4 (16.0%)	6 (20.0%)	10 (18.2%)
NAUSEA	5 (20.0%)	2 (6.7%)	7 (12.7%)
TRAUMA	4 (16.0%)	2 (6.7%)	6 (10.9%)
SOMNOLENCE	3 (12.0%)	3 (10.0%)	6 (10.9%)
EMOTIONAL LABILITY	2 (8.0%)	3 (10.0%)	5 (9.1%)
INFECTION	2 (8.0%)	3 (10.0%)	5 (9.1%)
WEIGHT GAIN	2 (8.0%)	3 (10.0%)	5 (9.1%)
ASTHMA	2 (8.0%)	2 (6.7%)	4 (7.3%)
DIARRHEA	2 (8.0%)	1 (3.3%)	3 (5.5%)
DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
ASTHENIA	0	3 (10.0%)	3 (5.5%)
ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
BACK PAIN	2 (8.0%)	0	2 (3.6%)
LEUKOPENIA	2 (8.0%)	0	2 (3.6%)
SINUSITIS	2 (8.0%)	0	2 (3.6%)
VOMITING	2 (8.0%)	0	2 (3.6%)
ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
AGITATION	1 (4.0%)	1 (3.3%)	2 (3.6%)
ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
HOSTILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
PHARYNGITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (3.6%)
CHEST PAIN	1 (4.0%)	0	1 (1.8%)
DEPRESSION	1 (4.0%)	0	1 (1.8%)
DRY MOUTH	1 (4.0%)	0	1 (1.8%)
LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
VERTIGO	1 (4.0%)	0	1 (1.8%)
WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
ACNE	0	1 (3.3%)	1 (1.8%)
ANXIETY	0	1 (3.3%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
FEVER	0	1 (3.3%)	1 (1.8%)
HAEMATURIA	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
MYALGIA	0	1 (3.3%)	1 (1.8%)
PAIN	0	1 (3.3%)	1 (1.8%)
PRURITUS	0	1 (3.3%)	1 (1.8%)
SYNCOPE	0	1 (3.3%)	1 (1.8%)
TOOTH CARIES	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
TOTAL	15 (75.0%)	18 (66.7%)	33 (70.2%)
HEADACHE	7 (35.0%)	8 (29.6%)	15 (31.9%)
RESPIRATORY DISORDER	3 (15.0%)	5 (18.5%)	8 (17.0%)
INFECTION	4 (20.0%)	3 (11.1%)	7 (14.9%)
ALLERGIC REACTION	3 (15.0%)	3 (11.1%)	6 (12.8%)
ASTHENIA	3 (15.0%)	3 (11.1%)	6 (12.8%)
INSOMNIA	2 (10.0%)	4 (14.8%)	6 (12.8%)
NAUSEA	0	5 (18.5%)	5 (10.6%)
ABDOMINAL PAIN	1 (5.0%)	3 (11.1%)	4 (8.5%)
HOSTILITY	1 (5.0%)	3 (11.1%)	4 (8.5%)
NERVOUSNESS	1 (5.0%)	3 (11.1%)	4 (8.5%)
NEUROSIS	3 (15.0%)	0	3 (6.4%)
SINUSITIS	3 (15.0%)	0	3 (6.4%)
ARTHRALGIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
ACNE	1 (5.0%)	2 (7.4%)	3 (6.4%)
ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
DIARRHEA	1 (5.0%)	2 (7.4%)	3 (6.4%)
ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
AGITATION	0	2 (7.4%)	2 (4.3%)
DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
DRY MOUTH	0	2 (7.4%)	2 (4.3%)
DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
TRAUMA	0	2 (7.4%)	2 (4.3%)
ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
BRADYCARDIA	1 (5.0%)	0	1 (2.1%)
DYSURIA	1 (5.0%)	0	1 (2.1%)
EYE PAIN	1 (5.0%)	0	1 (2.1%)
HAEMATURIA	1 (5.0%)	0	1 (2.1%)
MANIC REACTION	1 (5.0%)	0	1 (2.1%)
PAIN	1 (5.0%)	0	1 (2.1%)
PARESTHESIA	1 (5.0%)	0	1 (2.1%)
SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
THINKING ABNORMAL	1 (5.0%)	0	1 (2.1%)
TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
BACK PAIN	0	1 (3.7%)	1 (2.1%)
CONSTIPATION	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
DEPRESSION	0	1 (3.7%)	1 (2.1%)
EPISTAXIS	0	1 (3.7%)	1 (2.1%)
FEVER	0	1 (3.7%)	1 (2.1%)
FLATULENCE	0	1 (3.7%)	1 (2.1%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.7%)	1 (2.1%)
OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
PNEUMONIA	0	1 (3.7%)	1 (2.1%)
RASH	0	1 (3.7%)	1 (2.1%)
SYNCOPE	0	1 (3.7%)	1 (2.1%)
TREMOR	0	1 (3.7%)	1 (2.1%)
VOMITING	0	1 (3.7%)	1 (2.1%)
WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	2 (22.2%)	0	2 (11.1%)
DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	33 (73.3%)	36 (63.2%)	69 (67.6%)
HEADACHE	11 (24.4%)	14 (24.6%)	25 (24.5%)
RESPIRATORY DISORDER	7 (15.6%)	13 (22.8%)	20 (19.6%)
INFECTION	6 (13.3%)	6 (10.5%)	12 (11.8%)
NAUSEA	5 (11.1%)	7 (12.3%)	12 (11.8%)
ASTHENIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
INSOMNIA	3 (6.7%)	6 (10.5%)	9 (8.8%)
ALLERGIC REACTION	5 (11.1%)	3 (5.3%)	8 (7.8%)
TRAUMA	4 (8.9%)	4 (7.0%)	8 (7.8%)
SOMNOLENCE	4 (8.9%)	3 (5.3%)	7 (6.9%)
ASTHMA	3 (6.7%)	4 (7.0%)	7 (6.9%)
EMOTIONAL LABILITY	3 (6.7%)	4 (7.0%)	7 (6.9%)
NERVOUSNESS	3 (6.7%)	4 (7.0%)	7 (6.9%)
DIARRHEA	3 (6.7%)	3 (5.3%)	6 (5.9%)
WEIGHT GAIN	3 (6.7%)	3 (5.3%)	6 (5.9%)
ABDOMINAL PAIN	2 (4.4%)	4 (7.0%)	6 (5.9%)
HOSTILITY	2 (4.4%)	4 (7.0%)	6 (5.9%)
SINUSITIS	5 (11.1%)	0	5 (4.9%)
DYSPEPSIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
DIZZINESS	2 (4.4%)	2 (3.5%)	4 (3.9%)
RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
ACNE	1 (2.2%)	3 (5.3%)	4 (3.9%)
AGITATION	1 (2.2%)	3 (5.3%)	4 (3.9%)
DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
NEUROSIS	3 (6.7%)	0	3 (2.9%)
ARTHRALGIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
VOMITING	2 (4.4%)	1 (1.8%)	3 (2.9%)
ANXIETY	1 (2.2%)	2 (3.5%)	3 (2.9%)
BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
PHARYNGITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
LEUKOPENIA	2 (4.4%)	0	2 (2.0%)
DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
OTITIS MEDIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
FEVER	0	2 (3.5%)	2 (2.0%)
INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
SYNCOPE	0	2 (3.5%)	2 (2.0%)
WITHDRAWAL SYNDROME	0	2 (3.5%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
BRADYCARDIA	1 (2.2%)	0	1 (1.0%)
CHEST PAIN	1 (2.2%)	0	1 (1.0%)
DYSURIA	1 (2.2%)	0	1 (1.0%)
EYE PAIN	1 (2.2%)	0	1 (1.0%)
LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
MANIC REACTION	1 (2.2%)	0	1 (1.0%)
PARESTHESIA	1 (2.2%)	0	1 (1.0%)
THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
VERTIGO	1 (2.2%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
CONSTIPATION	0	1 (1.8%)	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
EPISTAXIS	0	1 (1.8%)	1 (1.0%)
FLATULENCE	0	1 (1.8%)	1 (1.0%)
HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)	1 (1.0%)
MYALGIA	0	1 (1.8%)	1 (1.0%)
PNEUMONIA	0	1 (1.8%)	1 (1.0%)
PRURITUS	0	1 (1.8%)	1 (1.0%)
RASH	0	1 (1.8%)	1 (1.0%)
TOOTH CARIES	0	1 (1.8%)	1 (1.0%)
TREMOR	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	2 (11.1%)	0	2 (4.8%)
DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	38 (76.0%)	44 (66.7%)	82 (70.7%)
RESPIRATORY DISORDER	13 (26.0%)	14 (21.2%)	27 (23.3%)
HEADACHE	11 (22.0%)	10 (15.2%)	21 (18.1%)
INFECTION	6 (12.0%)	12 (18.2%)	18 (15.5%)
TRAUMA	8 (16.0%)	6 (9.1%)	14 (12.1%)
NAUSEA	7 (14.0%)	6 (9.1%)	13 (11.2%)
ABDOMINAL PAIN	8 (16.0%)	4 (6.1%)	12 (10.3%)
WEIGHT GAIN	6 (12.0%)	6 (9.1%)	12 (10.3%)
VOMITING	6 (12.0%)	4 (6.1%)	10 (8.6%)
PHARYNGITIS	5 (10.0%)	5 (7.6%)	10 (8.6%)
DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
FEVER	5 (10.0%)	3 (4.5%)	8 (6.9%)
NERVOUSNESS	6 (12.0%)	1 (1.5%)	7 (6.0%)
DIARRHEA	4 (8.0%)	3 (4.5%)	7 (6.0%)
HOSTILITY	4 (8.0%)	3 (4.5%)	7 (6.0%)
RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
SOMNOLENCE	3 (6.0%)	4 (6.1%)	7 (6.0%)
INSOMNIA	2 (4.0%)	5 (7.6%)	7 (6.0%)
ALLERGIC REACTION	4 (8.0%)	2 (3.0%)	6 (5.2%)
EMOTIONAL LABILITY	3 (6.0%)	3 (4.5%)	6 (5.2%)
DEPRESSION	4 (8.0%)	1 (1.5%)	5 (4.3%)
SINUSITIS	4 (8.0%)	1 (1.5%)	5 (4.3%)
LEUKOPENIA	3 (6.0%)	2 (3.0%)	5 (4.3%)
AGITATION	2 (4.0%)	3 (4.5%)	5 (4.3%)
ASTHMA	2 (4.0%)	3 (4.5%)	5 (4.3%)
BACK PAIN	2 (4.0%)	3 (4.5%)	5 (4.3%)
ASTHENIA	0	5 (7.6%)	5 (4.3%)
INCREASED APPETITE	2 (4.0%)	2 (3.0%)	4 (3.4%)
BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
URINARY INCONTINENCE	1 (2.0%)	3 (4.5%)	4 (3.4%)
DRY MOUTH	3 (6.0%)	0	3 (2.6%)
ACNE	2 (4.0%)	1 (1.5%)	3 (2.6%)
CONTACT DERMATITIS	2 (4.0%)	1 (1.5%)	3 (2.6%)
OTITIS MEDIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
ANXIETY	1 (2.0%)	2 (3.0%)	3 (2.6%)
COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
HALLUCINATIONS	1 (2.0%)	2 (3.0%)	3 (2.6%)
MYALGIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
RASH	1 (2.0%)	2 (3.0%)	3 (2.6%)
WITHDRAWAL SYNDROME	1 (2.0%)	2 (3.0%)	3 (2.6%)
CONCENTRATION IMPAIRED	0	3 (4.5%)	3 (2.6%)
DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOOTH CARIES	0	3 (4.5%)	3 (2.6%)
HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
EPISTAXIS	0	2 (3.0%)	2 (1.7%)
HAEMATURIA	0	2 (3.0%)	2 (1.7%)
HYPESTHESIA	0	2 (3.0%)	2 (1.7%)
PAIN	0	2 (3.0%)	2 (1.7%)
PRURITUS	0	2 (3.0%)	2 (1.7%)
SYNCOPE	0	2 (3.0%)	2 (1.7%)
ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
CHEST PAIN	1 (2.0%)	0	1 (0.9%)
CONSTIPATION	1 (2.0%)	0	1 (0.9%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
FACE EDEMA	1 (2.0%)	0	1 (0.9%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
STOMATITIS	1 (2.0%)	0	1 (0.9%)
VERTIGO	1 (2.0%)	0	1 (0.9%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
ANEMIA	0	1 (1.5%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
PNEUMONIA	0	1 (1.5%)	1 (0.9%)
TREMOR	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	34 (77.3%)	45 (73.8%)	79 (75.2%)
HEADACHE	15 (34.1%)	14 (23.0%)	29 (27.6%)
RESPIRATORY DISORDER	4 (9.1%)	12 (19.7%)	16 (15.2%)
NERVOUSNESS	2 (4.5%)	12 (19.7%)	14 (13.3%)
INFECTION	7 (15.9%)	6 (9.8%)	13 (12.4%)
HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
ABDOMINAL PAIN	3 (6.8%)	8 (13.1%)	11 (10.5%)
INSOMNIA	4 (9.1%)	6 (9.8%)	10 (9.5%)
NAUSEA	4 (9.1%)	6 (9.8%)	10 (9.5%)
TRAUMA	4 (9.1%)	5 (8.2%)	9 (8.6%)
HOSTILITY	2 (4.5%)	7 (11.5%)	9 (8.6%)
RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
SINUSITIS	6 (13.6%)	1 (1.6%)	7 (6.7%)
ALLERGIC REACTION	3 (6.8%)	4 (6.6%)	7 (6.7%)
FEVER	4 (9.1%)	2 (3.3%)	6 (5.7%)
ASTHENIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
PHARYNGITIS	2 (4.5%)	4 (6.6%)	6 (5.7%)
DIARRHEA	3 (6.8%)	2 (3.3%)	5 (4.8%)
ANXIETY	2 (4.5%)	3 (4.9%)	5 (4.8%)
DIZZINESS	2 (4.5%)	3 (4.9%)	5 (4.8%)
DYSPEPSIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
OTITIS MEDIA	2 (4.5%)	3 (4.9%)	5 (4.8%)
NEUROSIS	4 (9.1%)	0	4 (3.8%)
ASTHMA	2 (4.5%)	2 (3.3%)	4 (3.8%)
COUGH INCREASED	2 (4.5%)	2 (3.3%)	4 (3.8%)
ARTHRALGIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
EAR PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
OTITIS EXTERNA	2 (4.5%)	1 (1.6%)	3 (2.9%)
PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
SOMNOLENCE	2 (4.5%)	1 (1.6%)	3 (2.9%)
ACNE	1 (2.3%)	2 (3.3%)	3 (2.9%)
AGITATION	0	3 (4.9%)	3 (2.9%)
CONTACT DERMATITIS	0	3 (4.9%)	3 (2.9%)
RASH	0	3 (4.9%)	3 (2.9%)
VASODILATATION	0	3 (4.9%)	3 (2.9%)
ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
BACK PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
DRY MOUTH	0	2 (3.3%)	2 (1.9%)
FLATULENCE	0	2 (3.3%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TREMOR	0	2 (3.3%)	2 (1.9%)
ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
ABSCESS	1 (2.3%)	0	1 (1.0%)
ANEMIA	1 (2.3%)	0	1 (1.0%)
BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
DYSURIA	1 (2.3%)	0	1 (1.0%)
EYE PAIN	1 (2.3%)	0	1 (1.0%)
HAEMATOMA	1 (2.3%)	0	1 (1.0%)
HAEMATURIA	1 (2.3%)	0	1 (1.0%)
MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
MYALGIA	1 (2.3%)	0	1 (1.0%)
PARESTHESIA	1 (2.3%)	0	1 (1.0%)
THINKING ABNORMAL	1 (2.3%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
CONSTIPATION	0	1 (1.6%)	1 (1.0%)
DEPRESSION	0	1 (1.6%)	1 (1.0%)
EPISTAXIS	0	1 (1.6%)	1 (1.0%)
GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.6%)	1 (1.0%)
PNEUMONIA	0	1 (1.6%)	1 (1.0%)
SYNCOPE	0	1 (1.6%)	1 (1.0%)
TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
VERTIGO	0	1 (1.6%)	1 (1.0%)
VOMITING	0	1 (1.6%)	1 (1.0%)
WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	3 (13.6%)	1 (4.8%)	4 (9.3%)
DYSMENORRHEA	3 (13.6%)	1 (4.8%)	4 (9.3%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	72 (76.6%)	89 (70.1%)	161 (72.9%)
HEADACHE	26 (27.7%)	24 (18.9%)	50 (22.6%)
RESPIRATORY DISORDER	17 (18.1%)	26 (20.5%)	43 (19.5%)
INFECTION	13 (13.8%)	18 (14.2%)	31 (14.0%)
TRAUMA	12 (12.8%)	11 (8.7%)	23 (10.4%)
ABDOMINAL PAIN	11 (11.7%)	12 (9.4%)	23 (10.4%)
NAUSEA	11 (11.7%)	12 (9.4%)	23 (10.4%)
NERVOUSNESS	8 (8.5%)	13 (10.2%)	21 (9.5%)
INSOMNIA	6 (6.4%)	11 (8.7%)	17 (7.7%)
PHARYNGITIS	7 (7.4%)	9 (7.1%)	16 (7.2%)
HOSTILITY	6 (6.4%)	10 (7.9%)	16 (7.2%)
RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
FEVER	9 (9.6%)	5 (3.9%)	14 (6.3%)
DYSPEPSIA	7 (7.4%)	7 (5.5%)	14 (6.3%)
WEIGHT GAIN	7 (7.4%)	7 (5.5%)	14 (6.3%)
ALLERGIC REACTION	7 (7.4%)	6 (4.7%)	13 (5.9%)
HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
SINUSITIS	10 (10.6%)	2 (1.6%)	12 (5.4%)
DIARRHEA	7 (7.4%)	5 (3.9%)	12 (5.4%)
VOMITING	6 (6.4%)	5 (3.9%)	11 (5.0%)
ASTHENIA	3 (3.2%)	8 (6.3%)	11 (5.0%)
SOMNOLENCE	5 (5.3%)	5 (3.9%)	10 (4.5%)
ASTHMA	4 (4.3%)	5 (3.9%)	9 (4.1%)
DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
EMOTIONAL LABILITY	4 (4.3%)	4 (3.1%)	8 (3.6%)
OTITIS MEDIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
ANXIETY	3 (3.2%)	5 (3.9%)	8 (3.6%)
DIZZINESS	3 (3.2%)	5 (3.9%)	8 (3.6%)
AGITATION	2 (2.1%)	6 (4.7%)	8 (3.6%)
BACK PAIN	3 (3.2%)	4 (3.1%)	7 (3.2%)
COUGH INCREASED	3 (3.2%)	4 (3.1%)	7 (3.2%)
DEPRESSION	4 (4.3%)	2 (1.6%)	6 (2.7%)
ACNE	3 (3.2%)	3 (2.4%)	6 (2.7%)
CONTACT DERMATITIS	2 (2.1%)	4 (3.1%)	6 (2.7%)
RASH	1 (1.1%)	5 (3.9%)	6 (2.7%)
ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
LEUKOPENIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
URINARY INCONTINENCE	1 (1.1%)	4 (3.1%)	5 (2.3%)
NEUROSIS	4 (4.3%)	0	4 (1.8%)
ARTHRALGIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
INCREASED APPETITE	2 (2.1%)	2 (1.6%)	4 (1.8%)
MYALGIA	2 (2.1%)	2 (1.6%)	4 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
CONCENTRATION IMPAIRED	1 (1.1%)	3 (2.4%)	4 (1.8%)
TOOTH CARIES	0	4 (3.1%)	4 (1.8%)
EAR PAIN	2 (2.1%)	1 (0.8%)	3 (1.4%)
OTITIS EXTERNA	2 (2.1%)	1 (0.8%)	3 (1.4%)
HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
HALLUCINATIONS	1 (1.1%)	2 (1.6%)	3 (1.4%)
WITHDRAWAL SYNDROME	1 (1.1%)	2 (1.6%)	3 (1.4%)
EPISTAXIS	0	3 (2.4%)	3 (1.4%)
SYNCOPE	0	3 (2.4%)	3 (1.4%)
TREMOR	0	3 (2.4%)	3 (1.4%)
VASODILATATION	0	3 (2.4%)	3 (1.4%)
ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
LACK OF EMOTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
FLATULENCE	0	2 (1.6%)	2 (0.9%)
GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
HYPESTHESIA	0	2 (1.6%)	2 (0.9%)
LIVER FUNCTION TESTS ABNORMAL	0	2 (1.6%)	2 (0.9%)
PNEUMONIA	0	2 (1.6%)	2 (0.9%)
PRURITUS	0	2 (1.6%)	2 (0.9%)
ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
ABSCESS	1 (1.1%)	0	1 (0.5%)
BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
CHEST PAIN	1 (1.1%)	0	1 (0.5%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
DYSURIA	1 (1.1%)	0	1 (0.5%)
EYE PAIN	1 (1.1%)	0	1 (0.5%)
FACE EDEMA	1 (1.1%)	0	1 (0.5%)
HAEMATOMA	1 (1.1%)	0	1 (0.5%)
HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
PARESTHESIA	1 (1.1%)	0	1 (0.5%)
STOMATITIS	1 (1.1%)	0	1 (0.5%)
THINKING ABNORMAL	1 (1.1%)	0	1 (0.5%)
TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	3 (6.7%)	1 (2.0%)	4 (4.2%)
DYSMENORRHEA	3 (6.7%)	1 (2.0%)	4 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=51)	Placebo (N=66)	Total (N=117)
Body System	Preferred Term			
TOTAL	TOTAL	3 (5.9%)	6 (9.1%)	9 (7.7%)
Nervous System	TOTAL	3 (5.9%)	4 (6.1%)	7 (6.0%)
	EMOTIONAL LABILITY	2 (3.9%)	1 (1.5%)	3 (2.6%)
	DEPRESSION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HOSTILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
Body as a Whole	TOTAL	0	1 (1.5%)	1 (0.9%)
	TRAUMA	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ASTHMA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=37)	Total (N=65)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=61)	Total (N=106)
Body System	Preferred Term			
TOTAL	TOTAL	2 (4.4%)	1 (1.6%)	3 (2.8%)
Body as a Whole	TOTAL	2 (4.4%)	0	2 (1.9%)
	ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (0.9%)
	ABSCESS	1 (2.2%)	0	1 (0.9%)
Nervous System	TOTAL	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=21)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=96)	Placebo (N=127)	Total (N=223)
Body System	Preferred Term			
TOTAL	TOTAL	5 (5.2%)	7 (5.5%)	12 (5.4%)
Nervous System	TOTAL	3 (3.1%)	5 (3.9%)	8 (3.6%)
	EMOTIONAL LABILITY	2 (2.1%)	1 (0.8%)	3 (1.3%)
	DEPRESSION	1 (1.0%)	1 (0.8%)	2 (0.9%)
	HOSTILITY	1 (1.0%)	1 (0.8%)	2 (0.9%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	2 (2.1%)	1 (0.8%)	3 (1.3%)
	ABNORMAL LABORATORY VALUE	1 (1.0%)	0	1 (0.4%)
	ABSCESS	1 (1.0%)	0	1 (0.4%)
	TRAUMA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	0	1 (0.8%)	1 (0.4%)
	ASTHMA	0	1 (0.8%)	1 (0.4%)

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=77)	Total (N=127)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=46)	Placebo (N=50)	Total (N=96)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	16 (64.0%)	22 (61.1%)	38 (62.3%)
Respiratory System	TOTAL	9 (36.0%)	11 (30.6%)	20 (32.8%)
	RESPIRATORY DISORDER	4 (16.0%)	3 (8.3%)	7 (11.5%)
	PHARYNGITIS	2 (8.0%)	4 (11.1%)	6 (9.8%)
	RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
	SINUSITIS	2 (8.0%)	0	2 (3.3%)
	COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
	EPISTAXIS	0	2 (5.6%)	2 (3.3%)
	YAWN	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	7 (28.0%)	13 (36.1%)	20 (32.8%)
	HEADACHE	4 (16.0%)	3 (8.3%)	7 (11.5%)
	INFECTION	1 (4.0%)	5 (13.9%)	6 (9.8%)
	ABDOMINAL PAIN	3 (12.0%)	2 (5.6%)	5 (8.2%)
	TRAUMA	3 (12.0%)	1 (2.8%)	4 (6.6%)
	FEVER	1 (4.0%)	2 (5.6%)	3 (4.9%)
	BACK PAIN	0	3 (8.3%)	3 (4.9%)
	ALLERGIC REACTION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ASTHENIA	0	2 (5.6%)	2 (3.3%)
	FACE EDEMA	1 (4.0%)	0	1 (1.6%)
Digestive System	TOTAL	6 (24.0%)	9 (25.0%)	15 (24.6%)
	DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	NAUSEA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	VOMITING	0	2 (5.6%)	2 (3.3%)
	INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	DIARRHEA	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	4 (16.0%)	2 (5.6%)	6 (9.8%)
	ACNE	2 (8.0%)	0	2 (3.3%)
	RASH	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONTACT DERMATITIS	1 (4.0%)	0	1 (1.6%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
	PRURITUS	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	3 (12.0%)	5 (13.9%)	8 (13.1%)
	INSOMNIA	0	3 (8.3%)	3 (4.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Nervous System	DEPRESSION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	AGITATION	1 (4.0%)	0	1 (1.6%)
	HALLUCINATIONS	1 (4.0%)	0	1 (1.6%)
	NERVOUSNESS	1 (4.0%)	0	1 (1.6%)
	ANXIETY	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.0%)	2 (5.6%)	4 (6.6%)
	WEIGHT GAIN	2 (8.0%)	2 (5.6%)	4 (6.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	LEUKOPENIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ANEMIA	0	1 (2.8%)	1 (1.6%)
Musculoskeletal System	TOTAL	1 (4.0%)	0	1 (1.6%)
	ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	3 (8.3%)	4 (6.6%)
	URINARY INCONTINENCE	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
	CYSTITIS	0	1 (2.8%)	1 (1.6%)
	HAEMATURIA	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.6%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	0	1 (2.8%)	1 (1.6%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	15 (60.0%)	19 (52.8%)	34 (55.7%)
Body as a Whole	TOTAL	7 (28.0%)	10 (27.8%)	17 (27.9%)
	INFECTION	3 (12.0%)	5 (13.9%)	8 (13.1%)
	FEVER	3 (12.0%)	1 (2.8%)	4 (6.6%)
	HEADACHE	3 (12.0%)	1 (2.8%)	4 (6.6%)
	TRAUMA	2 (8.0%)	2 (5.6%)	4 (6.6%)
	ABDOMINAL PAIN	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ALLERGIC REACTION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	PAIN	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	6 (24.0%)	4 (11.1%)	10 (16.4%)
	VOMITING	4 (16.0%)	2 (5.6%)	6 (9.8%)
	DIARRHEA	2 (8.0%)	0	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	STOMATITIS	1 (4.0%)	0	1 (1.6%)
	NAUSEA	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	6 (24.0%)	7 (19.4%)	13 (21.3%)
	AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
	HOSTILITY	2 (8.0%)	0	2 (3.3%)
	NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.6%)
	VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
	HALLUCINATIONS	0	1 (2.8%)	1 (1.6%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
	INSOMNIA	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	6 (24.0%)	7 (19.4%)	13 (21.3%)
	RESPIRATORY DISORDER	5 (20.0%)	4 (11.1%)	9 (14.8%)
	PHARYNGITIS	2 (8.0%)	0	2 (3.3%)
	BRONCHITIS	0	1 (2.8%)	1 (1.6%)
	PNEUMONIA	0	1 (2.8%)	1 (1.6%)
	SINUSITIS	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	3 (12.0%)	1 (2.8%)	4 (6.6%)
	CONTACT DERMATITIS	1 (4.0%)	1 (2.8%)	2 (3.3%)
	ACNE	1 (4.0%)	0	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Skin and Appendages	HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.0%)	2 (5.6%)	4 (6.6%)
	WEIGHT GAIN	2 (8.0%)	1 (2.8%)	3 (4.9%)
	DEHYDRATION	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	1 (4.0%)	0	1 (1.6%)
	OTITIS MEDIA	1 (4.0%)	0	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	0	1 (1.6%)
	URINARY INCONTINENCE	1 (4.0%)	0	1 (1.6%)
Cardiovascular System	TOTAL	0	2 (5.6%)	2 (3.3%)
	MIGRAINE	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	0	1 (2.8%)	1 (1.6%)
	LEUKOPENIA	0	1 (2.8%)	1 (1.6%)
Musculoskeletal System	TOTAL	0	1 (2.8%)	1 (1.6%)
	ARTHROSIS	0	1 (2.8%)	1 (1.6%)
	MYALGIA	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	2 (8.0%)	7 (19.4%)	9 (14.8%)
Nervous System	TOTAL	2 (8.0%)	3 (8.3%)	5 (8.2%)
	HOSTILITY	1 (4.0%)	1 (2.8%)	2 (3.3%)
	DEPRESSION	1 (4.0%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
	AGITATION	0	1 (2.8%)	1 (1.6%)
	EUPHORIA	0	1 (2.8%)	1 (1.6%)
	PARALYSIS	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	0	1 (2.8%)	1 (1.6%)
	TRAUMA	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.6%)
	MIGRAINE	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.6%)
	ASTHMA	0	1 (2.8%)	1 (1.6%)
Skin and Appendages	TOTAL	0	1 (2.8%)	1 (1.6%)
	RASH	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	0	1 (2.8%)	1 (1.6%)
	OTITIS MEDIA	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.8%)	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	15 (62.5%)	22 (64.7%)	37 (63.8%)
Body as a Whole	TOTAL	8 (33.3%)	13 (38.2%)	21 (36.2%)
	HEADACHE	5 (20.8%)	5 (14.7%)	10 (17.2%)
	TRAUMA	2 (8.3%)	3 (8.8%)	5 (8.6%)
	ABDOMINAL PAIN	0	5 (14.7%)	5 (8.6%)
	FEVER	2 (8.3%)	1 (2.9%)	3 (5.2%)
	PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	BACK PAIN	1 (4.2%)	0	1 (1.7%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	7 (29.2%)	5 (14.7%)	12 (20.7%)
	NAUSEA	4 (16.7%)	0	4 (6.9%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	DIARRHEA	2 (8.3%)	0	2 (3.4%)
	DYSPEPSIA	2 (8.3%)	0	2 (3.4%)
	FLATULENCE	0	1 (2.9%)	1 (1.7%)
	GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
	TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
Respiratory System	TOTAL	5 (20.8%)	9 (26.5%)	14 (24.1%)
	RESPIRATORY DISORDER	1 (4.2%)	6 (17.6%)	7 (12.1%)
	RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
	PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
	COUGH INCREASED	2 (8.3%)	0	2 (3.4%)
	SINUSITIS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ASTHMA	1 (4.2%)	0	1 (1.7%)
Nervous System	TOTAL	4 (16.7%)	12 (35.3%)	16 (27.6%)
	NERVOUSNESS	1 (4.2%)	5 (14.7%)	6 (10.3%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	HYPERKINESIA	3 (12.5%)	0	3 (5.2%)
	DIZZINESS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	HOSTILITY	1 (4.2%)	1 (2.9%)	2 (3.4%)
	MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ANXIETY	1 (4.2%)	0	1 (1.7%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
	VERTIGO	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
Cardiovascular System	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
	HAEMATOMA	1 (4.2%)	0	1 (1.7%)
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0	1 (1.7%)
	ANEMIA	1 (4.2%)	0	1 (1.7%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.7%)
	MYALGIA	1 (4.2%)	0	1 (1.7%)
Skin and Appendages	TOTAL	1 (4.2%)	2 (5.9%)	3 (5.2%)
	RASH	0	2 (5.9%)	2 (3.4%)
	MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
	CONTACT DERMATITIS	0	1 (2.9%)	1 (1.7%)
	HERPES SIMPLEX	0	1 (2.9%)	1 (1.7%)
Special Senses	TOTAL	1 (4.2%)	3 (8.8%)	4 (6.9%)
	OTITIS EXTERNA	1 (4.2%)	1 (2.9%)	2 (3.4%)
	EAR PAIN	0	1 (2.9%)	1 (1.7%)
	OTITIS MEDIA	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	12 (50.0%)	20 (58.8%)	32 (55.2%)
Body as a Whole	TOTAL	9 (37.5%)	4 (11.8%)	13 (22.4%)
	HEADACHE	5 (20.8%)	1 (2.9%)	6 (10.3%)
	TRAUMA	3 (12.5%)	0	3 (5.2%)
	INFECTION	2 (8.3%)	1 (2.9%)	3 (5.2%)
	ABDOMINAL PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
	FEVER	1 (4.2%)	0	1 (1.7%)
Nervous System	TOTAL	4 (16.7%)	15 (44.1%)	19 (32.8%)
	HYPERKINESIA	3 (12.5%)	3 (8.8%)	6 (10.3%)
	NERVOUSNESS	0	6 (17.6%)	6 (10.3%)
	HOSTILITY	0	3 (8.8%)	3 (5.2%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ANXIETY	0	2 (5.9%)	2 (3.4%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DIZZINESS	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	PSYCHOSIS	0	1 (2.9%)	1 (1.7%)
Special Senses	TOTAL	3 (12.5%)	1 (2.9%)	4 (6.9%)
	OTITIS MEDIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
	EAR PAIN	1 (4.2%)	0	1 (1.7%)
	OTITIS EXTERNA	1 (4.2%)	0	1 (1.7%)
Respiratory System	TOTAL	1 (4.2%)	2 (5.9%)	3 (5.2%)
	COUGH INCREASED	1 (4.2%)	1 (2.9%)	2 (3.4%)
	RESPIRATORY DISORDER	1 (4.2%)	1 (2.9%)	2 (3.4%)
	SINUSITIS	1 (4.2%)	0	1 (1.7%)
	RHINITIS	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	0	2 (5.9%)	2 (3.4%)
	DYSPEPSIA	0	1 (2.9%)	1 (1.7%)
	GINGIVITIS	0	1 (2.9%)	1 (1.7%)
	NAUSEA	0	1 (2.9%)	1 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Skin and Appendages	TOTAL	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
Skin and Appendages	CONTACT DERMATITIS	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	2 (8.3%)	3 (8.8%)	5 (8.6%)
Body as a Whole	TOTAL	2 (8.3%)	0	2 (3.4%)
	ABSCESS	1 (4.2%)	0	1 (1.7%)
	INFECTION	1 (4.2%)	0	1 (1.7%)
Respiratory System	TOTAL	1 (4.2%)	0	1 (1.7%)
	PHARYNGITIS	1 (4.2%)	0	1 (1.7%)
Nervous System	TOTAL	0	3 (8.8%)	3 (5.2%)
	HOSTILITY	0	1 (2.9%)	1 (1.7%)
	HYPERKINESIA	0	1 (2.9%)	1 (1.7%)
	NERVOUSNESS	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (8.3%)	1 (4.0%)
Urogenital System	TOTAL	0	1 (8.3%)	1 (4.0%)
	DYSMENORRHEA	0	1 (8.3%)	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (7.7%)	0	1 (4.0%)
Urogenital System	TOTAL	1 (7.7%)	0	1 (4.0%)
	DYSMENORRHEA	1 (7.7%)	0	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	31 (63.3%)	44 (62.9%)	75 (63.0%)
Body as a Whole	TOTAL	15 (30.6%)	26 (37.1%)	41 (34.5%)
	HEADACHE	9 (18.4%)	8 (11.4%)	17 (14.3%)
	ABDOMINAL PAIN	3 (6.1%)	7 (10.0%)	10 (8.4%)
	TRAUMA	5 (10.2%)	4 (5.7%)	9 (7.6%)
	FEVER	3 (6.1%)	3 (4.3%)	6 (5.0%)
	INFECTION	1 (2.0%)	5 (7.1%)	6 (5.0%)
	BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ALLERGIC REACTION	1 (2.0%)	2 (2.9%)	3 (2.5%)
	PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ASTHENIA	0	2 (2.9%)	2 (1.7%)
	FACE EDEMA	1 (2.0%)	0	1 (0.8%)
Respiratory System	TOTAL	14 (28.6%)	20 (28.6%)	34 (28.6%)
	RESPIRATORY DISORDER	5 (10.2%)	9 (12.9%)	14 (11.8%)
	RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
	PHARYNGITIS	4 (8.2%)	7 (10.0%)	11 (9.2%)
	COUGH INCREASED	3 (6.1%)	1 (1.4%)	4 (3.4%)
	SINUSITIS	3 (6.1%)	1 (1.4%)	4 (3.4%)
	EPISTAXIS	0	2 (2.9%)	2 (1.7%)
	ASTHMA	1 (2.0%)	0	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	13 (26.5%)	14 (20.0%)	27 (22.7%)
	DYSPEPSIA	5 (10.2%)	3 (4.3%)	8 (6.7%)
	NAUSEA	5 (10.2%)	1 (1.4%)	6 (5.0%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	DIARRHEA	2 (4.1%)	1 (1.4%)	3 (2.5%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
	TOOTH CARIES	0	2 (2.9%)	2 (1.7%)
	VOMITING	0	2 (2.9%)	2 (1.7%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.4%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	7 (14.3%)	17 (24.3%)	24 (20.2%)
	INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
	NERVOUSNESS	2 (4.1%)	5 (7.1%)	7 (5.9%)
	HYPERKINESIA	4 (8.2%)	1 (1.4%)	5 (4.2%)
	DIZZINESS	1 (2.0%)	2 (2.9%)	3 (2.5%)
	AGITATION	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Nervous System	ANXIETY	1 (2.0%)	1 (1.4%)	2 (1.7%)
	DEPRESSION	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HOSTILITY	1 (2.0%)	1 (1.4%)	2 (1.7%)
	MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
	HALLUCINATIONS	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
	TREMOR	0	1 (1.4%)	1 (0.8%)
	VERTIGO	0	1 (1.4%)	1 (0.8%)
Skin and Appendages	TOTAL	5 (10.2%)	4 (5.7%)	9 (7.6%)
	RASH	1 (2.0%)	3 (4.3%)	4 (3.4%)
	ACNE	2 (4.1%)	0	2 (1.7%)
	CONTACT DERMATITIS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.8%)
	PRURITUS	0	1 (1.4%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (4.1%)	1 (1.4%)	3 (2.5%)
	ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	LEUKOPENIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.1%)	2 (2.9%)	4 (3.4%)
	WEIGHT GAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
Musculoskeletal System	TOTAL	2 (4.1%)	0	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
	MYALGIA	1 (2.0%)	0	1 (0.8%)
Cardiovascular System	TOTAL	1 (2.0%)	4 (5.7%)	5 (4.2%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	HAEMATOMA	1 (2.0%)	0	1 (0.8%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	1 (2.0%)	4 (5.7%)	5 (4.2%)
	OTITIS EXTERNA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
	EAR PAIN	0	1 (1.4%)	1 (0.8%)
	OTITIS MEDIA	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Urogenital System	TOTAL	1 (2.0%)	4 (5.7%)	5 (4.2%)
	URINARY INCONTINENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
	CYSTITIS	0	1 (1.4%)	1 (0.8%)
	HAEMATURIA	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	27 (55.1%)	39 (55.7%)	66 (55.5%)
Body as a Whole	TOTAL	16 (32.7%)	14 (20.0%)	30 (25.2%)
	INFECTION	5 (10.2%)	6 (8.6%)	11 (9.2%)
	HEADACHE	8 (16.3%)	2 (2.9%)	10 (8.4%)
	TRAUMA	5 (10.2%)	2 (2.9%)	7 (5.9%)
	FEVER	4 (8.2%)	1 (1.4%)	5 (4.2%)
	ABDOMINAL PAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
	PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ALLERGIC REACTION	1 (2.0%)	1 (1.4%)	2 (1.7%)
Nervous System	TOTAL	10 (20.4%)	22 (31.4%)	32 (26.9%)
	NERVOUSNESS	2 (4.1%)	6 (8.6%)	8 (6.7%)
	HYPERKINESIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
	HOSTILITY	2 (4.1%)	3 (4.3%)	5 (4.2%)
	AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ANXIETY	0	2 (2.9%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	DEPRESSION	1 (2.0%)	0	1 (0.8%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
	CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.8%)
	DIZZINESS	0	1 (1.4%)	1 (0.8%)
	HALLUCINATIONS	0	1 (1.4%)	1 (0.8%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
	INSOMNIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.8%)
	TREMOR	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	7 (14.3%)	9 (12.9%)	16 (13.4%)
	RESPIRATORY DISORDER	6 (12.2%)	5 (7.1%)	11 (9.2%)
	PHARYNGITIS	2 (4.1%)	0	2 (1.7%)
	COUGH INCREASED	1 (2.0%)	1 (1.4%)	2 (1.7%)
	SINUSITIS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	BRONCHITIS	0	1 (1.4%)	1 (0.8%)
	PNEUMONIA	0	1 (1.4%)	1 (0.8%)
	RHINITIS	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	6 (12.2%)	6 (8.6%)	12 (10.1%)
	VOMITING	4 (8.2%)	2 (2.9%)	6 (5.0%)
	DIARRHEA	2 (4.1%)	0	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Digestive System	NAUSEA	0	2 (2.9%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	STOMATITIS	1 (2.0%)	0	1 (0.8%)
	DYSPEPSIA	0	1 (1.4%)	1 (0.8%)
	GINGIVITIS	0	1 (1.4%)	1 (0.8%)
	TOOTH CARIES	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	4 (8.2%)	1 (1.4%)	5 (4.2%)
	OTITIS MEDIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
	EAR PAIN	1 (2.0%)	0	1 (0.8%)
	OTITIS EXTERNA	1 (2.0%)	0	1 (0.8%)
Skin and Appendages	TOTAL	3 (6.1%)	2 (2.9%)	5 (4.2%)
	CONTACT DERMATITIS	1 (2.0%)	2 (2.9%)	3 (2.5%)
	ACNE	1 (2.0%)	0	1 (0.8%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.1%)	3 (4.3%)	5 (4.2%)
	WEIGHT GAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
	DEHYDRATION	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	1 (2.0%)	0	1 (0.8%)
	URINARY INCONTINENCE	1 (2.0%)	0	1 (0.8%)
Cardiovascular System	TOTAL	0	2 (2.9%)	2 (1.7%)
	MIGRAINE	0	1 (1.4%)	1 (0.8%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	0	1 (1.4%)	1 (0.8%)
	LEUKOPENIA	0	1 (1.4%)	1 (0.8%)
Musculoskeletal System	TOTAL	0	1 (1.4%)	1 (0.8%)
	ARTHROSIS	0	1 (1.4%)	1 (0.8%)
	MYALGIA	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	4 (8.2%)	10 (14.3%)	14 (11.8%)
Body as a Whole	TOTAL	2 (4.1%)	1 (1.4%)	3 (2.5%)
	ABSCESS	1 (2.0%)	0	1 (0.8%)
	INFECTION	1 (2.0%)	0	1 (0.8%)
	TRAUMA	0	1 (1.4%)	1 (0.8%)
Nervous System	TOTAL	2 (4.1%)	6 (8.6%)	8 (6.7%)
	HOSTILITY	1 (2.0%)	2 (2.9%)	3 (2.5%)
	DEPRESSION	1 (2.0%)	0	1 (0.8%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
	AGITATION	0	1 (1.4%)	1 (0.8%)
	EUPHORIA	0	1 (1.4%)	1 (0.8%)
	HYPERKINESIA	0	1 (1.4%)	1 (0.8%)
	NERVOUSNESS	0	1 (1.4%)	1 (0.8%)
	PARALYSIS	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	PHARYNGITIS	1 (2.0%)	0	1 (0.8%)
	ASTHMA	0	1 (1.4%)	1 (0.8%)
Cardiovascular System	TOTAL	0	1 (1.4%)	1 (0.8%)
	MIGRAINE	0	1 (1.4%)	1 (0.8%)
Skin and Appendages	TOTAL	0	1 (1.4%)	1 (0.8%)
	RASH	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.8%)
	OTITIS MEDIA	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	0	1 (1.4%)	1 (0.8%)
	URINARY INCONTINENCE	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.8%)	1 (1.9%)
Urogenital System	TOTAL	0	1 (3.8%)	1 (1.9%)
	DYSMENORRHEA	0	1 (3.8%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.7%)	0	1 (1.9%)
Urogenital System	TOTAL	1 (3.7%)	0	1 (1.9%)
	DYSMENORRHEA	1 (3.7%)	0	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	13 (52.0%)	18 (60.0%)	31 (56.4%)
Nervous System	TOTAL	8 (32.0%)	6 (20.0%)	14 (25.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	NERVOUSNESS	2 (8.0%)	0	2 (3.6%)
	SOMNOLENCE	2 (8.0%)	0	2 (3.6%)
	DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	EMOTIONAL LABILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
	VERTIGO	1 (4.0%)	0	1 (1.8%)
	AGITATION	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
Body as a Whole	TOTAL	6 (24.0%)	7 (23.3%)	13 (23.6%)
	HEADACHE	2 (8.0%)	5 (16.7%)	7 (12.7%)
	ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
	ASTHENIA	0	2 (6.7%)	2 (3.6%)
	TRAUMA	0	2 (6.7%)	2 (3.6%)
	BACK PAIN	1 (4.0%)	0	1 (1.8%)
	CHEST PAIN	1 (4.0%)	0	1 (1.8%)
	INFECTION	0	1 (3.3%)	1 (1.8%)
	PAIN	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	4 (16.0%)	6 (20.0%)	10 (18.2%)
	NAUSEA	3 (12.0%)	2 (6.7%)	5 (9.1%)
	DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DRY MOUTH	1 (4.0%)	0	1 (1.8%)
	VOMITING	1 (4.0%)	0	1 (1.8%)
	DIARRHEA	0	1 (3.3%)	1 (1.8%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.8%)
Respiratory System	TOTAL	4 (16.0%)	8 (26.7%)	12 (21.8%)
	RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)
	RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ASTHMA	0	2 (6.7%)	2 (3.6%)
	COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
	PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	0	1 (1.8%)
	LEUKOPENIA	1 (4.0%)	0	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
Special Senses	TOTAL	1 (4.0%)	0	1 (1.8%)
	OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
	HAEMATURIA	0	1 (3.3%)	1 (1.8%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.8%)
	SYNCOPE	0	1 (3.3%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (10.0%)	3 (5.5%)
	WEIGHT GAIN	0	3 (10.0%)	3 (5.5%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.8%)
	PRURITUS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	14 (56.0%)	9 (30.0%)	23 (41.8%)
Body as a Whole	TOTAL	8 (32.0%)	4 (13.3%)	12 (21.8%)
	TRAUMA	4 (16.0%)	1 (3.3%)	5 (9.1%)
	HEADACHE	3 (12.0%)	1 (3.3%)	4 (7.3%)
	BACK PAIN	2 (8.0%)	0	2 (3.6%)
	ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
	INFECTION	1 (4.0%)	1 (3.3%)	2 (3.6%)
	ASTHENIA	0	1 (3.3%)	1 (1.8%)
	FEVER	0	1 (3.3%)	1 (1.8%)
Respiratory System	TOTAL	4 (16.0%)	3 (10.0%)	7 (12.7%)
	RESPIRATORY DISORDER	2 (8.0%)	1 (3.3%)	3 (5.5%)
	BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
	ASTHMA	1 (4.0%)	0	1 (1.8%)
	SINUSITIS	1 (4.0%)	0	1 (1.8%)
Digestive System	TOTAL	3 (12.0%)	1 (3.3%)	4 (7.3%)
	NAUSEA	2 (8.0%)	0	2 (3.6%)
	DIARRHEA	1 (4.0%)	0	1 (1.8%)
	VOMITING	1 (4.0%)	0	1 (1.8%)
	DYSPEPSIA	0	1 (3.3%)	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.0%)	0	2 (3.6%)
	WEIGHT GAIN	1 (4.0%)	0	1 (1.8%)
	WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
Nervous System	TOTAL	2 (8.0%)	5 (16.7%)	7 (12.7%)
	SOMNOLENCE	1 (4.0%)	2 (6.7%)	3 (5.5%)
	EMOTIONAL LABILITY	0	2 (6.7%)	2 (3.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.8%)
	AGITATION	0	1 (3.3%)	1 (1.8%)
	HOSTILITY	0	1 (3.3%)	1 (1.8%)
	NERVOUSNESS	0	1 (3.3%)	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.8%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.8%)
	ACNE	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	3 (12.0%)	4 (13.3%)	7 (12.7%)
Body as a Whole	TOTAL	2 (8.0%)	0	2 (3.6%)
	INFECTION	1 (4.0%)	0	1 (1.8%)
	TRAUMA	1 (4.0%)	0	1 (1.8%)
Nervous System	TOTAL	1 (4.0%)	3 (10.0%)	4 (7.3%)
	EMOTIONAL LABILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
	AGITATION	1 (4.0%)	0	1 (1.8%)
	LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
	ANXIETY	0	1 (3.3%)	1 (1.8%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	0	1 (3.3%)	1 (1.8%)
	TOOTH CARIES	0	1 (3.3%)	1 (1.8%)

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Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (13.3%)	2 (8.3%)
Urogenital System	TOTAL	0	2 (13.3%)	2 (8.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	13 (65.0%)	14 (51.9%)	27 (57.4%)
Body as a Whole	TOTAL	11 (55.0%)	7 (25.9%)	18 (38.3%)
	HEADACHE	5 (25.0%)	6 (22.2%)	11 (23.4%)
	ALLERGIC REACTION	2 (10.0%)	2 (7.4%)	4 (8.5%)
	ASTHENIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
	INFECTION	2 (10.0%)	1 (3.7%)	3 (6.4%)
	ABDOMINAL PAIN	1 (5.0%)	0	1 (2.1%)
	ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
	PAIN	1 (5.0%)	0	1 (2.1%)
	FEVER	0	1 (3.7%)	1 (2.1%)
	TRAUMA	0	1 (3.7%)	1 (2.1%)
Nervous System	TOTAL	3 (15.0%)	3 (11.1%)	6 (12.8%)
	NEUROSIS	2 (10.0%)	0	2 (4.3%)
	INSOMNIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DIZZINESS	1 (5.0%)	0	1 (2.1%)
	AGITATION	0	1 (3.7%)	1 (2.1%)
	HOSTILITY	0	1 (3.7%)	1 (2.1%)
	NERVOUSNESS	0	1 (3.7%)	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	3 (15.0%)	3 (11.1%)	6 (12.8%)
	RESPIRATORY DISORDER	1 (5.0%)	2 (7.4%)	3 (6.4%)
	RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	SINUSITIS	1 (5.0%)	0	1 (2.1%)
	EPISTAXIS	0	1 (3.7%)	1 (2.1%)
Urogenital System	TOTAL	3 (15.0%)	0	3 (6.4%)
	ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
	DYSURIA	1 (5.0%)	0	1 (2.1%)
	HAEMATURIA	1 (5.0%)	0	1 (2.1%)
Special Senses	TOTAL	2 (10.0%)	1 (3.7%)	3 (6.4%)
	BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
	EYE PAIN	1 (5.0%)	0	1 (2.1%)
	ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
Musculoskeletal System	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	ARTHRALGIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
Digestive System	TOTAL	0	5 (18.5%)	5 (10.6%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
Digestive System	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	NAUSEA	0	2 (7.4%)	2 (4.3%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
	ULCERATIVE STOMATITIS	0	1 (3.7%)	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	1 (3.7%)	1 (2.1%)
	LEUKOCYTOSIS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	0	4 (14.8%)	4 (8.5%)
	ACNE	0	2 (7.4%)	2 (4.3%)
	CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
	RASH	0	1 (3.7%)	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
	URTICARIA	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=20)	 Placebo (N=27)	 Total (N=47)
TOTAL	TOTAL	11 (55.0%)	14 (51.9%)	25 (53.2%)
Body as a Whole	TOTAL	6 (30.0%)	7 (25.9%)	13 (27.7%)
	HEADACHE	2 (10.0%)	4 (14.8%)	6 (12.8%)
	ASTHENIA	2 (10.0%)	2 (7.4%)	4 (8.5%)
	INFECTION	2 (10.0%)	1 (3.7%)	3 (6.4%)
	ALLERGIC REACTION	1 (5.0%)	1 (3.7%)	2 (4.3%)
	ABDOMINAL PAIN	0	2 (7.4%)	2 (4.3%)
	BACK PAIN	0	1 (3.7%)	1 (2.1%)
Nervous System	TOTAL	5 (25.0%)	7 (25.9%)	12 (25.5%)
	HOSTILITY	1 (5.0%)	2 (7.4%)	3 (6.4%)
	INSOMNIA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	NERVOUSNESS	1 (5.0%)	2 (7.4%)	3 (6.4%)
	ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	AGITATION	0	1 (3.7%)	1 (2.1%)
	DEPRESSION	0	1 (3.7%)	1 (2.1%)
	DIZZINESS	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	3 (15.0%)	5 (18.5%)	8 (17.0%)
	RESPIRATORY DISORDER	1 (5.0%)	3 (11.1%)	4 (8.5%)
	ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	SINUSITIS	1 (5.0%)	0	1 (2.1%)
	PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
	PNEUMONIA	0	1 (3.7%)	1 (2.1%)
Digestive System	TOTAL	2 (10.0%)	4 (14.8%)	6 (12.8%)
	DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	NAUSEA	0	2 (7.4%)	2 (4.3%)
	TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Musculoskeletal System	TOTAL	1 (5.0%)	0	1 (2.1%)
	ARTHRALGIA	1 (5.0%)	0	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
Skin and Appendages	TOTAL	1 (5.0%)	0	1 (2.1%)
	ACNE	1 (5.0%)	0	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	1 (3.7%)	1 (2.1%)
	EOSINOPHILIA	0	1 (3.7%)	1 (2.1%)
	MONOCYTOSIS	0	1 (3.7%)	1 (2.1%)
Special Senses	TOTAL	0	1 (3.7%)	1 (2.1%)
	OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	2 (10.0%)	2 (7.4%)	4 (8.5%)
Nervous System	TOTAL	2 (10.0%)	1 (3.7%)	3 (6.4%)
	NEUROSIS	1 (5.0%)	0	1 (2.1%)
	SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
	HOSTILITY	0	1 (3.7%)	1 (2.1%)
Body as a Whole	TOTAL	0	1 (3.7%)	1 (2.1%)
	ABDOMINAL PAIN	0	1 (3.7%)	1 (2.1%)
	INFECTION	0	1 (3.7%)	1 (2.1%)
Cardiovascular System	TOTAL	0	1 (3.7%)	1 (2.1%)
	SYNCOPE	0	1 (3.7%)	1 (2.1%)
Digestive System	TOTAL	0	1 (3.7%)	1 (2.1%)
	NAUSEA	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	0	2 (11.1%)
Urogenital System	TOTAL	2 (22.2%)	0	2 (11.1%)
	DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	26 (57.8%)	32 (56.1%)	58 (56.9%)
Body as a Whole	TOTAL	17 (37.8%)	14 (24.6%)	31 (30.4%)
	HEADACHE	7 (15.6%)	11 (19.3%)	18 (17.6%)
	ALLERGIC REACTION	4 (8.9%)	2 (3.5%)	6 (5.9%)
	ASTHENIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	INFECTION	2 (4.4%)	2 (3.5%)	4 (3.9%)
	TRAUMA	0	3 (5.3%)	3 (2.9%)
	PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
	ABDOMINAL PAIN	1 (2.2%)	0	1 (1.0%)
	ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
	BACK PAIN	1 (2.2%)	0	1 (1.0%)
	CHEST PAIN	1 (2.2%)	0	1 (1.0%)
	FEVER	0	1 (1.8%)	1 (1.0%)
Nervous System	TOTAL	11 (24.4%)	9 (15.8%)	20 (19.6%)
	INSOMNIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	DIZZINESS	2 (4.4%)	1 (1.8%)	3 (2.9%)
	NERVOUSNESS	2 (4.4%)	1 (1.8%)	3 (2.9%)
	NEUROSIS	2 (4.4%)	0	2 (2.0%)
	SOMNOLENCE	2 (4.4%)	0	2 (2.0%)
	EMOTIONAL LABILITY	1 (2.2%)	1 (1.8%)	2 (2.0%)
	AGITATION	0	2 (3.5%)	2 (2.0%)
	VERTIGO	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	HOSTILITY	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	7 (15.6%)	11 (19.3%)	18 (17.6%)
	RESPIRATORY DISORDER	5 (11.1%)	9 (15.8%)	14 (13.7%)
	RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
	ASTHMA	0	2 (3.5%)	2 (2.0%)
	SINUSITIS	1 (2.2%)	0	1 (1.0%)
	COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
	EPISTAXIS	0	1 (1.8%)	1 (1.0%)
	PHARYNGITIS	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	4 (8.9%)	11 (19.3%)	15 (14.7%)
	NAUSEA	3 (6.7%)	4 (7.0%)	7 (6.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	DYSPEPSIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
	DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Digestive System	INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
	VOMITING	1 (2.2%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	DIARRHEA	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	GASTROINTESTINAL DISORDER	0	1 (1.8%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.8%)	1 (1.0%)
Urogenital System	TOTAL	4 (8.9%)	1 (1.8%)	5 (4.9%)
	ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
	HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	DYSURIA	1 (2.2%)	0	1 (1.0%)
Special Senses	TOTAL	3 (6.7%)	1 (1.8%)	4 (3.9%)
	BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
	EYE PAIN	1 (2.2%)	0	1 (1.0%)
	OTITIS MEDIA	1 (2.2%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.2%)	1 (1.8%)	2 (2.0%)
	LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.8%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.2%)	1 (1.8%)	2 (2.0%)
	ARTHRALGIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
Cardiovascular System	TOTAL	0	1 (1.8%)	1 (1.0%)
	SYNCOPE	0	1 (1.8%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (5.3%)	3 (2.9%)
	WEIGHT GAIN	0	3 (5.3%)	3 (2.9%)
Skin and Appendages	TOTAL	0	5 (8.8%)	5 (4.9%)
	ACNE	0	2 (3.5%)	2 (2.0%)
	CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)
	PRURITUS	0	1 (1.8%)	1 (1.0%)
	RASH	0	1 (1.8%)	1 (1.0%)
	SWEATING	0	1 (1.8%)	1 (1.0%)
	URTICARIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	25 (55.6%)	23 (40.4%)	48 (47.1%)
Body as a Whole	TOTAL	14 (31.1%)	11 (19.3%)	25 (24.5%)
	HEADACHE	5 (11.1%)	5 (8.8%)	10 (9.8%)
	TRAUMA	4 (8.9%)	1 (1.8%)	5 (4.9%)
	INFECTION	3 (6.7%)	2 (3.5%)	5 (4.9%)
	ASTHENIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
	ABDOMINAL PAIN	1 (2.2%)	3 (5.3%)	4 (3.9%)
	BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
	ALLERGIC REACTION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	FEVER	0	1 (1.8%)	1 (1.0%)
Nervous System	TOTAL	7 (15.6%)	12 (21.1%)	19 (18.6%)
	EMOTIONAL LABILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
	HOSTILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
	NERVOUSNESS	1 (2.2%)	3 (5.3%)	4 (3.9%)
	INSOMNIA	1 (2.2%)	2 (3.5%)	3 (2.9%)
	SOMNOLENCE	1 (2.2%)	2 (3.5%)	3 (2.9%)
	ANXIETY	1 (2.2%)	1 (1.8%)	2 (2.0%)
	DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	AGITATION	0	2 (3.5%)	2 (2.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	DIZZINESS	0	1 (1.8%)	1 (1.0%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	7 (15.6%)	8 (14.0%)	15 (14.7%)
	RESPIRATORY DISORDER	3 (6.7%)	4 (7.0%)	7 (6.9%)
	ASTHMA	2 (4.4%)	2 (3.5%)	4 (3.9%)
	BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	SINUSITIS	2 (4.4%)	0	2 (2.0%)
	PHARYNGITIS	0	1 (1.8%)	1 (1.0%)
	PNEUMONIA	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	5 (11.1%)	5 (8.8%)	10 (9.8%)
	NAUSEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
	DIARRHEA	2 (4.4%)	1 (1.8%)	3 (2.9%)
	DYSPEPSIA	0	3 (5.3%)	3 (2.9%)
	TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
	VOMITING	1 (2.2%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	3 (6.7%)	1 (1.8%)	4 (3.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	WEIGHT GAIN	2 (4.4%)	0	2 (2.0%)
	WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
Musculoskeletal System	TOTAL	1 (2.2%)	0	1 (1.0%)
	ARTHRALGIA	1 (2.2%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.2%)	1 (1.8%)	2 (2.0%)
	ACNE	1 (2.2%)	1 (1.8%)	2 (2.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.8%)	1 (1.0%)
	EOSINOPHILIA	0	1 (1.8%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.8%)	1 (1.0%)
Special Senses	TOTAL	0	1 (1.8%)	1 (1.0%)
	OTITIS MEDIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	5 (11.1%)	6 (10.5%)	11 (10.8%)
Nervous System	TOTAL	3 (6.7%)	4 (7.0%)	7 (6.9%)
	EMOTIONAL LABILITY	1 (2.2%)	1 (1.8%)	2 (2.0%)
	AGITATION	1 (2.2%)	0	1 (1.0%)
	LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
	NEUROSIS	1 (2.2%)	0	1 (1.0%)
	SOMNOLENCE	1 (2.2%)	0	1 (1.0%)
	ANXIETY	0	1 (1.8%)	1 (1.0%)
	HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
	HOSTILITY	0	1 (1.8%)	1 (1.0%)
Body as a Whole	TOTAL	2 (4.4%)	1 (1.8%)	3 (2.9%)
	INFECTION	1 (2.2%)	1 (1.8%)	2 (2.0%)
	TRAUMA	1 (2.2%)	0	1 (1.0%)
	ABDOMINAL PAIN	0	1 (1.8%)	1 (1.0%)
Cardiovascular System	TOTAL	0	1 (1.8%)	1 (1.0%)
	SYNCOPE	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	0	2 (3.5%)	2 (2.0%)
	NAUSEA	0	1 (1.8%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (8.3%)	2 (4.8%)
Urogenital System	TOTAL	0	2 (8.3%)	2 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	2 (11.1%)	0	2 (4.8%)
Urogenital System	TOTAL	2 (11.1%)	0	2 (4.8%)
	DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	29 (58.0%)	40 (60.6%)	69 (59.5%)
Body as a Whole	TOTAL	13 (26.0%)	20 (30.3%)	33 (28.4%)
	HEADACHE	6 (12.0%)	8 (12.1%)	14 (12.1%)
	INFECTION	1 (2.0%)	6 (9.1%)	7 (6.0%)
	TRAUMA	3 (6.0%)	3 (4.5%)	6 (5.2%)
	ABDOMINAL PAIN	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ALLERGIC REACTION	3 (6.0%)	1 (1.5%)	4 (3.4%)
	BACK PAIN	1 (2.0%)	3 (4.5%)	4 (3.4%)
	ASTHENIA	0	4 (6.1%)	4 (3.4%)
	FEVER	1 (2.0%)	2 (3.0%)	3 (2.6%)
	CHEST PAIN	1 (2.0%)	0	1 (0.9%)
	FACE EDEMA	1 (2.0%)	0	1 (0.9%)
	PAIN	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	13 (26.0%)	19 (28.8%)	32 (27.6%)
	RESPIRATORY DISORDER	8 (16.0%)	10 (15.2%)	18 (15.5%)
	RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
	PHARYNGITIS	2 (4.0%)	5 (7.6%)	7 (6.0%)
	COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
	SINUSITIS	2 (4.0%)	0	2 (1.7%)
	ASTHMA	0	2 (3.0%)	2 (1.7%)
	EPISTAXIS	0	2 (3.0%)	2 (1.7%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	11 (22.0%)	11 (16.7%)	22 (19.0%)
	INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
	NERVOUSNESS	3 (6.0%)	0	3 (2.6%)
	DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	SOMNOLENCE	2 (4.0%)	0	2 (1.7%)
	AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	DEPRESSION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	EMOTIONAL LABILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HALLUCINATIONS	1 (2.0%)	0	1 (0.9%)
	VERTIGO	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	10 (20.0%)	15 (22.7%)	25 (21.6%)
	DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Digestive System	NAUSEA	4 (8.0%)	3 (4.5%)	7 (6.0%)
	DRY MOUTH	3 (6.0%)	0	3 (2.6%)
	INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	VOMITING	1 (2.0%)	2 (3.0%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	DIARRHEA	0	2 (3.0%)	2 (1.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	4 (8.0%)	3 (4.5%)	7 (6.0%)
	ACNE	2 (4.0%)	0	2 (1.7%)
	RASH	1 (2.0%)	1 (1.5%)	2 (1.7%)
	PRURITUS	0	2 (3.0%)	2 (1.7%)
	CONTACT DERMATITIS	1 (2.0%)	0	1 (0.9%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (4.0%)	1 (1.5%)	3 (2.6%)
	LEUKOPENIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	ANEMIA	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.0%)	5 (7.6%)	7 (6.0%)
	WEIGHT GAIN	2 (4.0%)	5 (7.6%)	7 (6.0%)
Urogenital System	TOTAL	2 (4.0%)	4 (6.1%)	6 (5.2%)
	ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HAEMATURIA	0	2 (3.0%)	2 (1.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (2.0%)	0	1 (0.9%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
Special Senses	TOTAL	1 (2.0%)	1 (1.5%)	2 (1.7%)
	OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.7%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)
	SYNCOPE	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	29 (58.0%)	28 (42.4%)	57 (49.1%)
Body as a Whole	TOTAL	15 (30.0%)	14 (21.2%)	29 (25.0%)
	INFECTION	4 (8.0%)	6 (9.1%)	10 (8.6%)
	TRAUMA	6 (12.0%)	3 (4.5%)	9 (7.8%)
	HEADACHE	6 (12.0%)	2 (3.0%)	8 (6.9%)
	FEVER	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
	BACK PAIN	2 (4.0%)	0	2 (1.7%)
	ALLERGIC REACTION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ASTHENIA	0	1 (1.5%)	1 (0.9%)
	PAIN	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	10 (20.0%)	10 (15.2%)	20 (17.2%)
	RESPIRATORY DISORDER	7 (14.0%)	5 (7.6%)	12 (10.3%)
	BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
	PHARYNGITIS	2 (4.0%)	0	2 (1.7%)
	SINUSITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ASTHMA	1 (2.0%)	0	1 (0.9%)
	PNEUMONIA	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	9 (18.0%)	5 (7.6%)	14 (12.1%)
	VOMITING	5 (10.0%)	2 (3.0%)	7 (6.0%)
	DIARRHEA	3 (6.0%)	0	3 (2.6%)
	NAUSEA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	STOMATITIS	1 (2.0%)	0	1 (0.9%)
	DYSPEPSIA	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	8 (16.0%)	12 (18.2%)	20 (17.2%)
	AGITATION	1 (2.0%)	3 (4.5%)	4 (3.4%)
	SOMNOLENCE	1 (2.0%)	3 (4.5%)	4 (3.4%)
	HOSTILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
	NERVOUSNESS	2 (4.0%)	1 (1.5%)	3 (2.6%)
	DEPRESSION	2 (4.0%)	0	2 (1.7%)
	EMOTIONAL LABILITY	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	INSOMNIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Nervous System	TREMOR	0	1 (1.5%)	1 (0.9%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.0%)	2 (3.0%)	6 (5.2%)
	WEIGHT GAIN	3 (6.0%)	1 (1.5%)	4 (3.4%)
	WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
	DEHYDRATION	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ACNE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	CONTACT DERMATITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
Special Senses	TOTAL	1 (2.0%)	0	1 (0.9%)
	OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
Urogenital System	TOTAL	1 (2.0%)	0	1 (0.9%)
	URINARY INCONTINENCE	1 (2.0%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
	SYNCOPE	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.9%)
	LEUKOPENIA	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ARTHROSIS	0	1 (1.5%)	1 (0.9%)
	MYALGIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	5 (10.0%)	11 (16.7%)	16 (13.8%)
Nervous System	TOTAL	3 (6.0%)	6 (9.1%)	9 (7.8%)
	EMOTIONAL LABILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
	AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HOSTILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
	DEPRESSION	1 (2.0%)	0	1 (0.9%)
	LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	EUPHORIA	0	1 (1.5%)	1 (0.9%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
Body as a Whole	TOTAL	2 (4.0%)	1 (1.5%)	3 (2.6%)
	TRAUMA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	INFECTION	1 (2.0%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ASTHMA	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.9%)
	RASH	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.9%)

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Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (6.9%)	2 (3.8%)
Urogenital System	TOTAL	0	2 (6.9%)	2 (3.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.9%)

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Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	28 (63.6%)	36 (59.0%)	64 (61.0%)
Body as a Whole	TOTAL	19 (43.2%)	20 (32.8%)	39 (37.1%)
	HEADACHE	10 (22.7%)	11 (18.0%)	21 (20.0%)
	TRAUMA	2 (4.5%)	4 (6.6%)	6 (5.7%)
	ABDOMINAL PAIN	1 (2.3%)	5 (8.2%)	6 (5.7%)
	ALLERGIC REACTION	2 (4.5%)	3 (4.9%)	5 (4.8%)
	FEVER	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ASTHENIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	INFECTION	2 (4.5%)	1 (1.6%)	3 (2.9%)
	PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
	BACK PAIN	1 (2.3%)	0	1 (1.0%)
Respiratory System	TOTAL	8 (18.2%)	12 (19.7%)	20 (19.0%)
	RESPIRATORY DISORDER	2 (4.5%)	8 (13.1%)	10 (9.5%)
	RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
	PHARYNGITIS	2 (4.5%)	3 (4.9%)	5 (4.8%)
	SINUSITIS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	COUGH INCREASED	2 (4.5%)	0	2 (1.9%)
	ASTHMA	1 (2.3%)	0	1 (1.0%)
	EPISTAXIS	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	7 (15.9%)	10 (16.4%)	17 (16.2%)
	NAUSEA	4 (9.1%)	2 (3.3%)	6 (5.7%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DIARRHEA	2 (4.5%)	0	2 (1.9%)
	DYSPEPSIA	2 (4.5%)	0	2 (1.9%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	FLATULENCE	0	2 (3.3%)	2 (1.9%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	7 (15.9%)	15 (24.6%)	22 (21.0%)
	NERVOUSNESS	1 (2.3%)	6 (9.8%)	7 (6.7%)
	INSOMNIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	HYPERKINESIA	3 (6.8%)	0	3 (2.9%)
	NEUROSIS	3 (6.8%)	0	3 (2.9%)
	DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	HOSTILITY	1 (2.3%)	2 (3.3%)	3 (2.9%)
	MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Nervous System	AGITATION	0	2 (3.3%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	ANXIETY	1 (2.3%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	VERTIGO	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	3 (6.8%)	4 (6.6%)	7 (6.7%)
	OTITIS EXTERNA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
	EYE PAIN	1 (2.3%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
	EAR PAIN	0	1 (1.6%)	1 (1.0%)
	OTITIS MEDIA	0	1 (1.6%)	1 (1.0%)
Urogenital System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
	DYSURIA	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	1 (2.3%)	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ARTHRALGIA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MYALGIA	1 (2.3%)	0	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	3 (4.9%)	4 (3.8%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	HAEMATOMA	1 (2.3%)	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ANEMIA	1 (2.3%)	0	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	6 (9.8%)	7 (6.7%)
	RASH	0	3 (4.9%)	3 (2.9%)
	ACNE	0	2 (3.3%)	2 (1.9%)
	CONTACT DERMATITIS	0	2 (3.3%)	2 (1.9%)
	MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
	URTICARIA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	23 (52.3%)	34 (55.7%)	57 (54.3%)
Body as a Whole	TOTAL	15 (34.1%)	11 (18.0%)	26 (24.8%)
	HEADACHE	7 (15.9%)	5 (8.2%)	12 (11.4%)
	INFECTION	4 (9.1%)	2 (3.3%)	6 (5.7%)
	ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ABDOMINAL PAIN	1 (2.3%)	3 (4.9%)	4 (3.8%)
	TRAUMA	3 (6.8%)	0	3 (2.9%)
	ALLERGIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	FEVER	1 (2.3%)	0	1 (1.0%)
	BACK PAIN	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	9 (20.5%)	22 (36.1%)	31 (29.5%)
	NERVOUSNESS	1 (2.3%)	8 (13.1%)	9 (8.6%)
	HYPERKINESIA	4 (9.1%)	4 (6.6%)	8 (7.6%)
	HOSTILITY	1 (2.3%)	5 (8.2%)	6 (5.7%)
	ANXIETY	1 (2.3%)	3 (4.9%)	4 (3.8%)
	INSOMNIA	1 (2.3%)	2 (3.3%)	3 (2.9%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
	AGITATION	0	2 (3.3%)	2 (1.9%)
	DIZZINESS	0	2 (3.3%)	2 (1.9%)
	DEPRESSION	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	4 (9.1%)	7 (11.5%)	11 (10.5%)
	RESPIRATORY DISORDER	2 (4.5%)	4 (6.6%)	6 (5.7%)
	ASTHMA	1 (2.3%)	2 (3.3%)	3 (2.9%)
	SINUSITIS	2 (4.5%)	0	2 (1.9%)
	COUGH INCREASED	1 (2.3%)	1 (1.6%)	2 (1.9%)
	PHARYNGITIS	0	1 (1.6%)	1 (1.0%)
	PNEUMONIA	0	1 (1.6%)	1 (1.0%)
	RHINITIS	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	3 (6.8%)	2 (3.3%)	5 (4.8%)
	OTITIS MEDIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	EAR PAIN	1 (2.3%)	0	1 (1.0%)
	OTITIS EXTERNA	1 (2.3%)	0	1 (1.0%)
Digestive System	TOTAL	2 (4.5%)	6 (9.8%)	8 (7.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Digestive System	DYSPEPSIA	0	3 (4.9%)	3 (2.9%)
	NAUSEA	0	3 (4.9%)	3 (2.9%)
	DIARRHEA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
	GINGIVITIS	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.3%)	0	1 (1.0%)
	ARTHRALGIA	1 (2.3%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ACNE	1 (2.3%)	0	1 (1.0%)
	CONTACT DERMATITIS	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.6%)	1 (1.0%)
	EOSINOPHILIA	0	1 (1.6%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	4 (9.1%)	5 (8.2%)	9 (8.6%)
Body as a Whole	TOTAL	2 (4.5%)	1 (1.6%)	3 (2.9%)
	INFECTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ABSCESS	1 (2.3%)	0	1 (1.0%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	2 (4.5%)	4 (6.6%)	6 (5.7%)
	HOSTILITY	0	2 (3.3%)	2 (1.9%)
	NEUROSIS	1 (2.3%)	0	1 (1.0%)
	SOMNOLENCE	1 (2.3%)	0	1 (1.0%)
	HYPERKINESIA	0	1 (1.6%)	1 (1.0%)
	NERVOUSNESS	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	1 (2.3%)	0	1 (1.0%)
	PHARYNGITIS	1 (2.3%)	0	1 (1.0%)
Cardiovascular System	TOTAL	0	1 (1.6%)	1 (1.0%)
	SYNCOPE	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	0	1 (1.6%)	1 (1.0%)
	NAUSEA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.8%)	1 (2.3%)
Urogenital System	TOTAL	0	1 (4.8%)	1 (2.3%)
	DYSMENORRHEA	0	1 (4.8%)	1 (2.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.6%)	0	3 (7.0%)
Urogenital System	TOTAL	3 (13.6%)	0	3 (7.0%)
	DYSMENORRHEA	3 (13.6%)	0	3 (7.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	57 (60.6%)	76 (59.8%)	133 (60.2%)
Body as a Whole	TOTAL	32 (34.0%)	40 (31.5%)	72 (32.6%)
	HEADACHE	16 (17.0%)	19 (15.0%)	35 (15.8%)
	TRAUMA	5 (5.3%)	7 (5.5%)	12 (5.4%)
	ABDOMINAL PAIN	4 (4.3%)	7 (5.5%)	11 (5.0%)
	INFECTION	3 (3.2%)	7 (5.5%)	10 (4.5%)
	ALLERGIC REACTION	5 (5.3%)	4 (3.1%)	9 (4.1%)
	FEVER	3 (3.2%)	4 (3.1%)	7 (3.2%)
	ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
	BACK PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
	PAIN	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
	CHEST PAIN	1 (1.1%)	0	1 (0.5%)
	FACE EDEMA	1 (1.1%)	0	1 (0.5%)
Respiratory System	TOTAL	21 (22.3%)	31 (24.4%)	52 (23.5%)
	RESPIRATORY DISORDER	10 (10.6%)	18 (14.2%)	28 (12.7%)
	RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
	PHARYNGITIS	4 (4.3%)	8 (6.3%)	12 (5.4%)
	SINUSITIS	4 (4.3%)	1 (0.8%)	5 (2.3%)
	COUGH INCREASED	3 (3.2%)	2 (1.6%)	5 (2.3%)
	ASTHMA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	EPISTAXIS	0	3 (2.4%)	3 (1.4%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Nervous System	TOTAL	18 (19.1%)	26 (20.5%)	44 (19.9%)
	INSOMNIA	4 (4.3%)	8 (6.3%)	12 (5.4%)
	NERVOUSNESS	4 (4.3%)	6 (4.7%)	10 (4.5%)
	DIZZINESS	3 (3.2%)	3 (2.4%)	6 (2.7%)
	HYPERKINESIA	4 (4.3%)	1 (0.8%)	5 (2.3%)
	AGITATION	1 (1.1%)	3 (2.4%)	4 (1.8%)
	NEUROSIS	3 (3.2%)	0	3 (1.4%)
	HOSTILITY	1 (1.1%)	2 (1.6%)	3 (1.4%)
	SOMNOLENCE	2 (2.1%)	0	2 (0.9%)
	ANXIETY	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEPRESSION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	EMOTIONAL LABILITY	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TREMOR	0	2 (1.6%)	2 (0.9%)
	HALLUCINATIONS	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Nervous System	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	17 (18.1%)	25 (19.7%)	42 (19.0%)
	NAUSEA	8 (8.5%)	5 (3.9%)	13 (5.9%)
	DYSPEPSIA	7 (7.4%)	4 (3.1%)	11 (5.0%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
	DIARRHEA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	VOMITING	1 (1.1%)	2 (1.6%)	3 (1.4%)
	FLATULENCE	0	2 (1.6%)	2 (0.9%)
	GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
	TOOTH CARIES	0	2 (1.6%)	2 (0.9%)
	CONSTIPATION	0	1 (0.8%)	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.5%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	5 (5.3%)	9 (7.1%)	14 (6.3%)
	RASH	1 (1.1%)	4 (3.1%)	5 (2.3%)
	ACNE	2 (2.1%)	2 (1.6%)	4 (1.8%)
	CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PRURITUS	0	2 (1.6%)	2 (0.9%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.5%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
	URTICARIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	5 (5.3%)	5 (3.9%)	10 (4.5%)
	ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	URINARY INCONTINENCE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DYSURIA	1 (1.1%)	0	1 (0.5%)
	CYSTITIS	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	4 (4.3%)	5 (3.9%)	9 (4.1%)
	OTITIS EXTERNA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	OTITIS MEDIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
	BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
	EYE PAIN	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Special Senses	EAR PAIN	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	3 (3.2%)	2 (1.6%)	5 (2.3%)
	LEUKOPENIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	3 (3.2%)	1 (0.8%)	4 (1.8%)
	ARTHRALGIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	MYALGIA	1 (1.1%)	0	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	2 (2.1%)	5 (3.9%)	7 (3.2%)
	WEIGHT GAIN	2 (2.1%)	5 (3.9%)	7 (3.2%)
Cardiovascular System	TOTAL	1 (1.1%)	5 (3.9%)	6 (2.7%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	HAEMATOMA	1 (1.1%)	0	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	52 (55.3%)	62 (48.8%)	114 (51.6%)
Body as a Whole	TOTAL	30 (31.9%)	25 (19.7%)	55 (24.9%)
	HEADACHE	13 (13.8%)	7 (5.5%)	20 (9.0%)
	INFECTION	8 (8.5%)	8 (6.3%)	16 (7.2%)
	TRAUMA	9 (9.6%)	3 (2.4%)	12 (5.4%)
	ABDOMINAL PAIN	3 (3.2%)	5 (3.9%)	8 (3.6%)
	FEVER	4 (4.3%)	2 (1.6%)	6 (2.7%)
	ASTHENIA	2 (2.1%)	3 (2.4%)	5 (2.3%)
	ALLERGIC REACTION	2 (2.1%)	2 (1.6%)	4 (1.8%)
	BACK PAIN	2 (2.1%)	1 (0.8%)	3 (1.4%)
	PAIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
Nervous System	TOTAL	17 (18.1%)	34 (26.8%)	51 (23.1%)
	NERVOUSNESS	3 (3.2%)	9 (7.1%)	12 (5.4%)
	HOSTILITY	3 (3.2%)	6 (4.7%)	9 (4.1%)
	HYPERKINESIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
	SOMNOLENCE	2 (2.1%)	4 (3.1%)	6 (2.7%)
	AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
	ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EMOTIONAL LABILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	INSOMNIA	1 (1.1%)	3 (2.4%)	4 (1.8%)
	DEPRESSION	2 (2.1%)	1 (0.8%)	3 (1.4%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIZZINESS	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
	CONCENTRATION IMPAIRED	0	1 (0.8%)	1 (0.5%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)
	TREMOR	0	1 (0.8%)	1 (0.5%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	14 (14.9%)	17 (13.4%)	31 (14.0%)
	RESPIRATORY DISORDER	9 (9.6%)	9 (7.1%)	18 (8.1%)
	SINUSITIS	3 (3.2%)	1 (0.8%)	4 (1.8%)
	ASTHMA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
	PHARYNGITIS	2 (2.1%)	1 (0.8%)	3 (1.4%)
	COUGH INCREASED	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PNEUMONIA	0	2 (1.6%)	2 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Respiratory System	RHINITIS	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	11 (11.7%)	11 (8.7%)	22 (10.0%)
	VOMITING	5 (5.3%)	2 (1.6%)	7 (3.2%)
	NAUSEA	2 (2.1%)	4 (3.1%)	6 (2.7%)
	DIARRHEA	4 (4.3%)	1 (0.8%)	5 (2.3%)
	DYSPEPSIA	0	4 (3.1%)	4 (1.8%)
	CONSTIPATION	1 (1.1%)	0	1 (0.5%)
	STOMATITIS	1 (1.1%)	0	1 (0.5%)
	TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
	GINGIVITIS	0	1 (0.8%)	1 (0.5%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	5 (5.3%)	4 (3.1%)	9 (4.1%)
	WEIGHT GAIN	4 (4.3%)	2 (1.6%)	6 (2.7%)
	WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEHYDRATION	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	4 (4.3%)	3 (2.4%)	7 (3.2%)
	ACNE	2 (2.1%)	1 (0.8%)	3 (1.4%)
	CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
Special Senses	TOTAL	4 (4.3%)	2 (1.6%)	6 (2.7%)
	OTITIS MEDIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	EAR PAIN	1 (1.1%)	0	1 (0.5%)
	OTITIS EXTERNA	1 (1.1%)	0	1 (0.5%)
Musculoskeletal System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ARTHRALGIA	1 (1.1%)	0	1 (0.5%)
	ARTHROSIS	0	1 (0.8%)	1 (0.5%)
	MYALGIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	0	1 (0.5%)
	URINARY INCONTINENCE	1 (1.1%)	0	1 (0.5%)
Cardiovascular System	TOTAL	0	2 (1.6%)	2 (0.9%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	0	2 (1.6%)	2 (0.9%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Hemic and Lymphatic System	LEUKOPENIA	0	1 (0.8%)	1 (0.5%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	9 (9.6%)	16 (12.6%)	25 (11.3%)
Nervous System	TOTAL	5 (5.3%)	10 (7.9%)	15 (6.8%)
	HOSTILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EMOTIONAL LABILITY	2 (2.1%)	1 (0.8%)	3 (1.4%)
	AGITATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEPRESSION	1 (1.1%)	0	1 (0.5%)
	LACK OF EMOTION	1 (1.1%)	0	1 (0.5%)
	NEUROSIS	1 (1.1%)	0	1 (0.5%)
	SOMNOLENCE	1 (1.1%)	0	1 (0.5%)
	ANXIETY	0	1 (0.8%)	1 (0.5%)
	EUPHORIA	0	1 (0.8%)	1 (0.5%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
	HYPERKINESIA	0	1 (0.8%)	1 (0.5%)
	NERVOUSNESS	0	1 (0.8%)	1 (0.5%)
	PARALYSIS	0	1 (0.8%)	1 (0.5%)
Body as a Whole	TOTAL	4 (4.3%)	2 (1.6%)	6 (2.7%)
	INFECTION	2 (2.1%)	1 (0.8%)	3 (1.4%)
	TRAUMA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PHARYNGITIS	1 (1.1%)	0	1 (0.5%)
	ASTHMA	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	0	2 (1.6%)	2 (0.9%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	0	2 (1.6%)	2 (0.9%)
	NAUSEA	0	1 (0.8%)	1 (0.5%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.5%)
	RASH	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.5%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	0	1 (0.8%)	1 (0.5%)
	URINARY INCONTINENCE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	3 (6.0%)	3 (3.2%)
Urogenital System	TOTAL	0	3 (6.0%)	3 (3.2%)
	DYSMENORRHEA	0	1 (2.0%)	1 (1.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	0	3 (3.2%)
Urogenital System	TOTAL	3 (6.7%)	0	3 (3.2%)
	DYSMENORRHEA	3 (6.7%)	0	3 (3.2%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	 Placebo (N=36)	 Total (N=61)
TOTAL	16 (64.0%)	21 (58.3%)	37 (60.7%)
HEADACHE	4 (16.0%)	3 (8.3%)	7 (11.5%)
RESPIRATORY DISORDER	4 (16.0%)	3 (8.3%)	7 (11.5%)
DYSPEPSIA	3 (12.0%)	3 (8.3%)	6 (9.8%)
PHARYNGITIS	2 (8.0%)	4 (11.1%)	6 (9.8%)
INFECTION	1 (4.0%)	5 (13.9%)	6 (9.8%)
ABDOMINAL PAIN	3 (12.0%)	2 (5.6%)	5 (8.2%)
RHINITIS	2 (8.0%)	3 (8.3%)	5 (8.2%)
TRAUMA	3 (12.0%)	1 (2.8%)	4 (6.6%)
WEIGHT GAIN	2 (8.0%)	2 (5.6%)	4 (6.6%)
FEVER	1 (4.0%)	2 (5.6%)	3 (4.9%)
BACK PAIN	0	3 (8.3%)	3 (4.9%)
INSOMNIA	0	3 (8.3%)	3 (4.9%)
ACNE	2 (8.0%)	0	2 (3.3%)
DRY MOUTH	2 (8.0%)	0	2 (3.3%)
SINUSITIS	2 (8.0%)	0	2 (3.3%)
ALLERGIC REACTION	1 (4.0%)	1 (2.8%)	2 (3.3%)
COUGH INCREASED	1 (4.0%)	1 (2.8%)	2 (3.3%)
DEPRESSION	1 (4.0%)	1 (2.8%)	2 (3.3%)
HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
LEUKOPENIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
NAUSEA	1 (4.0%)	1 (2.8%)	2 (3.3%)
RASH	1 (4.0%)	1 (2.8%)	2 (3.3%)
URINARY INCONTINENCE	1 (4.0%)	1 (2.8%)	2 (3.3%)
ASTHENIA	0	2 (5.6%)	2 (3.3%)
EPISTAXIS	0	2 (5.6%)	2 (3.3%)
VOMITING	0	2 (5.6%)	2 (3.3%)
AGITATION	1 (4.0%)	0	1 (1.6%)
ARTHRALGIA	1 (4.0%)	0	1 (1.6%)
CONTACT DERMATITIS	1 (4.0%)	0	1 (1.6%)
FACE EDEMA	1 (4.0%)	0	1 (1.6%)
HALLUCINATIONS	1 (4.0%)	0	1 (1.6%)
INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
NERVOUSNESS	1 (4.0%)	0	1 (1.6%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)
ALBUMINURIA	0	1 (2.8%)	1 (1.6%)
ANEMIA	0	1 (2.8%)	1 (1.6%)
ANXIETY	0	1 (2.8%)	1 (1.6%)
DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
DIARRHEA	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
HAEMATURIA	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Preferred Term			
HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.6%)
PRURITUS	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	 Placebo (N=36)	 Total (N=61)
TOTAL	15 (60.0%)	19 (52.8%)	34 (55.7%)
RESPIRATORY DISORDER	5 (20.0%)	4 (11.1%)	9 (14.8%)
INFECTION	3 (12.0%)	5 (13.9%)	8 (13.1%)
VOMITING	4 (16.0%)	2 (5.6%)	6 (9.8%)
FEVER	3 (12.0%)	1 (2.8%)	4 (6.6%)
HEADACHE	3 (12.0%)	1 (2.8%)	4 (6.6%)
TRAUMA	2 (8.0%)	2 (5.6%)	4 (6.6%)
WEIGHT GAIN	2 (8.0%)	1 (2.8%)	3 (4.9%)
AGITATION	1 (4.0%)	2 (5.6%)	3 (4.9%)
DIARRHEA	2 (8.0%)	0	2 (3.3%)
HOSTILITY	2 (8.0%)	0	2 (3.3%)
NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
PHARYNGITIS	2 (8.0%)	0	2 (3.3%)
ABDOMINAL PAIN	1 (4.0%)	1 (2.8%)	2 (3.3%)
ALLERGIC REACTION	1 (4.0%)	1 (2.8%)	2 (3.3%)
CONTACT DERMATITIS	1 (4.0%)	1 (2.8%)	2 (3.3%)
ACNE	1 (4.0%)	0	1 (1.6%)
CONSTIPATION	1 (4.0%)	0	1 (1.6%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
DEPRESSION	1 (4.0%)	0	1 (1.6%)
HERPES ZOSTER	1 (4.0%)	0	1 (1.6%)
OTITIS MEDIA	1 (4.0%)	0	1 (1.6%)
STOMATITIS	1 (4.0%)	0	1 (1.6%)
URINARY INCONTINENCE	1 (4.0%)	0	1 (1.6%)
VESTIBULAR DISORDER	1 (4.0%)	0	1 (1.6%)
BRONCHITIS	0	1 (2.8%)	1 (1.6%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.6%)
HALLUCINATIONS	0	1 (2.8%)	1 (1.6%)
HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
INSOMNIA	0	1 (2.8%)	1 (1.6%)
LEUKOPENIA	0	1 (2.8%)	1 (1.6%)
MYALGIA	0	1 (2.8%)	1 (1.6%)
NAUSEA	0	1 (2.8%)	1 (1.6%)
PAIN	0	1 (2.8%)	1 (1.6%)
PNEUMONIA	0	1 (2.8%)	1 (1.6%)
SINUSITIS	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
SYNCOPE	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Preferred Term			
TOTAL	2 (8.0%)	6 (16.7%)	8 (13.1%)
HOSTILITY	1 (4.0%)	1 (2.8%)	2 (3.3%)
DEPRESSION	1 (4.0%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
AGITATION	0	1 (2.8%)	1 (1.6%)
ASTHMA	0	1 (2.8%)	1 (1.6%)
OTITIS MEDIA	0	1 (2.8%)	1 (1.6%)
RASH	0	1 (2.8%)	1 (1.6%)
TRAUMA	0	1 (2.8%)	1 (1.6%)
URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
TOTAL	15 (62.5%)	22 (64.7%)	37 (63.8%)
HEADACHE	5 (20.8%)	5 (14.7%)	10 (17.2%)
RESPIRATORY DISORDER	1 (4.2%)	6 (17.6%)	7 (12.1%)
RHINITIS	3 (12.5%)	3 (8.8%)	6 (10.3%)
NERVOUSNESS	1 (4.2%)	5 (14.7%)	6 (10.3%)
PHARYNGITIS	2 (8.3%)	3 (8.8%)	5 (8.6%)
TRAUMA	2 (8.3%)	3 (8.8%)	5 (8.6%)
ABDOMINAL PAIN	0	5 (14.7%)	5 (8.6%)
NAUSEA	4 (16.7%)	0	4 (6.9%)
DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
HYPERKINESIA	3 (12.5%)	0	3 (5.2%)
FEVER	2 (8.3%)	1 (2.9%)	3 (5.2%)
VASODILATATION	0	3 (8.8%)	3 (5.2%)
COUGH INCREASED	2 (8.3%)	0	2 (3.4%)
DIARRHEA	2 (8.3%)	0	2 (3.4%)
DYSPEPSIA	2 (8.3%)	0	2 (3.4%)
DIZZINESS	1 (4.2%)	1 (2.9%)	2 (3.4%)
HOSTILITY	1 (4.2%)	1 (2.9%)	2 (3.4%)
MYOCLONUS	1 (4.2%)	1 (2.9%)	2 (3.4%)
OTITIS EXTERNA	1 (4.2%)	1 (2.9%)	2 (3.4%)
PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
SINUSITIS	1 (4.2%)	1 (2.9%)	2 (3.4%)
RASH	0	2 (5.9%)	2 (3.4%)
ANEMIA	1 (4.2%)	0	1 (1.7%)
ANXIETY	1 (4.2%)	0	1 (1.7%)
ASTHMA	1 (4.2%)	0	1 (1.7%)
BACK PAIN	1 (4.2%)	0	1 (1.7%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
HAEMATOMA	1 (4.2%)	0	1 (1.7%)
MACULOPAPULAR RASH	1 (4.2%)	0	1 (1.7%)
MYALGIA	1 (4.2%)	0	1 (1.7%)
NEUROSIS	1 (4.2%)	0	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.7%)
CONTACT DERMATITIS	0	1 (2.9%)	1 (1.7%)
EAR PAIN	0	1 (2.9%)	1 (1.7%)
FLATULENCE	0	1 (2.9%)	1 (1.7%)
GASTROENTERITIS	0	1 (2.9%)	1 (1.7%)
OTITIS MEDIA	0	1 (2.9%)	1 (1.7%)
TOOTH CARIES	0	1 (2.9%)	1 (1.7%)
TREMOR	0	1 (2.9%)	1 (1.7%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
VERTIGO	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=24)	 Placebo (N=34)	 Total (N=58)
TOTAL	12 (50.0%)	18 (52.9%)	30 (51.7%)
HEADACHE	5 (20.8%)	1 (2.9%)	6 (10.3%)
HYPERKINESIA	3 (12.5%)	3 (8.8%)	6 (10.3%)
NERVOUSNESS	0	6 (17.6%)	6 (10.3%)
TRAUMA	3 (12.5%)	0	3 (5.2%)
INFECTION	2 (8.3%)	1 (2.9%)	3 (5.2%)
OTITIS MEDIA	2 (8.3%)	1 (2.9%)	3 (5.2%)
HOSTILITY	0	3 (8.8%)	3 (5.2%)
ABDOMINAL PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
COUGH INCREASED	1 (4.2%)	1 (2.9%)	2 (3.4%)
PAIN	1 (4.2%)	1 (2.9%)	2 (3.4%)
RESPIRATORY DISORDER	1 (4.2%)	1 (2.9%)	2 (3.4%)
SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
ANXIETY	0	2 (5.9%)	2 (3.4%)
EAR PAIN	1 (4.2%)	0	1 (1.7%)
FEVER	1 (4.2%)	0	1 (1.7%)
OTITIS EXTERNA	1 (4.2%)	0	1 (1.7%)
SINUSITIS	1 (4.2%)	0	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
CONTACT DERMATITIS	0	1 (2.9%)	1 (1.7%)
DIZZINESS	0	1 (2.9%)	1 (1.7%)
DYSPEPSIA	0	1 (2.9%)	1 (1.7%)
LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
MANIC REACTION	0	1 (2.9%)	1 (1.7%)
NAUSEA	0	1 (2.9%)	1 (1.7%)
RHINITIS	0	1 (2.9%)	1 (1.7%)
WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Preferred Term			
TOTAL	2 (8.3%)	3 (8.8%)	5 (8.6%)
ABSCESS	1 (4.2%)	0	1 (1.7%)
INFECTION	1 (4.2%)	0	1 (1.7%)
PHARYNGITIS	1 (4.2%)	0	1 (1.7%)
HOSTILITY	0	1 (2.9%)	1 (1.7%)
HYPERKINESIA	0	1 (2.9%)	1 (1.7%)
NERVOUSNESS	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	0	1 (8.3%)	1 (4.0%)
DYSMENORRHEA	0	1 (8.3%)	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	1 (7.7%)	0	1 (4.0%)
DYSMENORRHEA	1 (7.7%)	0	1 (4.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	31 (63.3%)	43 (61.4%)	74 (62.2%)
HEADACHE	9 (18.4%)	8 (11.4%)	17 (14.3%)
RESPIRATORY DISORDER	5 (10.2%)	9 (12.9%)	14 (11.8%)
RHINITIS	5 (10.2%)	6 (8.6%)	11 (9.2%)
PHARYNGITIS	4 (8.2%)	7 (10.0%)	11 (9.2%)
ABDOMINAL PAIN	3 (6.1%)	7 (10.0%)	10 (8.4%)
TRAUMA	5 (10.2%)	4 (5.7%)	9 (7.6%)
DYSPEPSIA	5 (10.2%)	3 (4.3%)	8 (6.7%)
INSOMNIA	2 (4.1%)	5 (7.1%)	7 (5.9%)
NERVOUSNESS	2 (4.1%)	5 (7.1%)	7 (5.9%)
NAUSEA	5 (10.2%)	1 (1.4%)	6 (5.0%)
FEVER	3 (6.1%)	3 (4.3%)	6 (5.0%)
INFECTION	1 (2.0%)	5 (7.1%)	6 (5.0%)
HYPERKINESIA	4 (8.2%)	1 (1.4%)	5 (4.2%)
DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
COUGH INCREASED	3 (6.1%)	1 (1.4%)	4 (3.4%)
SINUSITIS	3 (6.1%)	1 (1.4%)	4 (3.4%)
WEIGHT GAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
BACK PAIN	1 (2.0%)	3 (4.3%)	4 (3.4%)
RASH	1 (2.0%)	3 (4.3%)	4 (3.4%)
DIARRHEA	2 (4.1%)	1 (1.4%)	3 (2.5%)
ALLERGIC REACTION	1 (2.0%)	2 (2.9%)	3 (2.5%)
DIZZINESS	1 (2.0%)	2 (2.9%)	3 (2.5%)
URINARY INCONTINENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
VASODILATATION	0	3 (4.3%)	3 (2.5%)
ACNE	2 (4.1%)	0	2 (1.7%)
DRY MOUTH	2 (4.1%)	0	2 (1.7%)
AGITATION	1 (2.0%)	1 (1.4%)	2 (1.7%)
ANEMIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
ANXIETY	1 (2.0%)	1 (1.4%)	2 (1.7%)
CONTACT DERMATITIS	1 (2.0%)	1 (1.4%)	2 (1.7%)
DEPRESSION	1 (2.0%)	1 (1.4%)	2 (1.7%)
HOSTILITY	1 (2.0%)	1 (1.4%)	2 (1.7%)
LEUKOPENIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
MACULOPAPULAR RASH	1 (2.0%)	1 (1.4%)	2 (1.7%)
MYOCLONUS	1 (2.0%)	1 (1.4%)	2 (1.7%)
OTITIS EXTERNA	1 (2.0%)	1 (1.4%)	2 (1.7%)
PAIN	1 (2.0%)	1 (1.4%)	2 (1.7%)
ASTHENIA	0	2 (2.9%)	2 (1.7%)
EPISTAXIS	0	2 (2.9%)	2 (1.7%)
GASTROENTERITIS	0	2 (2.9%)	2 (1.7%)
TOOTH CARIES	0	2 (2.9%)	2 (1.7%)
VOMITING	0	2 (2.9%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
ARTHRALGIA	1 (2.0%)	0	1 (0.8%)
ASTHMA	1 (2.0%)	0	1 (0.8%)
CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
FACE EDEMA	1 (2.0%)	0	1 (0.8%)
HAEMATOMA	1 (2.0%)	0	1 (0.8%)
HALLUCINATIONS	1 (2.0%)	0	1 (0.8%)
INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
MYALGIA	1 (2.0%)	0	1 (0.8%)
NEUROSIS	1 (2.0%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)
ALBUMINURIA	0	1 (1.4%)	1 (0.8%)
EAR PAIN	0	1 (1.4%)	1 (0.8%)
FLATULENCE	0	1 (1.4%)	1 (0.8%)
HAEMATURIA	0	1 (1.4%)	1 (0.8%)
HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
OTITIS MEDIA	0	1 (1.4%)	1 (0.8%)
PRURITUS	0	1 (1.4%)	1 (0.8%)
TREMOR	0	1 (1.4%)	1 (0.8%)
VERTIGO	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	27 (55.1%)	37 (52.9%)	64 (53.8%)
RESPIRATORY DISORDER	6 (12.2%)	5 (7.1%)	11 (9.2%)
INFECTION	5 (10.2%)	6 (8.6%)	11 (9.2%)
HEADACHE	8 (16.3%)	2 (2.9%)	10 (8.4%)
NERVOUSNESS	2 (4.1%)	6 (8.6%)	8 (6.7%)
TRAUMA	5 (10.2%)	2 (2.9%)	7 (5.9%)
VOMITING	4 (8.2%)	2 (2.9%)	6 (5.0%)
HYPERKINESIA	3 (6.1%)	3 (4.3%)	6 (5.0%)
FEVER	4 (8.2%)	1 (1.4%)	5 (4.2%)
HOSTILITY	2 (4.1%)	3 (4.3%)	5 (4.2%)
OTITIS MEDIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
ABDOMINAL PAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
WEIGHT GAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
AGITATION	1 (2.0%)	3 (4.3%)	4 (3.4%)
CONTACT DERMATITIS	1 (2.0%)	2 (2.9%)	3 (2.5%)
PAIN	1 (2.0%)	2 (2.9%)	3 (2.5%)
SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
DIARRHEA	2 (4.1%)	0	2 (1.7%)
PHARYNGITIS	2 (4.1%)	0	2 (1.7%)
ALLERGIC REACTION	1 (2.0%)	1 (1.4%)	2 (1.7%)
COUGH INCREASED	1 (2.0%)	1 (1.4%)	2 (1.7%)
SINUSITIS	1 (2.0%)	1 (1.4%)	2 (1.7%)
ANXIETY	0	2 (2.9%)	2 (1.7%)
NAUSEA	0	2 (2.9%)	2 (1.7%)
ACNE	1 (2.0%)	0	1 (0.8%)
CONSTIPATION	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
DEPRESSION	1 (2.0%)	0	1 (0.8%)
EAR PAIN	1 (2.0%)	0	1 (0.8%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.8%)
OTITIS EXTERNA	1 (2.0%)	0	1 (0.8%)
STOMATITIS	1 (2.0%)	0	1 (0.8%)
URINARY INCONTINENCE	1 (2.0%)	0	1 (0.8%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.8%)
BRONCHITIS	0	1 (1.4%)	1 (0.8%)
CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.8%)
DIZZINESS	0	1 (1.4%)	1 (0.8%)
DYSPEPSIA	0	1 (1.4%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.4%)	1 (0.8%)
HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
INSOMNIA	0	1 (1.4%)	1 (0.8%)
LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
LEUKOPENIA	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Preferred Term			
MANIC REACTION	0	1 (1.4%)	1 (0.8%)
MYALGIA	0	1 (1.4%)	1 (0.8%)
PNEUMONIA	0	1 (1.4%)	1 (0.8%)
RHINITIS	0	1 (1.4%)	1 (0.8%)
SYNCOPE	0	1 (1.4%)	1 (0.8%)
TOOTH CARIES	0	1 (1.4%)	1 (0.8%)
TREMOR	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	4 (8.2%)	9 (12.9%)	13 (10.9%)
HOSTILITY	1 (2.0%)	2 (2.9%)	3 (2.5%)
ABSCESS	1 (2.0%)	0	1 (0.8%)
DEPRESSION	1 (2.0%)	0	1 (0.8%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
INFECTION	1 (2.0%)	0	1 (0.8%)
PHARYNGITIS	1 (2.0%)	0	1 (0.8%)
AGITATION	0	1 (1.4%)	1 (0.8%)
ASTHMA	0	1 (1.4%)	1 (0.8%)
HYPERKINESIA	0	1 (1.4%)	1 (0.8%)
NERVOUSNESS	0	1 (1.4%)	1 (0.8%)
OTITIS MEDIA	0	1 (1.4%)	1 (0.8%)
RASH	0	1 (1.4%)	1 (0.8%)
TRAUMA	0	1 (1.4%)	1 (0.8%)
URINARY INCONTINENCE	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
TOTAL	0	1 (3.8%)	1 (1.9%)
DYSMENORRHEA	0	1 (3.8%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
TOTAL	1 (3.7%)	0	1 (1.9%)
DYSMENORRHEA	1 (3.7%)	0	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=27)	 Placebo (N=26)	 Total (N=53)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	 Placebo (N=30)	 Total (N=55)
TOTAL	13 (52.0%)	17 (56.7%)	30 (54.5%)
RESPIRATORY DISORDER	4 (16.0%)	7 (23.3%)	11 (20.0%)
HEADACHE	2 (8.0%)	5 (16.7%)	7 (12.7%)
NAUSEA	3 (12.0%)	2 (6.7%)	5 (9.1%)
DYSPEPSIA	2 (8.0%)	1 (3.3%)	3 (5.5%)
INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
WEIGHT GAIN	0	3 (10.0%)	3 (5.5%)
ALLERGIC REACTION	2 (8.0%)	0	2 (3.6%)
NERVOUSNESS	2 (8.0%)	0	2 (3.6%)
SOMNOLENCE	2 (8.0%)	0	2 (3.6%)
ALBUMINURIA	1 (4.0%)	1 (3.3%)	2 (3.6%)
DIZZINESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
EMOTIONAL LABILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
RHINITIS	1 (4.0%)	1 (3.3%)	2 (3.6%)
ASTHENIA	0	2 (6.7%)	2 (3.6%)
ASTHMA	0	2 (6.7%)	2 (3.6%)
DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
INCREASED APPETITE	0	2 (6.7%)	2 (3.6%)
TRAUMA	0	2 (6.7%)	2 (3.6%)
BACK PAIN	1 (4.0%)	0	1 (1.8%)
CHEST PAIN	1 (4.0%)	0	1 (1.8%)
DRY MOUTH	1 (4.0%)	0	1 (1.8%)
LEUKOPENIA	1 (4.0%)	0	1 (1.8%)
OTITIS MEDIA	1 (4.0%)	0	1 (1.8%)
VERTIGO	1 (4.0%)	0	1 (1.8%)
VOMITING	1 (4.0%)	0	1 (1.8%)
AGITATION	0	1 (3.3%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
COUGH INCREASED	0	1 (3.3%)	1 (1.8%)
DIARRHEA	0	1 (3.3%)	1 (1.8%)
HAEMATURIA	0	1 (3.3%)	1 (1.8%)
INFECTION	0	1 (3.3%)	1 (1.8%)
PAIN	0	1 (3.3%)	1 (1.8%)
PHARYNGITIS	0	1 (3.3%)	1 (1.8%)
PRURITUS	0	1 (3.3%)	1 (1.8%)
SYNCOPE	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	 Placebo (N=30)	 Total (N=55)
TOTAL	14 (56.0%)	9 (30.0%)	23 (41.8%)
TRAUMA	4 (16.0%)	1 (3.3%)	5 (9.1%)
HEADACHE	3 (12.0%)	1 (3.3%)	4 (7.3%)
RESPIRATORY DISORDER	2 (8.0%)	1 (3.3%)	3 (5.5%)
BRONCHITIS	1 (4.0%)	2 (6.7%)	3 (5.5%)
SOMNOLENCE	1 (4.0%)	2 (6.7%)	3 (5.5%)
BACK PAIN	2 (8.0%)	0	2 (3.6%)
NAUSEA	2 (8.0%)	0	2 (3.6%)
ABDOMINAL PAIN	1 (4.0%)	1 (3.3%)	2 (3.6%)
INFECTION	1 (4.0%)	1 (3.3%)	2 (3.6%)
EMOTIONAL LABILITY	0	2 (6.7%)	2 (3.6%)
ASTHMA	1 (4.0%)	0	1 (1.8%)
DEPRESSION	1 (4.0%)	0	1 (1.8%)
DIARRHEA	1 (4.0%)	0	1 (1.8%)
SINUSITIS	1 (4.0%)	0	1 (1.8%)
VOMITING	1 (4.0%)	0	1 (1.8%)
WEIGHT GAIN	1 (4.0%)	0	1 (1.8%)
WEIGHT LOSS	1 (4.0%)	0	1 (1.8%)
ACNE	0	1 (3.3%)	1 (1.8%)
AGITATION	0	1 (3.3%)	1 (1.8%)
ASTHENIA	0	1 (3.3%)	1 (1.8%)
DYSPEPSIA	0	1 (3.3%)	1 (1.8%)
FEVER	0	1 (3.3%)	1 (1.8%)
HOSTILITY	0	1 (3.3%)	1 (1.8%)
NERVOUSNESS	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
TOTAL	3 (12.0%)	4 (13.3%)	7 (12.7%)
EMOTIONAL LABILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
AGITATION	1 (4.0%)	0	1 (1.8%)
INFECTION	1 (4.0%)	0	1 (1.8%)
LACK OF EMOTION	1 (4.0%)	0	1 (1.8%)
TRAUMA	1 (4.0%)	0	1 (1.8%)
ANXIETY	0	1 (3.3%)	1 (1.8%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
TOOTH CARIES	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=20)	 Placebo (N=27)	 Total (N=47)
TOTAL	13 (65.0%)	14 (51.9%)	27 (57.4%)
HEADACHE	5 (25.0%)	6 (22.2%)	11 (23.4%)
ALLERGIC REACTION	2 (10.0%)	2 (7.4%)	4 (8.5%)
ASTHENIA	2 (10.0%)	1 (3.7%)	3 (6.4%)
INFECTION	2 (10.0%)	1 (3.7%)	3 (6.4%)
RESPIRATORY DISORDER	1 (5.0%)	2 (7.4%)	3 (6.4%)
ALBUMINURIA	2 (10.0%)	0	2 (4.3%)
NEUROSIS	2 (10.0%)	0	2 (4.3%)
ARTHRALGIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
INSOMNIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
RHINITIS	1 (5.0%)	1 (3.7%)	2 (4.3%)
ACNE	0	2 (7.4%)	2 (4.3%)
DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
DRY MOUTH	0	2 (7.4%)	2 (4.3%)
NAUSEA	0	2 (7.4%)	2 (4.3%)
ABDOMINAL PAIN	1 (5.0%)	0	1 (2.1%)
ABNORMAL LABORATORY VALUE	1 (5.0%)	0	1 (2.1%)
BLEPHARITIS	1 (5.0%)	0	1 (2.1%)
DIZZINESS	1 (5.0%)	0	1 (2.1%)
DYSURIA	1 (5.0%)	0	1 (2.1%)
EYE PAIN	1 (5.0%)	0	1 (2.1%)
HAEMATURIA	1 (5.0%)	0	1 (2.1%)
PAIN	1 (5.0%)	0	1 (2.1%)
SINUSITIS	1 (5.0%)	0	1 (2.1%)
ABNORMAL VISION	0	1 (3.7%)	1 (2.1%)
AGITATION	0	1 (3.7%)	1 (2.1%)
CONSTIPATION	0	1 (3.7%)	1 (2.1%)
CONTACT DERMATITIS	0	1 (3.7%)	1 (2.1%)
EPISTAXIS	0	1 (3.7%)	1 (2.1%)
FEVER	0	1 (3.7%)	1 (2.1%)
FLATULENCE	0	1 (3.7%)	1 (2.1%)
HOSTILITY	0	1 (3.7%)	1 (2.1%)
NERVOUSNESS	0	1 (3.7%)	1 (2.1%)
RASH	0	1 (3.7%)	1 (2.1%)
TRAUMA	0	1 (3.7%)	1 (2.1%)
TREMOR	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
TOTAL	11 (55.0%)	14 (51.9%)	25 (53.2%)
HEADACHE	2 (10.0%)	4 (14.8%)	6 (12.8%)
ASTHENIA	2 (10.0%)	2 (7.4%)	4 (8.5%)
RESPIRATORY DISORDER	1 (5.0%)	3 (11.1%)	4 (8.5%)
INFECTION	2 (10.0%)	1 (3.7%)	3 (6.4%)
ASTHMA	1 (5.0%)	2 (7.4%)	3 (6.4%)
HOSTILITY	1 (5.0%)	2 (7.4%)	3 (6.4%)
INSOMNIA	1 (5.0%)	2 (7.4%)	3 (6.4%)
NERVOUSNESS	1 (5.0%)	2 (7.4%)	3 (6.4%)
ALLERGIC REACTION	1 (5.0%)	1 (3.7%)	2 (4.3%)
ANXIETY	1 (5.0%)	1 (3.7%)	2 (4.3%)
DIARRHEA	1 (5.0%)	1 (3.7%)	2 (4.3%)
EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
ABDOMINAL PAIN	0	2 (7.4%)	2 (4.3%)
DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
NAUSEA	0	2 (7.4%)	2 (4.3%)
ACNE	1 (5.0%)	0	1 (2.1%)
ARTHRALGIA	1 (5.0%)	0	1 (2.1%)
MANIC REACTION	1 (5.0%)	0	1 (2.1%)
SINUSITIS	1 (5.0%)	0	1 (2.1%)
TOOTH DISORDER	1 (5.0%)	0	1 (2.1%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
AGITATION	0	1 (3.7%)	1 (2.1%)
BACK PAIN	0	1 (3.7%)	1 (2.1%)
DEPRESSION	0	1 (3.7%)	1 (2.1%)
DIZZINESS	0	1 (3.7%)	1 (2.1%)
OTITIS MEDIA	0	1 (3.7%)	1 (2.1%)
PHARYNGITIS	0	1 (3.7%)	1 (2.1%)
PNEUMONIA	0	1 (3.7%)	1 (2.1%)
WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
TOTAL	2 (10.0%)	2 (7.4%)	4 (8.5%)
NEUROSIS	1 (5.0%)	0	1 (2.1%)
SOMNOLENCE	1 (5.0%)	0	1 (2.1%)
ABDOMINAL PAIN	0	1 (3.7%)	1 (2.1%)
HOSTILITY	0	1 (3.7%)	1 (2.1%)
INFECTION	0	1 (3.7%)	1 (2.1%)
NAUSEA	0	1 (3.7%)	1 (2.1%)
SYNCOPE	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	2 (22.2%)	0	2 (11.1%)
DYSMENORRHEA	2 (22.2%)	0	2 (11.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	26 (57.8%)	31 (54.4%)	57 (55.9%)
HEADACHE	7 (15.6%)	11 (19.3%)	18 (17.6%)
RESPIRATORY DISORDER	5 (11.1%)	9 (15.8%)	14 (13.7%)
NAUSEA	3 (6.7%)	4 (7.0%)	7 (6.9%)
ALLERGIC REACTION	4 (8.9%)	2 (3.5%)	6 (5.9%)
ASTHENIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
INSOMNIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
ALBUMINURIA	3 (6.7%)	1 (1.8%)	4 (3.9%)
INFECTION	2 (4.4%)	2 (3.5%)	4 (3.9%)
RHINITIS	2 (4.4%)	2 (3.5%)	4 (3.9%)
DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
DIZZINESS	2 (4.4%)	1 (1.8%)	3 (2.9%)
DYSPEPSIA	2 (4.4%)	1 (1.8%)	3 (2.9%)
NERVOUSNESS	2 (4.4%)	1 (1.8%)	3 (2.9%)
DRY MOUTH	1 (2.2%)	2 (3.5%)	3 (2.9%)
TRAUMA	0	3 (5.3%)	3 (2.9%)
WEIGHT GAIN	0	3 (5.3%)	3 (2.9%)
NEUROSIS	2 (4.4%)	0	2 (2.0%)
SOMNOLENCE	2 (4.4%)	0	2 (2.0%)
ARTHRALGIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
EMOTIONAL LABILITY	1 (2.2%)	1 (1.8%)	2 (2.0%)
HAEMATURIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
PAIN	1 (2.2%)	1 (1.8%)	2 (2.0%)
ACNE	0	2 (3.5%)	2 (2.0%)
AGITATION	0	2 (3.5%)	2 (2.0%)
ASTHMA	0	2 (3.5%)	2 (2.0%)
INCREASED APPETITE	0	2 (3.5%)	2 (2.0%)
ABDOMINAL PAIN	1 (2.2%)	0	1 (1.0%)
ABNORMAL LABORATORY VALUE	1 (2.2%)	0	1 (1.0%)
BACK PAIN	1 (2.2%)	0	1 (1.0%)
BLEPHARITIS	1 (2.2%)	0	1 (1.0%)
CHEST PAIN	1 (2.2%)	0	1 (1.0%)
DYSURIA	1 (2.2%)	0	1 (1.0%)
EYE PAIN	1 (2.2%)	0	1 (1.0%)
LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
OTITIS MEDIA	1 (2.2%)	0	1 (1.0%)
SINUSITIS	1 (2.2%)	0	1 (1.0%)
VERTIGO	1 (2.2%)	0	1 (1.0%)
VOMITING	1 (2.2%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.8%)	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
CONSTIPATION	0	1 (1.8%)	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Preferred Term			
COUGH INCREASED	0	1 (1.8%)	1 (1.0%)
DIARRHEA	0	1 (1.8%)	1 (1.0%)
EPISTAXIS	0	1 (1.8%)	1 (1.0%)
FEVER	0	1 (1.8%)	1 (1.0%)
FLATULENCE	0	1 (1.8%)	1 (1.0%)
HOSTILITY	0	1 (1.8%)	1 (1.0%)
PHARYNGITIS	0	1 (1.8%)	1 (1.0%)
PRURITUS	0	1 (1.8%)	1 (1.0%)
RASH	0	1 (1.8%)	1 (1.0%)
SYNCOPE	0	1 (1.8%)	1 (1.0%)
TREMOR	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	25 (55.6%)	23 (40.4%)	48 (47.1%)
HEADACHE	5 (11.1%)	5 (8.8%)	10 (9.8%)
RESPIRATORY DISORDER	3 (6.7%)	4 (7.0%)	7 (6.9%)
TRAUMA	4 (8.9%)	1 (1.8%)	5 (4.9%)
INFECTION	3 (6.7%)	2 (3.5%)	5 (4.9%)
ASTHENIA	2 (4.4%)	3 (5.3%)	5 (4.9%)
ASTHMA	2 (4.4%)	2 (3.5%)	4 (3.9%)
NAUSEA	2 (4.4%)	2 (3.5%)	4 (3.9%)
ABDOMINAL PAIN	1 (2.2%)	3 (5.3%)	4 (3.9%)
EMOTIONAL LABILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
HOSTILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
NERVOUSNESS	1 (2.2%)	3 (5.3%)	4 (3.9%)
BACK PAIN	2 (4.4%)	1 (1.8%)	3 (2.9%)
DIARRHEA	2 (4.4%)	1 (1.8%)	3 (2.9%)
BRONCHITIS	1 (2.2%)	2 (3.5%)	3 (2.9%)
INSOMNIA	1 (2.2%)	2 (3.5%)	3 (2.9%)
SOMNOLENCE	1 (2.2%)	2 (3.5%)	3 (2.9%)
DYSPEPSIA	0	3 (5.3%)	3 (2.9%)
SINUSITIS	2 (4.4%)	0	2 (2.0%)
WEIGHT GAIN	2 (4.4%)	0	2 (2.0%)
ACNE	1 (2.2%)	1 (1.8%)	2 (2.0%)
ALLERGIC REACTION	1 (2.2%)	1 (1.8%)	2 (2.0%)
ANXIETY	1 (2.2%)	1 (1.8%)	2 (2.0%)
DEPRESSION	1 (2.2%)	1 (1.8%)	2 (2.0%)
HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
WEIGHT LOSS	1 (2.2%)	1 (1.8%)	2 (2.0%)
AGITATION	0	2 (3.5%)	2 (2.0%)
ARTHRALGIA	1 (2.2%)	0	1 (1.0%)
MANIC REACTION	1 (2.2%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.2%)	0	1 (1.0%)
VOMITING	1 (2.2%)	0	1 (1.0%)
DIZZINESS	0	1 (1.8%)	1 (1.0%)
FEVER	0	1 (1.8%)	1 (1.0%)
OTITIS MEDIA	0	1 (1.8%)	1 (1.0%)
PHARYNGITIS	0	1 (1.8%)	1 (1.0%)
PNEUMONIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	5 (11.1%)	6 (10.5%)	11 (10.8%)
EMOTIONAL LABILITY	1 (2.2%)	1 (1.8%)	2 (2.0%)
INFECTION	1 (2.2%)	1 (1.8%)	2 (2.0%)
AGITATION	1 (2.2%)	0	1 (1.0%)
LACK OF EMOTION	1 (2.2%)	0	1 (1.0%)
NEUROSIS	1 (2.2%)	0	1 (1.0%)
SOMNOLENCE	1 (2.2%)	0	1 (1.0%)
TRAUMA	1 (2.2%)	0	1 (1.0%)
ABDOMINAL PAIN	0	1 (1.8%)	1 (1.0%)
ANXIETY	0	1 (1.8%)	1 (1.0%)
HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
HOSTILITY	0	1 (1.8%)	1 (1.0%)
NAUSEA	0	1 (1.8%)	1 (1.0%)
SYNCOPE	0	1 (1.8%)	1 (1.0%)
TOOTH CARIES	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	2 (11.1%)	0	2 (4.8%)
DYSMENORRHEA	2 (11.1%)	0	2 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	29 (58.0%)	38 (57.6%)	67 (57.8%)
RESPIRATORY DISORDER	8 (16.0%)	10 (15.2%)	18 (15.5%)
HEADACHE	6 (12.0%)	8 (12.1%)	14 (12.1%)
DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
NAUSEA	4 (8.0%)	3 (4.5%)	7 (6.0%)
RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
PHARYNGITIS	2 (4.0%)	5 (7.6%)	7 (6.0%)
WEIGHT GAIN	2 (4.0%)	5 (7.6%)	7 (6.0%)
INFECTION	1 (2.0%)	6 (9.1%)	7 (6.0%)
TRAUMA	3 (6.0%)	3 (4.5%)	6 (5.2%)
INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
ABDOMINAL PAIN	3 (6.0%)	2 (3.0%)	5 (4.3%)
ALLERGIC REACTION	3 (6.0%)	1 (1.5%)	4 (3.4%)
BACK PAIN	1 (2.0%)	3 (4.5%)	4 (3.4%)
ASTHENIA	0	4 (6.1%)	4 (3.4%)
DRY MOUTH	3 (6.0%)	0	3 (2.6%)
NERVOUSNESS	3 (6.0%)	0	3 (2.6%)
LEUKOPENIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
FEVER	1 (2.0%)	2 (3.0%)	3 (2.6%)
INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
VOMITING	1 (2.0%)	2 (3.0%)	3 (2.6%)
DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
ACNE	2 (4.0%)	0	2 (1.7%)
SINUSITIS	2 (4.0%)	0	2 (1.7%)
SOMNOLENCE	2 (4.0%)	0	2 (1.7%)
AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
DEPRESSION	1 (2.0%)	1 (1.5%)	2 (1.7%)
EMOTIONAL LABILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
RASH	1 (2.0%)	1 (1.5%)	2 (1.7%)
URINARY INCONTINENCE	1 (2.0%)	1 (1.5%)	2 (1.7%)
ASTHMA	0	2 (3.0%)	2 (1.7%)
DIARRHEA	0	2 (3.0%)	2 (1.7%)
EPISTAXIS	0	2 (3.0%)	2 (1.7%)
HAEMATURIA	0	2 (3.0%)	2 (1.7%)
PRURITUS	0	2 (3.0%)	2 (1.7%)
ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
CHEST PAIN	1 (2.0%)	0	1 (0.9%)
CONTACT DERMATITIS	1 (2.0%)	0	1 (0.9%)
FACE EDEMA	1 (2.0%)	0	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
HALLUCINATIONS	1 (2.0%)	0	1 (0.9%)
OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
VERTIGO	1 (2.0%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
ANEMIA	0	1 (1.5%)	1 (0.9%)
ANXIETY	0	1 (1.5%)	1 (0.9%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
PAIN	0	1 (1.5%)	1 (0.9%)
SYNCOPE	0	1 (1.5%)	1 (0.9%)
TOOTH CARIES	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	29 (58.0%)	28 (42.4%)	57 (49.1%)
RESPIRATORY DISORDER	7 (14.0%)	5 (7.6%)	12 (10.3%)
INFECTION	4 (8.0%)	6 (9.1%)	10 (8.6%)
TRAUMA	6 (12.0%)	3 (4.5%)	9 (7.8%)
HEADACHE	6 (12.0%)	2 (3.0%)	8 (6.9%)
VOMITING	5 (10.0%)	2 (3.0%)	7 (6.0%)
FEVER	3 (6.0%)	2 (3.0%)	5 (4.3%)
WEIGHT GAIN	3 (6.0%)	1 (1.5%)	4 (3.4%)
ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
AGITATION	1 (2.0%)	3 (4.5%)	4 (3.4%)
BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
SOMNOLENCE	1 (2.0%)	3 (4.5%)	4 (3.4%)
DIARRHEA	3 (6.0%)	0	3 (2.6%)
HOSTILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
NAUSEA	2 (4.0%)	1 (1.5%)	3 (2.6%)
NERVOUSNESS	2 (4.0%)	1 (1.5%)	3 (2.6%)
BACK PAIN	2 (4.0%)	0	2 (1.7%)
DEPRESSION	2 (4.0%)	0	2 (1.7%)
PHARYNGITIS	2 (4.0%)	0	2 (1.7%)
ACNE	1 (2.0%)	1 (1.5%)	2 (1.7%)
ALLERGIC REACTION	1 (2.0%)	1 (1.5%)	2 (1.7%)
CONTACT DERMATITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
SINUSITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
EMOTIONAL LABILITY	0	2 (3.0%)	2 (1.7%)
ASTHMA	1 (2.0%)	0	1 (0.9%)
CONSTIPATION	1 (2.0%)	0	1 (0.9%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
STOMATITIS	1 (2.0%)	0	1 (0.9%)
URINARY INCONTINENCE	1 (2.0%)	0	1 (0.9%)
VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
ASTHENIA	0	1 (1.5%)	1 (0.9%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
DYSPEPSIA	0	1 (1.5%)	1 (0.9%)
HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
INSOMNIA	0	1 (1.5%)	1 (0.9%)
LEUKOPENIA	0	1 (1.5%)	1 (0.9%)
MYALGIA	0	1 (1.5%)	1 (0.9%)
PAIN	0	1 (1.5%)	1 (0.9%)
PNEUMONIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Preferred Term			
SYNCOPE	0	1 (1.5%)	1 (0.9%)
TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
TREMOR	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	5 (10.0%)	10 (15.2%)	15 (12.9%)
EMOTIONAL LABILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
HOSTILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
TRAUMA	1 (2.0%)	1 (1.5%)	2 (1.7%)
DEPRESSION	1 (2.0%)	0	1 (0.9%)
INFECTION	1 (2.0%)	0	1 (0.9%)
LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
ANXIETY	0	1 (1.5%)	1 (0.9%)
ASTHMA	0	1 (1.5%)	1 (0.9%)
HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
OTITIS MEDIA	0	1 (1.5%)	1 (0.9%)
RASH	0	1 (1.5%)	1 (0.9%)
TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
URINARY INCONTINENCE	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	28 (63.6%)	36 (59.0%)	64 (61.0%)
HEADACHE	10 (22.7%)	11 (18.0%)	21 (20.0%)
RESPIRATORY DISORDER	2 (4.5%)	8 (13.1%)	10 (9.5%)
RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
NERVOUSNESS	1 (2.3%)	6 (9.8%)	7 (6.7%)
NAUSEA	4 (9.1%)	2 (3.3%)	6 (5.7%)
INSOMNIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
TRAUMA	2 (4.5%)	4 (6.6%)	6 (5.7%)
ABDOMINAL PAIN	1 (2.3%)	5 (8.2%)	6 (5.7%)
ALLERGIC REACTION	2 (4.5%)	3 (4.9%)	5 (4.8%)
PHARYNGITIS	2 (4.5%)	3 (4.9%)	5 (4.8%)
FEVER	2 (4.5%)	2 (3.3%)	4 (3.8%)
HYPERKINESIA	3 (6.8%)	0	3 (2.9%)
NEUROSIS	3 (6.8%)	0	3 (2.9%)
ASTHENIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
INFECTION	2 (4.5%)	1 (1.6%)	3 (2.9%)
PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
SINUSITIS	2 (4.5%)	1 (1.6%)	3 (2.9%)
HOSTILITY	1 (2.3%)	2 (3.3%)	3 (2.9%)
RASH	0	3 (4.9%)	3 (2.9%)
VASODILATATION	0	3 (4.9%)	3 (2.9%)
ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
COUGH INCREASED	2 (4.5%)	0	2 (1.9%)
DIARRHEA	2 (4.5%)	0	2 (1.9%)
DYSPEPSIA	2 (4.5%)	0	2 (1.9%)
ARTHRALGIA	1 (2.3%)	1 (1.6%)	2 (1.9%)
MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)
OTITIS EXTERNA	1 (2.3%)	1 (1.6%)	2 (1.9%)
ACNE	0	2 (3.3%)	2 (1.9%)
AGITATION	0	2 (3.3%)	2 (1.9%)
CONTACT DERMATITIS	0	2 (3.3%)	2 (1.9%)
DRY MOUTH	0	2 (3.3%)	2 (1.9%)
FLATULENCE	0	2 (3.3%)	2 (1.9%)
TREMOR	0	2 (3.3%)	2 (1.9%)
ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
ANEMIA	1 (2.3%)	0	1 (1.0%)
ANXIETY	1 (2.3%)	0	1 (1.0%)
ASTHMA	1 (2.3%)	0	1 (1.0%)
BACK PAIN	1 (2.3%)	0	1 (1.0%)
BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=44)	 Placebo (N=61)	 Total (N=105)
DYSURIA	1 (2.3%)	0	1 (1.0%)
EYE PAIN	1 (2.3%)	0	1 (1.0%)
HAEMATOMA	1 (2.3%)	0	1 (1.0%)
HAEMATURIA	1 (2.3%)	0	1 (1.0%)
MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
MYALGIA	1 (2.3%)	0	1 (1.0%)
ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
CONSTIPATION	0	1 (1.6%)	1 (1.0%)
EAR PAIN	0	1 (1.6%)	1 (1.0%)
EPISTAXIS	0	1 (1.6%)	1 (1.0%)
GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
OTITIS MEDIA	0	1 (1.6%)	1 (1.0%)
TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
VERTIGO	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	23 (52.3%)	32 (52.5%)	55 (52.4%)
HEADACHE	7 (15.9%)	5 (8.2%)	12 (11.4%)
NERVOUSNESS	1 (2.3%)	8 (13.1%)	9 (8.6%)
HYPERKINESIA	4 (9.1%)	4 (6.6%)	8 (7.6%)
INFECTION	4 (9.1%)	2 (3.3%)	6 (5.7%)
RESPIRATORY DISORDER	2 (4.5%)	4 (6.6%)	6 (5.7%)
HOSTILITY	1 (2.3%)	5 (8.2%)	6 (5.7%)
ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
OTITIS MEDIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
ABDOMINAL PAIN	1 (2.3%)	3 (4.9%)	4 (3.8%)
ANXIETY	1 (2.3%)	3 (4.9%)	4 (3.8%)
TRAUMA	3 (6.8%)	0	3 (2.9%)
ASTHMA	1 (2.3%)	2 (3.3%)	3 (2.9%)
INSOMNIA	1 (2.3%)	2 (3.3%)	3 (2.9%)
DYSPEPSIA	0	3 (4.9%)	3 (2.9%)
NAUSEA	0	3 (4.9%)	3 (2.9%)
SINUSITIS	2 (4.5%)	0	2 (1.9%)
ALLERGIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
COUGH INCREASED	1 (2.3%)	1 (1.6%)	2 (1.9%)
DIARRHEA	1 (2.3%)	1 (1.6%)	2 (1.9%)
EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
AGITATION	0	2 (3.3%)	2 (1.9%)
DIZZINESS	0	2 (3.3%)	2 (1.9%)
ACNE	1 (2.3%)	0	1 (1.0%)
ARTHRALGIA	1 (2.3%)	0	1 (1.0%)
EAR PAIN	1 (2.3%)	0	1 (1.0%)
FEVER	1 (2.3%)	0	1 (1.0%)
OTITIS EXTERNA	1 (2.3%)	0	1 (1.0%)
TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
BACK PAIN	0	1 (1.6%)	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.6%)	1 (1.0%)
DEPRESSION	0	1 (1.6%)	1 (1.0%)
LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
PHARYNGITIS	0	1 (1.6%)	1 (1.0%)
PNEUMONIA	0	1 (1.6%)	1 (1.0%)
RHINITIS	0	1 (1.6%)	1 (1.0%)
WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=44)	 Placebo (N=61)	 Total (N=105)
TOTAL	4 (9.1%)	5 (8.2%)	9 (8.6%)
INFECTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
HOSTILITY	0	2 (3.3%)	2 (1.9%)
ABSCESS	1 (2.3%)	0	1 (1.0%)
NEUROSIS	1 (2.3%)	0	1 (1.0%)
PHARYNGITIS	1 (2.3%)	0	1 (1.0%)
SOMNOLENCE	1 (2.3%)	0	1 (1.0%)
ABDOMINAL PAIN	0	1 (1.6%)	1 (1.0%)
HYPERKINESIA	0	1 (1.6%)	1 (1.0%)
NAUSEA	0	1 (1.6%)	1 (1.0%)
NERVOUSNESS	0	1 (1.6%)	1 (1.0%)
SYNCOPE	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	0	1 (4.8%)	1 (2.3%)
DYSMENORRHEA	0	1 (4.8%)	1 (2.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	3 (13.6%)	0	3 (7.0%)
DYSMENORRHEA	3 (13.6%)	0	3 (7.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	57 (60.6%)	74 (58.3%)	131 (59.3%)
HEADACHE	16 (17.0%)	19 (15.0%)	35 (15.8%)
RESPIRATORY DISORDER	10 (10.6%)	18 (14.2%)	28 (12.7%)
RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
NAUSEA	8 (8.5%)	5 (3.9%)	13 (5.9%)
TRAUMA	5 (5.3%)	7 (5.5%)	12 (5.4%)
INSOMNIA	4 (4.3%)	8 (6.3%)	12 (5.4%)
PHARYNGITIS	4 (4.3%)	8 (6.3%)	12 (5.4%)
DYSPEPSIA	7 (7.4%)	4 (3.1%)	11 (5.0%)
ABDOMINAL PAIN	4 (4.3%)	7 (5.5%)	11 (5.0%)
NERVOUSNESS	4 (4.3%)	6 (4.7%)	10 (4.5%)
INFECTION	3 (3.2%)	7 (5.5%)	10 (4.5%)
ALLERGIC REACTION	5 (5.3%)	4 (3.1%)	9 (4.1%)
DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
FEVER	3 (3.2%)	4 (3.1%)	7 (3.2%)
ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
WEIGHT GAIN	2 (2.1%)	5 (3.9%)	7 (3.2%)
DIZZINESS	3 (3.2%)	3 (2.4%)	6 (2.7%)
HYPERKINESIA	4 (4.3%)	1 (0.8%)	5 (2.3%)
SINUSITIS	4 (4.3%)	1 (0.8%)	5 (2.3%)
ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
COUGH INCREASED	3 (3.2%)	2 (1.6%)	5 (2.3%)
DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
BACK PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
RASH	1 (1.1%)	4 (3.1%)	5 (2.3%)
ACNE	2 (2.1%)	2 (1.6%)	4 (1.8%)
DIARRHEA	2 (2.1%)	2 (1.6%)	4 (1.8%)
PAIN	2 (2.1%)	2 (1.6%)	4 (1.8%)
AGITATION	1 (1.1%)	3 (2.4%)	4 (1.8%)
NEUROSIS	3 (3.2%)	0	3 (1.4%)
ARTHRALGIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
LEUKOPENIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
ASTHMA	1 (1.1%)	2 (1.6%)	3 (1.4%)
CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
HOSTILITY	1 (1.1%)	2 (1.6%)	3 (1.4%)
INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
URINARY INCONTINENCE	1 (1.1%)	2 (1.6%)	3 (1.4%)
VOMITING	1 (1.1%)	2 (1.6%)	3 (1.4%)
EPISTAXIS	0	3 (2.4%)	3 (1.4%)
VASODILATATION	0	3 (2.4%)	3 (1.4%)
SOMNOLENCE	2 (2.1%)	0	2 (0.9%)
ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
ANXIETY	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
DEPRESSION	1 (1.1%)	1 (0.8%)	2 (0.9%)
EMOTIONAL LABILITY	1 (1.1%)	1 (0.8%)	2 (0.9%)
MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
OTITIS EXTERNA	1 (1.1%)	1 (0.8%)	2 (0.9%)
OTITIS MEDIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
FLATULENCE	0	2 (1.6%)	2 (0.9%)
GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
PRURITUS	0	2 (1.6%)	2 (0.9%)
TOOTH CARIES	0	2 (1.6%)	2 (0.9%)
TREMOR	0	2 (1.6%)	2 (0.9%)
ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
CHEST PAIN	1 (1.1%)	0	1 (0.5%)
DYSURIA	1 (1.1%)	0	1 (0.5%)
EYE PAIN	1 (1.1%)	0	1 (0.5%)
FACE EDEMA	1 (1.1%)	0	1 (0.5%)
HAEMATOMA	1 (1.1%)	0	1 (0.5%)
HALLUCINATIONS	1 (1.1%)	0	1 (0.5%)
MYALGIA	1 (1.1%)	0	1 (0.5%)
CONSTIPATION	0	1 (0.8%)	1 (0.5%)
EAR PAIN	0	1 (0.8%)	1 (0.5%)
HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
SYNCOPE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	52 (55.3%)	60 (47.2%)	112 (50.7%)
HEADACHE	13 (13.8%)	7 (5.5%)	20 (9.0%)
RESPIRATORY DISORDER	9 (9.6%)	9 (7.1%)	18 (8.1%)
INFECTION	8 (8.5%)	8 (6.3%)	16 (7.2%)
TRAUMA	9 (9.6%)	3 (2.4%)	12 (5.4%)
NERVOUSNESS	3 (3.2%)	9 (7.1%)	12 (5.4%)
HOSTILITY	3 (3.2%)	6 (4.7%)	9 (4.1%)
HYPERKINESIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
ABDOMINAL PAIN	3 (3.2%)	5 (3.9%)	8 (3.6%)
VOMITING	5 (5.3%)	2 (1.6%)	7 (3.2%)
FEVER	4 (4.3%)	2 (1.6%)	6 (2.7%)
WEIGHT GAIN	4 (4.3%)	2 (1.6%)	6 (2.7%)
NAUSEA	2 (2.1%)	4 (3.1%)	6 (2.7%)
SOMNOLENCE	2 (2.1%)	4 (3.1%)	6 (2.7%)
AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
DIARRHEA	4 (4.3%)	1 (0.8%)	5 (2.3%)
OTITIS MEDIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
ASTHENIA	2 (2.1%)	3 (2.4%)	5 (2.3%)
SINUSITIS	3 (3.2%)	1 (0.8%)	4 (1.8%)
ALLERGIC REACTION	2 (2.1%)	2 (1.6%)	4 (1.8%)
ASTHMA	2 (2.1%)	2 (1.6%)	4 (1.8%)
ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
EMOTIONAL LABILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
INSOMNIA	1 (1.1%)	3 (2.4%)	4 (1.8%)
DYSPEPSIA	0	4 (3.1%)	4 (1.8%)
ACNE	2 (2.1%)	1 (0.8%)	3 (1.4%)
BACK PAIN	2 (2.1%)	1 (0.8%)	3 (1.4%)
DEPRESSION	2 (2.1%)	1 (0.8%)	3 (1.4%)
PHARYNGITIS	2 (2.1%)	1 (0.8%)	3 (1.4%)
CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
PAIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
COUGH INCREASED	1 (1.1%)	1 (0.8%)	2 (0.9%)
MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
DIZZINESS	0	2 (1.6%)	2 (0.9%)
PNEUMONIA	0	2 (1.6%)	2 (0.9%)
ARTHRALGIA	1 (1.1%)	0	1 (0.5%)
CONSTIPATION	1 (1.1%)	0	1 (0.5%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
EAR PAIN	1 (1.1%)	0	1 (0.5%)
HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
OTITIS EXTERNA	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Preferred Term			
STOMATITIS	1 (1.1%)	0	1 (0.5%)
TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
URINARY INCONTINENCE	1 (1.1%)	0	1 (0.5%)
VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
CONCENTRATION IMPAIRED	0	1 (0.8%)	1 (0.5%)
HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
LEUKOPENIA	0	1 (0.8%)	1 (0.5%)
MYALGIA	0	1 (0.8%)	1 (0.5%)
RHINITIS	0	1 (0.8%)	1 (0.5%)
SYNCOPE	0	1 (0.8%)	1 (0.5%)
TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
TREMOR	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=94)	 Placebo (N=127)	 Total (N=221)
TOTAL	9 (9.6%)	15 (11.8%)	24 (10.9%)
HOSTILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
EMOTIONAL LABILITY	2 (2.1%)	1 (0.8%)	3 (1.4%)
INFECTION	2 (2.1%)	1 (0.8%)	3 (1.4%)
AGITATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
TRAUMA	1 (1.1%)	1 (0.8%)	2 (0.9%)
ABSCESS	1 (1.1%)	0	1 (0.5%)
DEPRESSION	1 (1.1%)	0	1 (0.5%)
LACK OF EMOTION	1 (1.1%)	0	1 (0.5%)
NEUROSIS	1 (1.1%)	0	1 (0.5%)
PHARYNGITIS	1 (1.1%)	0	1 (0.5%)
SOMNOLENCE	1 (1.1%)	0	1 (0.5%)
ABDOMINAL PAIN	0	1 (0.8%)	1 (0.5%)
ANXIETY	0	1 (0.8%)	1 (0.5%)
ASTHMA	0	1 (0.8%)	1 (0.5%)
HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
HYPERKINESIA	0	1 (0.8%)	1 (0.5%)
NAUSEA	0	1 (0.8%)	1 (0.5%)
NERVOUSNESS	0	1 (0.8%)	1 (0.5%)
OTITIS MEDIA	0	1 (0.8%)	1 (0.5%)
RASH	0	1 (0.8%)	1 (0.5%)
SYNCOPE	0	1 (0.8%)	1 (0.5%)
TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
URINARY INCONTINENCE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	0	1 (2.0%)	1 (1.1%)
DYSMENORRHEA	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	3 (6.7%)	0	3 (3.2%)
DYSMENORRHEA	3 (6.7%)	0	3 (3.2%)

BRL 29060 - 716
Interim Output
Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	2 (25.0%)	1 (7.7%)	3 (14.3%)
Nervous System	TOTAL	1 (12.5%)	0	1 (4.8%)
	DEPRESSION	1 (12.5%)	0	1 (4.8%)
Respiratory System	TOTAL	1 (12.5%)	0	1 (4.8%)
	RESPIRATORY DISORDER	1 (12.5%)	0	1 (4.8%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.8%)
	NAUSEA	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	1 (12.5%)	4 (30.8%)	5 (23.8%)
Nervous System	TOTAL	1 (12.5%)	2 (15.4%)	3 (14.3%)
	DEPRESSION	1 (12.5%)	1 (7.7%)	2 (9.5%)
	HYSTERIA	0	1 (7.7%)	1 (4.8%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.8%)
	SYNCOPE	0	1 (7.7%)	1 (4.8%)
Special Searches	TOTAL	0	1 (7.7%)	1 (4.8%)
	PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	1 (12.5%)	0	1 (4.8%)
Body as a Whole	TOTAL	1 (12.5%)	0	1 (4.8%)
	FEVER	1 (12.5%)	0	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	1 (33.3%)	0	1 (12.5%)
Body as a Whole	TOTAL	1 (33.3%)	0	1 (12.5%)
	ABDOMINAL PAIN	1 (33.3%)	0	1 (12.5%)
	HEADACHE	1 (33.3%)	0	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	1 (33.3%)	1 (20.0%)	2 (25.0%)
Respiratory System	TOTAL	1 (33.3%)	0	1 (12.5%)
	SINUSITIS	1 (33.3%)	0	1 (12.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (20.0%)	1 (12.5%)
	WEIGHT GAIN	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (20.0%)	1 (12.5%)
Body as a Whole	TOTAL	0	1 (20.0%)	1 (12.5%)
	INFECTION	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	3 (27.3%)	1 (5.6%)	4 (13.8%)
Body as a Whole	TOTAL	1 (9.1%)	0	1 (3.4%)
	ABDOMINAL PAIN	1 (9.1%)	0	1 (3.4%)
	HEADACHE	1 (9.1%)	0	1 (3.4%)
Nervous System	TOTAL	1 (9.1%)	0	1 (3.4%)
	DEPRESSION	1 (9.1%)	0	1 (3.4%)
Respiratory System	TOTAL	1 (9.1%)	0	1 (3.4%)
	RESPIRATORY DISORDER	1 (9.1%)	0	1 (3.4%)
Digestive System	TOTAL	0	1 (5.6%)	1 (3.4%)
	NAUSEA	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	5 (27.8%)	7 (24.1%)
Nervous System	TOTAL	1 (9.1%)	2 (11.1%)	3 (10.3%)
	DEPRESSION	1 (9.1%)	1 (5.6%)	2 (6.9%)
	HYSTERIA	0	1 (5.6%)	1 (3.4%)
Respiratory System	TOTAL	1 (9.1%)	0	1 (3.4%)
	SINUSITIS	1 (9.1%)	0	1 (3.4%)
Cardiovascular System	TOTAL	0	1 (5.6%)	1 (3.4%)
	SYNCOPE	0	1 (5.6%)	1 (3.4%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.6%)	1 (3.4%)
	WEIGHT GAIN	0	1 (5.6%)	1 (3.4%)
Special Searches	TOTAL	0	1 (5.6%)	1 (3.4%)
	PUNCTURE SITE PAIN	0	1 (5.6%)	1 (3.4%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	1 (9.1%)	1 (5.6%)	2 (6.9%)
Body as a Whole	TOTAL	1 (9.1%)	1 (5.6%)	2 (6.9%)
	FEVER	1 (9.1%)	0	1 (3.4%)
	INFECTION	0	1 (5.6%)	1 (3.4%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	2 (22.2%)	4 (22.2%)
Hemic and Lymphatic System	TOTAL	1 (11.1%)	0	1 (5.6%)
	LEUKOPENIA	1 (11.1%)	0	1 (5.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (11.1%)	0	1 (5.6%)
	WEIGHT GAIN	1 (11.1%)	0	1 (5.6%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.6%)
	MYALGIA	0	1 (11.1%)	1 (5.6%)
Nervous System	TOTAL	0	2 (22.2%)	2 (11.1%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.6%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.6%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	1 (11.1%)	0	1 (5.6%)
Nervous System	TOTAL	1 (11.1%)	0	1 (5.6%)
	HOSTILITY	1 (11.1%)	0	1 (5.6%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (33.3%)	1 (20.0%)
Nervous System	TOTAL	0	1 (33.3%)	1 (20.0%)
	ABNORMAL DREAMS	0	1 (33.3%)	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	1 (50.0%)	1 (33.3%)	2 (40.0%)
Cardiovascular System	TOTAL	1 (50.0%)	0	1 (20.0%)
	BRADYCARDIA	1 (50.0%)	0	1 (20.0%)
Nervous System	TOTAL	0	1 (33.3%)	1 (20.0%)
	INSOMNIA	0	1 (33.3%)	1 (20.0%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	3 (25.0%)	5 (21.7%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (4.3%)
	LEUKOPENIA	1 (9.1%)	0	1 (4.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (4.3%)
	WEIGHT GAIN	1 (9.1%)	0	1 (4.3%)
Musculoskeletal System	TOTAL	0	1 (8.3%)	1 (4.3%)
	MYALGIA	0	1 (8.3%)	1 (4.3%)
Nervous System	TOTAL	0	3 (25.0%)	3 (13.0%)
	ABNORMAL DREAMS	0	1 (8.3%)	1 (4.3%)
	SOMNOLENCE	0	1 (8.3%)	1 (4.3%)
	WITHDRAWAL SYNDROME	0	1 (8.3%)	1 (4.3%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	1 (8.3%)	3 (13.0%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.3%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.3%)
Nervous System	TOTAL	1 (9.1%)	1 (8.3%)	2 (8.7%)
	HOSTILITY	1 (9.1%)	0	1 (4.3%)
	INSOMNIA	0	1 (8.3%)	1 (4.3%)

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Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	4 (23.5%)	3 (13.6%)	7 (17.9%)
Hemic and Lymphatic System	TOTAL	1 (5.9%)	0	1 (2.6%)
	LEUKOPENIA	1 (5.9%)	0	1 (2.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.9%)	0	1 (2.6%)
	WEIGHT GAIN	1 (5.9%)	0	1 (2.6%)
Nervous System	TOTAL	1 (5.9%)	2 (9.1%)	3 (7.7%)
	DEPRESSION	1 (5.9%)	0	1 (2.6%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.6%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.6%)
Respiratory System	TOTAL	1 (5.9%)	0	1 (2.6%)
	RESPIRATORY DISORDER	1 (5.9%)	0	1 (2.6%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.6%)
	NAUSEA	0	1 (4.5%)	1 (2.6%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.6%)
	MYALGIA	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	2 (11.8%)	4 (18.2%)	6 (15.4%)
Nervous System	TOTAL	2 (11.8%)	2 (9.1%)	4 (10.3%)
	DEPRESSION	1 (5.9%)	1 (4.5%)	2 (5.1%)
	HOSTILITY	1 (5.9%)	0	1 (2.6%)
	HYSTERIA	0	1 (4.5%)	1 (2.6%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.6%)
	SYNCOPE	0	1 (4.5%)	1 (2.6%)
Special Searches	TOTAL	0	1 (4.5%)	1 (2.6%)
	PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	1 (5.9%)	0	1 (2.6%)
Body as a Whole	TOTAL	1 (5.9%)	0	1 (2.6%)
	FEVER	1 (5.9%)	0	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	1 (20.0%)	1 (12.5%)	2 (15.4%)
Body as a Whole	TOTAL	1 (20.0%)	0	1 (7.7%)
	ABDOMINAL PAIN	1 (20.0%)	0	1 (7.7%)
	HEADACHE	1 (20.0%)	0	1 (7.7%)
Nervous System	TOTAL	0	1 (12.5%)	1 (7.7%)
	ABNORMAL DREAMS	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	2 (40.0%)	2 (25.0%)	4 (30.8%)
Cardiovascular System	TOTAL	1 (20.0%)	0	1 (7.7%)
	BRADYCARDIA	1 (20.0%)	0	1 (7.7%)
Respiratory System	TOTAL	1 (20.0%)	0	1 (7.7%)
	SINUSITIS	1 (20.0%)	0	1 (7.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (7.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (7.7%)
Nervous System	TOTAL	0	1 (12.5%)	1 (7.7%)
	INSOMNIA	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (12.5%)	1 (7.7%)
Body as a Whole	TOTAL	0	1 (12.5%)	1 (7.7%)
	INFECTION	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	5 (22.7%)	4 (13.3%)	9 (17.3%)
Body as a Whole	TOTAL	1 (4.5%)	0	1 (1.9%)
	ABDOMINAL PAIN	1 (4.5%)	0	1 (1.9%)
	HEADACHE	1 (4.5%)	0	1 (1.9%)
Hemic and Lymphatic System	TOTAL	1 (4.5%)	0	1 (1.9%)
	LEUKOPENIA	1 (4.5%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (4.5%)	0	1 (1.9%)
	WEIGHT GAIN	1 (4.5%)	0	1 (1.9%)
Nervous System	TOTAL	1 (4.5%)	3 (10.0%)	4 (7.7%)
	DEPRESSION	1 (4.5%)	0	1 (1.9%)
	ABNORMAL DREAMS	0	1 (3.3%)	1 (1.9%)
	SOMNOLENCE	0	1 (3.3%)	1 (1.9%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.9%)
Respiratory System	TOTAL	1 (4.5%)	0	1 (1.9%)
	RESPIRATORY DISORDER	1 (4.5%)	0	1 (1.9%)
Digestive System	TOTAL	0	1 (3.3%)	1 (1.9%)
	NAUSEA	0	1 (3.3%)	1 (1.9%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.9%)
	MYALGIA	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	4 (18.2%)	6 (20.0%)	10 (19.2%)
Nervous System	TOTAL	2 (9.1%)	3 (10.0%)	5 (9.6%)
	DEPRESSION	1 (4.5%)	1 (3.3%)	2 (3.8%)
	HOSTILITY	1 (4.5%)	0	1 (1.9%)
	HYSTERIA	0	1 (3.3%)	1 (1.9%)
	INSOMNIA	0	1 (3.3%)	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	BRADYCARDIA	1 (4.5%)	0	1 (1.9%)
	SYNCOPE	0	1 (3.3%)	1 (1.9%)
Respiratory System	TOTAL	1 (4.5%)	0	1 (1.9%)
	SINUSITIS	1 (4.5%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (3.3%)	1 (1.9%)
	WEIGHT GAIN	0	1 (3.3%)	1 (1.9%)
Special Searches	TOTAL	0	1 (3.3%)	1 (1.9%)
	PUNCTURE SITE PAIN	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
Body as a Whole	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	FEVER	1 (4.5%)	0	1 (1.9%)
	INFECTION	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Preferred Term			
TOTAL	2 (25.0%)	1 (7.7%)	3 (14.3%)
DEPRESSION	1 (12.5%)	0	1 (4.8%)
RESPIRATORY DISORDER	1 (12.5%)	0	1 (4.8%)
NAUSEA	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=8)	 Placebo (N=13)	 Total (N=21)
TOTAL	1 (12.5%)	4 (30.8%)	5 (23.8%)
DEPRESSION	1 (12.5%)	1 (7.7%)	2 (9.5%)
HYSTERIA	0	1 (7.7%)	1 (4.8%)
PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.8%)
SYNCOPE	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=8)	 Placebo (N=13)	 Total (N=21)
TOTAL	1 (12.5%)	0	1 (4.8%)
FEVER	1 (12.5%)	0	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=4)	 Placebo (N=10)	 Total (N=14)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=4)	 Placebo (N=3)	 Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=3)	 Placebo (N=5)	 Total (N=8)
TOTAL	1 (33.3%)	0	1 (12.5%)
ABDOMINAL PAIN	1 (33.3%)	0	1 (12.5%)
HEADACHE	1 (33.3%)	0	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
TOTAL	1 (33.3%)	1 (20.0%)	2 (25.0%)
SINUSITIS	1 (33.3%)	0	1 (12.5%)
WEIGHT GAIN	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Preferred Term			
TOTAL	0	1 (20.0%)	1 (12.5%)
INFECTION	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=18)	 Total (N=29)
TOTAL	3 (27.3%)	1 (5.6%)	4 (13.8%)
ABDOMINAL PAIN	1 (9.1%)	0	1 (3.4%)
DEPRESSION	1 (9.1%)	0	1 (3.4%)
HEADACHE	1 (9.1%)	0	1 (3.4%)
RESPIRATORY DISORDER	1 (9.1%)	0	1 (3.4%)
NAUSEA	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=18)	 Total (N=29)
TOTAL	2 (18.2%)	5 (27.8%)	7 (24.1%)
DEPRESSION	1 (9.1%)	1 (5.6%)	2 (6.9%)
SINUSITIS	1 (9.1%)	0	1 (3.4%)
HYSTERIA	0	1 (5.6%)	1 (3.4%)
PUNCTURE SITE PAIN	0	1 (5.6%)	1 (3.4%)
SYNCOPE	0	1 (5.6%)	1 (3.4%)
WEIGHT GAIN	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=18)	 Total (N=29)
TOTAL	1 (9.1%)	1 (5.6%)	2 (6.9%)
FEVER	1 (9.1%)	0	1 (3.4%)
INFECTION	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=6)	 Placebo (N=14)	 Total (N=20)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=9)	 Placebo (N=9)	 Total (N=18)
TOTAL	2 (22.2%)	2 (22.2%)	4 (22.2%)
LEUKOPENIA	1 (11.1%)	0	1 (5.6%)
WEIGHT GAIN	1 (11.1%)	0	1 (5.6%)
MYALGIA	0	1 (11.1%)	1 (5.6%)
SOMNOLENCE	0	1 (11.1%)	1 (5.6%)
WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	1 (11.1%)	0	1 (5.6%)
HOSTILITY	1 (11.1%)	0	1 (5.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=9)	 Placebo (N=9)	 Total (N=18)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=3)	 Placebo (N=2)	 Total (N=5)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
TOTAL	0	1 (33.3%)	1 (20.0%)
ABNORMAL DREAMS	0	1 (33.3%)	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=2)	 Placebo (N=3)	 Total (N=5)
TOTAL	1 (50.0%)	1 (33.3%)	2 (40.0%)
BRADYCARDIA	1 (50.0%)	0	1 (20.0%)
INSOMNIA	0	1 (33.3%)	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=12)	 Total (N=23)
TOTAL	2 (18.2%)	3 (25.0%)	5 (21.7%)
LEUKOPENIA	1 (9.1%)	0	1 (4.3%)
WEIGHT GAIN	1 (9.1%)	0	1 (4.3%)
ABNORMAL DREAMS	0	1 (8.3%)	1 (4.3%)
MYALGIA	0	1 (8.3%)	1 (4.3%)
SOMNOLENCE	0	1 (8.3%)	1 (4.3%)
WITHDRAWAL SYNDROME	0	1 (8.3%)	1 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=12)	 Total (N=23)
TOTAL	2 (18.2%)	1 (8.3%)	3 (13.0%)
BRADYCARDIA	1 (9.1%)	0	1 (4.3%)
HOSTILITY	1 (9.1%)	0	1 (4.3%)
INSOMNIA	0	1 (8.3%)	1 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=12)	 Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=7)	 Placebo (N=9)	 Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=4)	 Placebo (N=3)	 Total (N=7)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=17)	 Placebo (N=22)	 Total (N=39)
TOTAL	4 (23.5%)	3 (13.6%)	7 (17.9%)
DEPRESSION	1 (5.9%)	0	1 (2.6%)
LEUKOPENIA	1 (5.9%)	0	1 (2.6%)
RESPIRATORY DISORDER	1 (5.9%)	0	1 (2.6%)
WEIGHT GAIN	1 (5.9%)	0	1 (2.6%)
MYALGIA	0	1 (4.5%)	1 (2.6%)
NAUSEA	0	1 (4.5%)	1 (2.6%)
SOMNOLENCE	0	1 (4.5%)	1 (2.6%)
WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=17)	 Placebo (N=22)	 Total (N=39)
TOTAL	2 (11.8%)	4 (18.2%)	6 (15.4%)
DEPRESSION	1 (5.9%)	1 (4.5%)	2 (5.1%)
HOSTILITY	1 (5.9%)	0	1 (2.6%)
HYSTERIA	0	1 (4.5%)	1 (2.6%)
PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.6%)
SYNCOPE	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=17)	 Placebo (N=22)	 Total (N=39)
TOTAL	1 (5.9%)	0	1 (2.6%)
FEVER	1 (5.9%)	0	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=10)	 Placebo (N=17)	 Total (N=27)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=7)	 Placebo (N=5)	 Total (N=12)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=7)	 Placebo (N=5)	 Total (N=12)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=5)	 Placebo (N=8)	 Total (N=13)
TOTAL	1 (20.0%)	1 (12.5%)	2 (15.4%)
ABDOMINAL PAIN	1 (20.0%)	0	1 (7.7%)
HEADACHE	1 (20.0%)	0	1 (7.7%)
ABNORMAL DREAMS	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=5)	 Placebo (N=8)	 Total (N=13)
TOTAL	2 (40.0%)	2 (25.0%)	4 (30.8%)
BRADYCARDIA	1 (20.0%)	0	1 (7.7%)
SINUSITIS	1 (20.0%)	0	1 (7.7%)
INSOMNIA	0	1 (12.5%)	1 (7.7%)
WEIGHT GAIN	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Preferred Term			
TOTAL	0	1 (12.5%)	1 (7.7%)
INFECTION	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=2)	 Placebo (N=2)	 Total (N=4)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Preferred Term			
TOTAL	5 (22.7%)	4 (13.3%)	9 (17.3%)
ABDOMINAL PAIN	1 (4.5%)	0	1 (1.9%)
DEPRESSION	1 (4.5%)	0	1 (1.9%)
HEADACHE	1 (4.5%)	0	1 (1.9%)
LEUKOPENIA	1 (4.5%)	0	1 (1.9%)
RESPIRATORY DISORDER	1 (4.5%)	0	1 (1.9%)
WEIGHT GAIN	1 (4.5%)	0	1 (1.9%)
ABNORMAL DREAMS	0	1 (3.3%)	1 (1.9%)
MYALGIA	0	1 (3.3%)	1 (1.9%)
NAUSEA	0	1 (3.3%)	1 (1.9%)
SOMNOLENCE	0	1 (3.3%)	1 (1.9%)
WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Preferred Term			
TOTAL	4 (18.2%)	6 (20.0%)	10 (19.2%)
DEPRESSION	1 (4.5%)	1 (3.3%)	2 (3.8%)
BRADYCARDIA	1 (4.5%)	0	1 (1.9%)
HOSTILITY	1 (4.5%)	0	1 (1.9%)
SINUSITIS	1 (4.5%)	0	1 (1.9%)
HYSTERIA	0	1 (3.3%)	1 (1.9%)
INSOMNIA	0	1 (3.3%)	1 (1.9%)
PUNCTURE SITE PAIN	0	1 (3.3%)	1 (1.9%)
SYNCOPE	0	1 (3.3%)	1 (1.9%)
WEIGHT GAIN	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=22)	 Placebo (N=30)	 Total (N=52)
TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
FEVER	1 (4.5%)	0	1 (1.9%)
INFECTION	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	30 (60.0%)	40 (60.6%)	70 (60.3%)
Body as a Whole	TOTAL	13 (26.0%)	20 (30.3%)	33 (28.4%)
	HEADACHE	6 (12.0%)	8 (12.1%)	14 (12.1%)
	INFECTION	1 (2.0%)	6 (9.1%)	7 (6.0%)
	TRAUMA	3 (6.0%)	3 (4.5%)	6 (5.2%)
	ABDOMINAL PAIN	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ALLERGIC REACTION	3 (6.0%)	1 (1.5%)	4 (3.4%)
	BACK PAIN	1 (2.0%)	3 (4.5%)	4 (3.4%)
	ASTHENIA	0	4 (6.1%)	4 (3.4%)
	FEVER	1 (2.0%)	2 (3.0%)	3 (2.6%)
	CHEST PAIN	1 (2.0%)	0	1 (0.9%)
	FACE EDEMA	1 (2.0%)	0	1 (0.9%)
	PAIN	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	13 (26.0%)	19 (28.8%)	32 (27.6%)
	RESPIRATORY DISORDER	9 (18.0%)	10 (15.2%)	19 (16.4%)
	RHINITIS	3 (6.0%)	4 (6.1%)	7 (6.0%)
	PHARYNGITIS	2 (4.0%)	5 (7.6%)	7 (6.0%)
	COUGH INCREASED	1 (2.0%)	2 (3.0%)	3 (2.6%)
	SINUSITIS	2 (4.0%)	0	2 (1.7%)
	ASTHMA	0	2 (3.0%)	2 (1.7%)
	EPISTAXIS	0	2 (3.0%)	2 (1.7%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	12 (24.0%)	12 (18.2%)	24 (20.7%)
	INSOMNIA	1 (2.0%)	5 (7.6%)	6 (5.2%)
	NERVOUSNESS	3 (6.0%)	0	3 (2.6%)
	DEPRESSION	2 (4.0%)	1 (1.5%)	3 (2.6%)
	SOMNOLENCE	2 (4.0%)	1 (1.5%)	3 (2.6%)
	DIZZINESS	1 (2.0%)	2 (3.0%)	3 (2.6%)
	AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	EMOTIONAL LABILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HALLUCINATIONS	1 (2.0%)	0	1 (0.9%)
	VERTIGO	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	10 (20.0%)	16 (24.2%)	26 (22.4%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Digestive System	DYSPEPSIA	5 (10.0%)	4 (6.1%)	9 (7.8%)
	NAUSEA	4 (8.0%)	4 (6.1%)	8 (6.9%)
	DRY MOUTH	3 (6.0%)	0	3 (2.6%)
	INCREASED APPETITE	1 (2.0%)	2 (3.0%)	3 (2.6%)
	VOMITING	1 (2.0%)	2 (3.0%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	DIARRHEA	0	2 (3.0%)	2 (1.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	4 (8.0%)	3 (4.5%)	7 (6.0%)
	ACNE	2 (4.0%)	0	2 (1.7%)
	RASH	1 (2.0%)	1 (1.5%)	2 (1.7%)
	PRURITUS	0	2 (3.0%)	2 (1.7%)
	CONTACT DERMATITIS	1 (2.0%)	0	1 (0.9%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	3 (6.0%)	1 (1.5%)	4 (3.4%)
	LEUKOPENIA	3 (6.0%)	1 (1.5%)	4 (3.4%)
	ANEMIA	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	3 (6.0%)	5 (7.6%)	8 (6.9%)
	WEIGHT GAIN	3 (6.0%)	5 (7.6%)	8 (6.9%)
Urogenital System	TOTAL	2 (4.0%)	4 (6.1%)	6 (5.2%)
	ALBUMINURIA	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HAEMATURIA	0	2 (3.0%)	2 (1.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ARTHRALGIA	1 (2.0%)	0	1 (0.9%)
	MYALGIA	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	1 (2.0%)	1 (1.5%)	2 (1.7%)
	OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.7%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Cardiovascular System	SYNCOPE	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	30 (60.0%)	28 (42.4%)	58 (50.0%)
Body as a Whole	TOTAL	15 (30.0%)	14 (21.2%)	29 (25.0%)
	INFECTION	4 (8.0%)	6 (9.1%)	10 (8.6%)
	TRAUMA	6 (12.0%)	3 (4.5%)	9 (7.8%)
	HEADACHE	6 (12.0%)	2 (3.0%)	8 (6.9%)
	FEVER	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
	BACK PAIN	2 (4.0%)	0	2 (1.7%)
	ALLERGIC REACTION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ASTHENIA	0	1 (1.5%)	1 (0.9%)
	PAIN	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	10 (20.0%)	10 (15.2%)	20 (17.2%)
	RESPIRATORY DISORDER	7 (14.0%)	5 (7.6%)	12 (10.3%)
	BRONCHITIS	1 (2.0%)	3 (4.5%)	4 (3.4%)
	PHARYNGITIS	2 (4.0%)	0	2 (1.7%)
	SINUSITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
	ASTHMA	1 (2.0%)	0	1 (0.9%)
	PNEUMONIA	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	9 (18.0%)	5 (7.6%)	14 (12.1%)
	VOMITING	5 (10.0%)	2 (3.0%)	7 (6.0%)
	DIARRHEA	3 (6.0%)	0	3 (2.6%)
	NAUSEA	2 (4.0%)	1 (1.5%)	3 (2.6%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	STOMATITIS	1 (2.0%)	0	1 (0.9%)
	DYSPEPSIA	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Nervous System	TOTAL	9 (18.0%)	14 (21.2%)	23 (19.8%)
	HOSTILITY	3 (6.0%)	1 (1.5%)	4 (3.4%)
	AGITATION	1 (2.0%)	3 (4.5%)	4 (3.4%)
	SOMNOLENCE	1 (2.0%)	3 (4.5%)	4 (3.4%)
	DEPRESSION	2 (4.0%)	1 (1.5%)	3 (2.6%)
	NERVOUSNESS	2 (4.0%)	1 (1.5%)	3 (2.6%)
	EMOTIONAL LABILITY	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	VESTIBULAR DISORDER	1 (2.0%)	0	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	HYSTERIA	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Nervous System	INSOMNIA	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.0%)	2 (3.0%)	6 (5.2%)
	WEIGHT GAIN	3 (6.0%)	1 (1.5%)	4 (3.4%)
	WEIGHT LOSS	1 (2.0%)	0	1 (0.9%)
	DEHYDRATION	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	3 (6.0%)	2 (3.0%)	5 (4.3%)
	ACNE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	CONTACT DERMATITIS	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HERPES ZOSTER	1 (2.0%)	0	1 (0.9%)
Special Senses	TOTAL	1 (2.0%)	0	1 (0.9%)
	OTITIS MEDIA	1 (2.0%)	0	1 (0.9%)
Urogenital System	TOTAL	1 (2.0%)	0	1 (0.9%)
	URINARY INCONTINENCE	1 (2.0%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
	SYNCOPE	0	1 (1.5%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.9%)
	LEUKOPENIA	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ARTHROSIS	0	1 (1.5%)	1 (0.9%)
	MYALGIA	0	1 (1.5%)	1 (0.9%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.9%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	6 (12.0%)	11 (16.7%)	17 (14.7%)
Body as a Whole	TOTAL	3 (6.0%)	1 (1.5%)	4 (3.4%)
	TRAUMA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	FEVER	1 (2.0%)	0	1 (0.9%)
	INFECTION	1 (2.0%)	0	1 (0.9%)
Nervous System	TOTAL	3 (6.0%)	6 (9.1%)	9 (7.8%)
	EMOTIONAL LABILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
	AGITATION	1 (2.0%)	1 (1.5%)	2 (1.7%)
	HOSTILITY	1 (2.0%)	1 (1.5%)	2 (1.7%)
	DEPRESSION	1 (2.0%)	0	1 (0.9%)
	LACK OF EMOTION	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	EUPHORIA	0	1 (1.5%)	1 (0.9%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.9%)
	PARALYSIS	0	1 (1.5%)	1 (0.9%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.9%)
	MIGRAINE	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	0	1 (1.5%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ASTHMA	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.9%)
	RASH	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	2 (6.9%)	2 (3.8%)
Urogenital System	TOTAL	0	2 (6.9%)	2 (3.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	28 (63.6%)	36 (59.0%)	64 (61.0%)
Body as a Whole	TOTAL	19 (43.2%)	20 (32.8%)	39 (37.1%)
	HEADACHE	10 (22.7%)	11 (18.0%)	21 (20.0%)
	ABDOMINAL PAIN	2 (4.5%)	5 (8.2%)	7 (6.7%)
	TRAUMA	2 (4.5%)	4 (6.6%)	6 (5.7%)
	ALLERGIC REACTION	2 (4.5%)	3 (4.9%)	5 (4.8%)
	FEVER	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ASTHENIA	2 (4.5%)	1 (1.6%)	3 (2.9%)
	INFECTION	2 (4.5%)	1 (1.6%)	3 (2.9%)
	PAIN	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ABNORMAL LABORATORY VALUE	1 (2.3%)	0	1 (1.0%)
	BACK PAIN	1 (2.3%)	0	1 (1.0%)
Respiratory System	TOTAL	8 (18.2%)	12 (19.7%)	20 (19.0%)
	RESPIRATORY DISORDER	2 (4.5%)	8 (13.1%)	10 (9.5%)
	RHINITIS	4 (9.1%)	4 (6.6%)	8 (7.6%)
	PHARYNGITIS	2 (4.5%)	3 (4.9%)	5 (4.8%)
	SINUSITIS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	COUGH INCREASED	2 (4.5%)	0	2 (1.9%)
	ASTHMA	1 (2.3%)	0	1 (1.0%)
	EPISTAXIS	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	7 (15.9%)	10 (16.4%)	17 (16.2%)
	NAUSEA	4 (9.1%)	2 (3.3%)	6 (5.7%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DIARRHEA	2 (4.5%)	0	2 (1.9%)
	DYSPEPSIA	2 (4.5%)	0	2 (1.9%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	FLATULENCE	0	2 (3.3%)	2 (1.9%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	GASTROENTERITIS	0	1 (1.6%)	1 (1.0%)
	TOOTH CARIES	0	1 (1.6%)	1 (1.0%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	7 (15.9%)	16 (26.2%)	23 (21.9%)
	NERVOUSNESS	1 (2.3%)	6 (9.8%)	7 (6.7%)
	INSOMNIA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	HYPERKINESIA	3 (6.8%)	0	3 (2.9%)
	NEUROSIS	3 (6.8%)	0	3 (2.9%)
	DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	HOSTILITY	1 (2.3%)	2 (3.3%)	3 (2.9%)
	MYOCLONUS	1 (2.3%)	1 (1.6%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Nervous System	AGITATION	0	2 (3.3%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	ANXIETY	1 (2.3%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	ABNORMAL DREAMS	0	1 (1.6%)	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	VERTIGO	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	3 (6.8%)	4 (6.6%)	7 (6.7%)
	OTITIS EXTERNA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	BLEPHARITIS	1 (2.3%)	0	1 (1.0%)
	EYE PAIN	1 (2.3%)	0	1 (1.0%)
	ABNORMAL VISION	0	1 (1.6%)	1 (1.0%)
	EAR PAIN	0	1 (1.6%)	1 (1.0%)
	OTITIS MEDIA	0	1 (1.6%)	1 (1.0%)
Urogenital System	TOTAL	3 (6.8%)	1 (1.6%)	4 (3.8%)
	ALBUMINURIA	2 (4.5%)	0	2 (1.9%)
	DYSURIA	1 (2.3%)	0	1 (1.0%)
	HAEMATURIA	1 (2.3%)	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ARTHRALGIA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MYALGIA	1 (2.3%)	0	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	3 (4.9%)	4 (3.8%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	HAEMATOMA	1 (2.3%)	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ANEMIA	1 (2.3%)	0	1 (1.0%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	6 (9.8%)	7 (6.7%)
	RASH	0	3 (4.9%)	3 (2.9%)
	ACNE	0	2 (3.3%)	2 (1.9%)
	CONTACT DERMATITIS	0	2 (3.3%)	2 (1.9%)
	MACULOPAPULAR RASH	1 (2.3%)	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
	URTICARIA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	23 (52.3%)	35 (57.4%)	58 (55.2%)
Body as a Whole	TOTAL	15 (34.1%)	11 (18.0%)	26 (24.8%)
	HEADACHE	7 (15.9%)	5 (8.2%)	12 (11.4%)
	INFECTION	4 (9.1%)	2 (3.3%)	6 (5.7%)
	ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ABDOMINAL PAIN	1 (2.3%)	3 (4.9%)	4 (3.8%)
	TRAUMA	3 (6.8%)	0	3 (2.9%)
	ALLERGIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	PAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	FEVER	1 (2.3%)	0	1 (1.0%)
	BACK PAIN	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	9 (20.5%)	23 (37.7%)	32 (30.5%)
	NERVOUSNESS	1 (2.3%)	8 (13.1%)	9 (8.6%)
	HYPERKINESIA	4 (9.1%)	4 (6.6%)	8 (7.6%)
	HOSTILITY	1 (2.3%)	5 (8.2%)	6 (5.7%)
	ANXIETY	1 (2.3%)	3 (4.9%)	4 (3.8%)
	INSOMNIA	1 (2.3%)	3 (4.9%)	4 (3.8%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
	AGITATION	0	2 (3.3%)	2 (1.9%)
	DIZZINESS	0	2 (3.3%)	2 (1.9%)
	DEPRESSION	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	5 (11.4%)	7 (11.5%)	12 (11.4%)
	RESPIRATORY DISORDER	2 (4.5%)	4 (6.6%)	6 (5.7%)
	SINUSITIS	3 (6.8%)	0	3 (2.9%)
	ASTHMA	1 (2.3%)	2 (3.3%)	3 (2.9%)
	COUGH INCREASED	1 (2.3%)	1 (1.6%)	2 (1.9%)
	PHARYNGITIS	0	1 (1.6%)	1 (1.0%)
	PNEUMONIA	0	1 (1.6%)	1 (1.0%)
	RHINITIS	0	1 (1.6%)	1 (1.0%)
Special Senses	TOTAL	3 (6.8%)	2 (3.3%)	5 (4.8%)
	OTITIS MEDIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	EAR PAIN	1 (2.3%)	0	1 (1.0%)
	OTITIS EXTERNA	1 (2.3%)	0	1 (1.0%)
Digestive System	TOTAL	2 (4.5%)	6 (9.8%)	8 (7.6%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Digestive System	DYSPEPSIA	0	3 (4.9%)	3 (2.9%)
	NAUSEA	0	3 (4.9%)	3 (2.9%)
	DIARRHEA	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TOOTH DISORDER	1 (2.3%)	0	1 (1.0%)
	GINGIVITIS	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	0	1 (1.0%)
	BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.3%)	0	1 (1.0%)
	ARTHRALGIA	1 (2.3%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ACNE	1 (2.3%)	0	1 (1.0%)
	CONTACT DERMATITIS	0	1 (1.6%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.6%)	1 (1.0%)
	EOSINOPHILIA	0	1 (1.6%)	1 (1.0%)
	MONOCYTOSIS	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	4 (9.1%)	6 (9.8%)	10 (9.5%)
Body as a Whole	TOTAL	2 (4.5%)	2 (3.3%)	4 (3.8%)
	INFECTION	1 (2.3%)	2 (3.3%)	3 (2.9%)
	ABSCESS	1 (2.3%)	0	1 (1.0%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (1.0%)
Nervous System	TOTAL	2 (4.5%)	4 (6.6%)	6 (5.7%)
	HOSTILITY	0	2 (3.3%)	2 (1.9%)
	NEUROSIS	1 (2.3%)	0	1 (1.0%)
	SOMNOLENCE	1 (2.3%)	0	1 (1.0%)
	HYPERKINESIA	0	1 (1.6%)	1 (1.0%)
	NERVOUSNESS	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	1 (2.3%)	0	1 (1.0%)
	PHARYNGITIS	1 (2.3%)	0	1 (1.0%)
Cardiovascular System	TOTAL	0	1 (1.6%)	1 (1.0%)
	SYNCOPE	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	0	1 (1.6%)	1 (1.0%)
	NAUSEA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.8%)	1 (2.3%)
Urogenital System	TOTAL	0	1 (4.8%)	1 (2.3%)
	DYSMENORRHEA	0	1 (4.8%)	1 (2.3%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.6%)	0	3 (7.0%)
Urogenital System	TOTAL	3 (13.6%)	0	3 (7.0%)
	DYSMENORRHEA	3 (13.6%)	0	3 (7.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	58 (61.7%)	76 (59.8%)	134 (60.6%)
Body as a Whole	TOTAL	32 (34.0%)	40 (31.5%)	72 (32.6%)
	HEADACHE	16 (17.0%)	19 (15.0%)	35 (15.8%)
	ABDOMINAL PAIN	5 (5.3%)	7 (5.5%)	12 (5.4%)
	TRAUMA	5 (5.3%)	7 (5.5%)	12 (5.4%)
	INFECTION	3 (3.2%)	7 (5.5%)	10 (4.5%)
	ALLERGIC REACTION	5 (5.3%)	4 (3.1%)	9 (4.1%)
	FEVER	3 (3.2%)	4 (3.1%)	7 (3.2%)
	ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
	BACK PAIN	2 (2.1%)	3 (2.4%)	5 (2.3%)
	PAIN	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ABNORMAL LABORATORY VALUE	1 (1.1%)	0	1 (0.5%)
	CHEST PAIN	1 (1.1%)	0	1 (0.5%)
	FACE EDEMA	1 (1.1%)	0	1 (0.5%)
Respiratory System	TOTAL	21 (22.3%)	31 (24.4%)	52 (23.5%)
	RESPIRATORY DISORDER	11 (11.7%)	18 (14.2%)	29 (13.1%)
	RHINITIS	7 (7.4%)	8 (6.3%)	15 (6.8%)
	PHARYNGITIS	4 (4.3%)	8 (6.3%)	12 (5.4%)
	SINUSITIS	4 (4.3%)	1 (0.8%)	5 (2.3%)
	COUGH INCREASED	3 (3.2%)	2 (1.6%)	5 (2.3%)
	ASTHMA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	EPISTAXIS	0	3 (2.4%)	3 (1.4%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Nervous System	TOTAL	19 (20.2%)	28 (22.0%)	47 (21.3%)
	INSOMNIA	4 (4.3%)	8 (6.3%)	12 (5.4%)
	NERVOUSNESS	4 (4.3%)	6 (4.7%)	10 (4.5%)
	DIZZINESS	3 (3.2%)	3 (2.4%)	6 (2.7%)
	HYPERKINESIA	4 (4.3%)	1 (0.8%)	5 (2.3%)
	AGITATION	1 (1.1%)	3 (2.4%)	4 (1.8%)
	NEUROSIS	3 (3.2%)	0	3 (1.4%)
	DEPRESSION	2 (2.1%)	1 (0.8%)	3 (1.4%)
	SOMNOLENCE	2 (2.1%)	1 (0.8%)	3 (1.4%)
	HOSTILITY	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ANXIETY	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
	EMOTIONAL LABILITY	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MYOCLONUS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VERTIGO	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TREMOR	0	2 (1.6%)	2 (0.9%)
	HALLUCINATIONS	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Nervous System	ABNORMAL DREAMS	0	1 (0.8%)	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	17 (18.1%)	26 (20.5%)	43 (19.5%)
	NAUSEA	8 (8.5%)	6 (4.7%)	14 (6.3%)
	DYSPEPSIA	7 (7.4%)	4 (3.1%)	11 (5.0%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DRY MOUTH	3 (3.2%)	2 (1.6%)	5 (2.3%)
	DIARRHEA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	INCREASED APPETITE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	VOMITING	1 (1.1%)	2 (1.6%)	3 (1.4%)
	FLATULENCE	0	2 (1.6%)	2 (0.9%)
	GASTROENTERITIS	0	2 (1.6%)	2 (0.9%)
	TOOTH CARIES	0	2 (1.6%)	2 (0.9%)
	CONSTIPATION	0	1 (0.8%)	1 (0.5%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.5%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.5%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	5 (5.3%)	9 (7.1%)	14 (6.3%)
	RASH	1 (1.1%)	4 (3.1%)	5 (2.3%)
	ACNE	2 (2.1%)	2 (1.6%)	4 (1.8%)
	CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	MACULOPAPULAR RASH	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PRURITUS	0	2 (1.6%)	2 (0.9%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.5%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
	URTICARIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	5 (5.3%)	5 (3.9%)	10 (4.5%)
	ALBUMINURIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	HAEMATURIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	URINARY INCONTINENCE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	DYSURIA	1 (1.1%)	0	1 (0.5%)
	CYSTITIS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	4 (4.3%)	2 (1.6%)	6 (2.7%)
	LEUKOPENIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
	ANEMIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Special Senses	TOTAL	4 (4.3%)	5 (3.9%)	9 (4.1%)
	OTITIS EXTERNA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	OTITIS MEDIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABNORMAL VISION	0	2 (1.6%)	2 (0.9%)
	BLEPHARITIS	1 (1.1%)	0	1 (0.5%)
	EYE PAIN	1 (1.1%)	0	1 (0.5%)
	EAR PAIN	0	1 (0.8%)	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	3 (3.2%)	5 (3.9%)	8 (3.6%)
	WEIGHT GAIN	3 (3.2%)	5 (3.9%)	8 (3.6%)
Musculoskeletal System	TOTAL	3 (3.2%)	2 (1.6%)	5 (2.3%)
	ARTHRALGIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
	MYALGIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
Cardiovascular System	TOTAL	1 (1.1%)	5 (3.9%)	6 (2.7%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	HAEMATOMA	1 (1.1%)	0	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	53 (56.4%)	63 (49.6%)	116 (52.5%)
Body as a Whole	TOTAL	30 (31.9%)	25 (19.7%)	55 (24.9%)
	HEADACHE	13 (13.8%)	7 (5.5%)	20 (9.0%)
	INFECTION	8 (8.5%)	8 (6.3%)	16 (7.2%)
	TRAUMA	9 (9.6%)	3 (2.4%)	12 (5.4%)
	ABDOMINAL PAIN	3 (3.2%)	5 (3.9%)	8 (3.6%)
	FEVER	4 (4.3%)	2 (1.6%)	6 (2.7%)
	ASTHENIA	2 (2.1%)	3 (2.4%)	5 (2.3%)
	ALLERGIC REACTION	2 (2.1%)	2 (1.6%)	4 (1.8%)
	BACK PAIN	2 (2.1%)	1 (0.8%)	3 (1.4%)
	PAIN	1 (1.1%)	2 (1.6%)	3 (1.4%)
Nervous System	TOTAL	18 (19.1%)	37 (29.1%)	55 (24.9%)
	NERVOUSNESS	3 (3.2%)	9 (7.1%)	12 (5.4%)
	HOSTILITY	4 (4.3%)	6 (4.7%)	10 (4.5%)
	HYPERKINESIA	4 (4.3%)	4 (3.1%)	8 (3.6%)
	SOMNOLENCE	2 (2.1%)	4 (3.1%)	6 (2.7%)
	AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
	INSOMNIA	1 (1.1%)	4 (3.1%)	5 (2.3%)
	DEPRESSION	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EMOTIONAL LABILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIZZINESS	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	VESTIBULAR DISORDER	1 (1.1%)	0	1 (0.5%)
	CONCENTRATION IMPAIRED	0	1 (0.8%)	1 (0.5%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	HYSTERIA	0	1 (0.8%)	1 (0.5%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)
	TREMOR	0	1 (0.8%)	1 (0.5%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	15 (16.0%)	17 (13.4%)	32 (14.5%)
	RESPIRATORY DISORDER	9 (9.6%)	9 (7.1%)	18 (8.1%)
	SINUSITIS	4 (4.3%)	1 (0.8%)	5 (2.3%)
	ASTHMA	2 (2.1%)	2 (1.6%)	4 (1.8%)
	BRONCHITIS	1 (1.1%)	3 (2.4%)	4 (1.8%)
	PHARYNGITIS	2 (2.1%)	1 (0.8%)	3 (1.4%)
	COUGH INCREASED	1 (1.1%)	1 (0.8%)	2 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Respiratory System	PNEUMONIA	0	2 (1.6%)	2 (0.9%)
	RHINITIS	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	11 (11.7%)	11 (8.7%)	22 (10.0%)
	VOMITING	5 (5.3%)	2 (1.6%)	7 (3.2%)
	NAUSEA	2 (2.1%)	4 (3.1%)	6 (2.7%)
	DIARRHEA	4 (4.3%)	1 (0.8%)	5 (2.3%)
	DYSPEPSIA	0	4 (3.1%)	4 (1.8%)
	CONSTIPATION	1 (1.1%)	0	1 (0.5%)
	STOMATITIS	1 (1.1%)	0	1 (0.5%)
	TOOTH DISORDER	1 (1.1%)	0	1 (0.5%)
	GINGIVITIS	0	1 (0.8%)	1 (0.5%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
Metabolic and Nutritional Disorders	TOTAL	5 (5.3%)	4 (3.1%)	9 (4.1%)
	WEIGHT GAIN	4 (4.3%)	2 (1.6%)	6 (2.7%)
	WEIGHT LOSS	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEHYDRATION	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	4 (4.3%)	3 (2.4%)	7 (3.2%)
	ACNE	2 (2.1%)	1 (0.8%)	3 (1.4%)
	CONTACT DERMATITIS	1 (1.1%)	2 (1.6%)	3 (1.4%)
	HERPES ZOSTER	1 (1.1%)	0	1 (0.5%)
Special Senses	TOTAL	4 (4.3%)	2 (1.6%)	6 (2.7%)
	OTITIS MEDIA	3 (3.2%)	2 (1.6%)	5 (2.3%)
	EAR PAIN	1 (1.1%)	0	1 (0.5%)
	OTITIS EXTERNA	1 (1.1%)	0	1 (0.5%)
Cardiovascular System	TOTAL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Musculoskeletal System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ARTHRALGIA	1 (1.1%)	0	1 (0.5%)
	ARTHROSIS	0	1 (0.8%)	1 (0.5%)
	MYALGIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	0	1 (0.5%)
	URINARY INCONTINENCE	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Hemic and Lymphatic System	TOTAL	0	2 (1.6%)	2 (0.9%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.5%)
	LEUKOPENIA	0	1 (0.8%)	1 (0.5%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.5%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.5%)
	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	10 (10.6%)	17 (13.4%)	27 (12.2%)
Body as a Whole	TOTAL	5 (5.3%)	3 (2.4%)	8 (3.6%)
	INFECTION	2 (2.1%)	2 (1.6%)	4 (1.8%)
	TRAUMA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	ABSCESS	1 (1.1%)	0	1 (0.5%)
	FEVER	1 (1.1%)	0	1 (0.5%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.5%)
Nervous System	TOTAL	5 (5.3%)	10 (7.9%)	15 (6.8%)
	HOSTILITY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	EMOTIONAL LABILITY	2 (2.1%)	1 (0.8%)	3 (1.4%)
	AGITATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DEPRESSION	1 (1.1%)	0	1 (0.5%)
	LACK OF EMOTION	1 (1.1%)	0	1 (0.5%)
	NEUROSIS	1 (1.1%)	0	1 (0.5%)
	SOMNOLENCE	1 (1.1%)	0	1 (0.5%)
	ANXIETY	0	1 (0.8%)	1 (0.5%)
	EUPHORIA	0	1 (0.8%)	1 (0.5%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.5%)
	HYPERKINESIA	0	1 (0.8%)	1 (0.5%)
	NERVOUSNESS	0	1 (0.8%)	1 (0.5%)
	PARALYSIS	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	PHARYNGITIS	1 (1.1%)	0	1 (0.5%)
	ASTHMA	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	0	2 (1.6%)	2 (0.9%)
	MIGRAINE	0	1 (0.8%)	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	0	2 (1.6%)	2 (0.9%)
	NAUSEA	0	1 (0.8%)	1 (0.5%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.5%)
	RASH	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.5%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Urogenital System	URINARY INCONTINENCE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	3 (6.0%)	3 (3.2%)
Urogenital System	TOTAL	0	3 (6.0%)	3 (3.2%)
	DYSMENORRHEA	0	1 (2.0%)	1 (1.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	0	3 (3.2%)
Urogenital System	TOTAL	3 (6.7%)	0	3 (3.2%)
	DYSMENORRHEA	3 (6.7%)	0	3 (3.2%)

BRL 29060 - 716
Interim Output
Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	7 (21.2%)	4 (11.8%)	11 (16.4%)
Nervous System	TOTAL	3 (9.1%)	0	3 (4.5%)
	DEPRESSION	1 (3.0%)	0	1 (1.5%)
	INSOMNIA	1 (3.0%)	0	1 (1.5%)
	WITHDRAWAL SYNDROME	1 (3.0%)	0	1 (1.5%)
Respiratory System	TOTAL	3 (9.1%)	1 (2.9%)	4 (6.0%)
	RESPIRATORY DISORDER	1 (3.0%)	1 (2.9%)	2 (3.0%)
	PHARYNGITIS	1 (3.0%)	0	1 (1.5%)
	SINUSITIS	1 (3.0%)	0	1 (1.5%)
Body as a Whole	TOTAL	1 (3.0%)	2 (5.9%)	3 (4.5%)
	ABDOMINAL PAIN	1 (3.0%)	0	1 (1.5%)
	HEADACHE	1 (3.0%)	0	1 (1.5%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.5%)
	INFECTION	0	1 (2.9%)	1 (1.5%)
Digestive System	TOTAL	1 (3.0%)	2 (5.9%)	3 (4.5%)
	DIARRHEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
	FECAL INCONTINENCE	0	1 (2.9%)	1 (1.5%)
	NAUSEA	0	1 (2.9%)	1 (1.5%)
Musculoskeletal System	TOTAL	1 (3.0%)	0	1 (1.5%)
	MYALGIA	1 (3.0%)	0	1 (1.5%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.5%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	3 (9.1%)	5 (14.7%)	8 (11.9%)
Body as a Whole	TOTAL	2 (6.1%)	0	2 (3.0%)
	ABDOMINAL PAIN	2 (6.1%)	0	2 (3.0%)
	HEADACHE	1 (3.0%)	0	1 (1.5%)
Digestive System	TOTAL	1 (3.0%)	0	1 (1.5%)
	INCREASED APPETITE	1 (3.0%)	0	1 (1.5%)
	NAUSEA	1 (3.0%)	0	1 (1.5%)
Nervous System	TOTAL	1 (3.0%)	2 (5.9%)	3 (4.5%)
	ANXIETY	1 (3.0%)	0	1 (1.5%)
	NERVOUSNESS	1 (3.0%)	0	1 (1.5%)
	CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.5%)
	HOSTILITY	0	1 (2.9%)	1 (1.5%)
Respiratory System	TOTAL	1 (3.0%)	2 (5.9%)	3 (4.5%)
	RESPIRATORY DISORDER	0	2 (5.9%)	2 (3.0%)
	ASTHMA	1 (3.0%)	0	1 (1.5%)
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.5%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.5%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	4 (33.3%)	2 (8.0%)	6 (16.2%)
Body as a Whole	TOTAL	3 (25.0%)	1 (4.0%)	4 (10.8%)
	FEVER	1 (8.3%)	0	1 (2.7%)
	HEADACHE	1 (8.3%)	0	1 (2.7%)
	PAIN	1 (8.3%)	0	1 (2.7%)
	TRAUMA	0	1 (4.0%)	1 (2.7%)
Respiratory System	TOTAL	1 (8.3%)	0	1 (2.7%)
	RESPIRATORY DISORDER	1 (8.3%)	0	1 (2.7%)
Special Senses	TOTAL	1 (8.3%)	0	1 (2.7%)
	EAR PAIN	1 (8.3%)	0	1 (2.7%)
Digestive System	TOTAL	0	1 (4.0%)	1 (2.7%)
	DIARRHEA	0	1 (4.0%)	1 (2.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (4.0%)	1 (2.7%)
	VOMITING	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	2 (16.7%)	4 (16.0%)	6 (16.2%)
Nervous System	TOTAL	1 (8.3%)	0	1 (2.7%)
	PARESTHESIA	1 (8.3%)	0	1 (2.7%)
	THINKING ABNORMAL	1 (8.3%)	0	1 (2.7%)
Respiratory System	TOTAL	1 (8.3%)	1 (4.0%)	2 (5.4%)
	SINUSITIS	1 (8.3%)	0	1 (2.7%)
	COUGH INCREASED	0	1 (4.0%)	1 (2.7%)
Body as a Whole	TOTAL	0	1 (4.0%)	1 (2.7%)
	HEADACHE	0	1 (4.0%)	1 (2.7%)
Digestive System	TOTAL	0	1 (4.0%)	1 (2.7%)
	NAUSEA	0	1 (4.0%)	1 (2.7%)
Skin and Appendages	TOTAL	0	1 (4.0%)	1 (2.7%)
	FUNGAL DERMATITIS	0	1 (4.0%)	1 (2.7%)

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Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.0%)	1 (2.7%)
Body as a Whole	TOTAL	0	1 (4.0%)	1 (2.7%)
	INFECTION	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
TOTAL	TOTAL	11 (24.4%)	6 (10.2%)	17 (16.3%)
Body as a Whole	TOTAL	4 (8.9%)	3 (5.1%)	7 (6.7%)
	HEADACHE	2 (4.4%)	0	2 (1.9%)
	ABDOMINAL PAIN	1 (2.2%)	0	1 (1.0%)
	FEVER	1 (2.2%)	0	1 (1.0%)
	PAIN	1 (2.2%)	0	1 (1.0%)
	ALLERGIC REACTION	0	1 (1.7%)	1 (1.0%)
	INFECTION	0	1 (1.7%)	1 (1.0%)
	TRAUMA	0	1 (1.7%)	1 (1.0%)
Respiratory System	TOTAL	4 (8.9%)	1 (1.7%)	5 (4.8%)
	RESPIRATORY DISORDER	2 (4.4%)	1 (1.7%)	3 (2.9%)
	PHARYNGITIS	1 (2.2%)	0	1 (1.0%)
	SINUSITIS	1 (2.2%)	0	1 (1.0%)
Nervous System	TOTAL	3 (6.7%)	0	3 (2.9%)
	DEPRESSION	1 (2.2%)	0	1 (1.0%)
	INSOMNIA	1 (2.2%)	0	1 (1.0%)
	WITHDRAWAL SYNDROME	1 (2.2%)	0	1 (1.0%)
Digestive System	TOTAL	1 (2.2%)	3 (5.1%)	4 (3.8%)
	DIARRHEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
	FECAL INCONTINENCE	0	1 (1.7%)	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (1.0%)
	NAUSEA	0	1 (1.7%)	1 (1.0%)
	VOMITING	0	1 (1.7%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.2%)	0	1 (1.0%)
	MYALGIA	1 (2.2%)	0	1 (1.0%)
Special Senses	TOTAL	1 (2.2%)	0	1 (1.0%)
	EAR PAIN	1 (2.2%)	0	1 (1.0%)
Urogenital System	TOTAL	0	1 (1.7%)	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
TOTAL	TOTAL	5 (11.1%)	9 (15.3%)	14 (13.5%)
Body as a Whole	TOTAL	2 (4.4%)	1 (1.7%)	3 (2.9%)
	ABDOMINAL PAIN	2 (4.4%)	0	2 (1.9%)
	HEADACHE	1 (2.2%)	1 (1.7%)	2 (1.9%)
Nervous System	TOTAL	2 (4.4%)	2 (3.4%)	4 (3.8%)
	ANXIETY	1 (2.2%)	0	1 (1.0%)
	NERVOUSNESS	1 (2.2%)	0	1 (1.0%)
	PARESTHESIA	1 (2.2%)	0	1 (1.0%)
	THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (1.0%)
	HOSTILITY	0	1 (1.7%)	1 (1.0%)
Respiratory System	TOTAL	2 (4.4%)	3 (5.1%)	5 (4.8%)
	RESPIRATORY DISORDER	0	2 (3.4%)	2 (1.9%)
	ASTHMA	1 (2.2%)	0	1 (1.0%)
	SINUSITIS	1 (2.2%)	0	1 (1.0%)
	COUGH INCREASED	0	1 (1.7%)	1 (1.0%)
Digestive System	TOTAL	1 (2.2%)	1 (1.7%)	2 (1.9%)
	NAUSEA	1 (2.2%)	1 (1.7%)	2 (1.9%)
	INCREASED APPETITE	1 (2.2%)	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.7%)	1 (1.0%)
	LYMPHOCYTOSIS	0	1 (1.7%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.7%)	1 (1.0%)
	SGOT INCREASED	0	1 (1.7%)	1 (1.0%)
Skin and Appendages	TOTAL	0	1 (1.7%)	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (1.7%)	1 (1.0%)
Body as a Whole	TOTAL	0	1 (1.7%)	1 (1.0%)
	INFECTION	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=33)	 Placebo (N=34)	 Total (N=67)
TOTAL	7 (21.2%)	4 (11.8%)	11 (16.4%)
DIARRHEA	1 (3.0%)	1 (2.9%)	2 (3.0%)
RESPIRATORY DISORDER	1 (3.0%)	1 (2.9%)	2 (3.0%)
ABDOMINAL PAIN	1 (3.0%)	0	1 (1.5%)
DEPRESSION	1 (3.0%)	0	1 (1.5%)
HEADACHE	1 (3.0%)	0	1 (1.5%)
INSOMNIA	1 (3.0%)	0	1 (1.5%)
MYALGIA	1 (3.0%)	0	1 (1.5%)
PHARYNGITIS	1 (3.0%)	0	1 (1.5%)
SINUSITIS	1 (3.0%)	0	1 (1.5%)
WITHDRAWAL SYNDROME	1 (3.0%)	0	1 (1.5%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.5%)
FECAL INCONTINENCE	0	1 (2.9%)	1 (1.5%)
INFECTION	0	1 (2.9%)	1 (1.5%)
NAUSEA	0	1 (2.9%)	1 (1.5%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=33)	 Placebo (N=34)	 Total (N=67)
TOTAL	3 (9.1%)	5 (14.7%)	8 (11.9%)
ABDOMINAL PAIN	2 (6.1%)	0	2 (3.0%)
RESPIRATORY DISORDER	0	2 (5.9%)	2 (3.0%)
ANXIETY	1 (3.0%)	0	1 (1.5%)
ASTHMA	1 (3.0%)	0	1 (1.5%)
HEADACHE	1 (3.0%)	0	1 (1.5%)
INCREASED APPETITE	1 (3.0%)	0	1 (1.5%)
NAUSEA	1 (3.0%)	0	1 (1.5%)
NERVOUSNESS	1 (3.0%)	0	1 (1.5%)
CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.5%)
HOSTILITY	0	1 (2.9%)	1 (1.5%)
LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.5%)
SGOT INCREASED	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=33)	 Placebo (N=34)	 Total (N=67)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=12)	 Placebo (N=25)	 Total (N=37)
TOTAL	4 (33.3%)	2 (8.0%)	6 (16.2%)
EAR PAIN	1 (8.3%)	0	1 (2.7%)
FEVER	1 (8.3%)	0	1 (2.7%)
HEADACHE	1 (8.3%)	0	1 (2.7%)
PAIN	1 (8.3%)	0	1 (2.7%)
RESPIRATORY DISORDER	1 (8.3%)	0	1 (2.7%)
DIARRHEA	0	1 (4.0%)	1 (2.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (4.0%)	1 (2.7%)
TRAUMA	0	1 (4.0%)	1 (2.7%)
VOMITING	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=12)	 Placebo (N=25)	 Total (N=37)
TOTAL	2 (16.7%)	4 (16.0%)	6 (16.2%)
PARESTHESIA	1 (8.3%)	0	1 (2.7%)
SINUSITIS	1 (8.3%)	0	1 (2.7%)
THINKING ABNORMAL	1 (8.3%)	0	1 (2.7%)
COUGH INCREASED	0	1 (4.0%)	1 (2.7%)
FUNGAL DERMATITIS	0	1 (4.0%)	1 (2.7%)
HEADACHE	0	1 (4.0%)	1 (2.7%)
NAUSEA	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Preferred Term			
TOTAL	0	1 (4.0%)	1 (2.7%)
INFECTION	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=45)	 Placebo (N=59)	 Total (N=104)
TOTAL	11 (24.4%)	6 (10.2%)	17 (16.3%)
RESPIRATORY DISORDER	2 (4.4%)	1 (1.7%)	3 (2.9%)
DIARRHEA	1 (2.2%)	2 (3.4%)	3 (2.9%)
HEADACHE	2 (4.4%)	0	2 (1.9%)
ABDOMINAL PAIN	1 (2.2%)	0	1 (1.0%)
DEPRESSION	1 (2.2%)	0	1 (1.0%)
EAR PAIN	1 (2.2%)	0	1 (1.0%)
FEVER	1 (2.2%)	0	1 (1.0%)
INSOMNIA	1 (2.2%)	0	1 (1.0%)
MYALGIA	1 (2.2%)	0	1 (1.0%)
PAIN	1 (2.2%)	0	1 (1.0%)
PHARYNGITIS	1 (2.2%)	0	1 (1.0%)
SINUSITIS	1 (2.2%)	0	1 (1.0%)
WITHDRAWAL SYNDROME	1 (2.2%)	0	1 (1.0%)
ALLERGIC REACTION	0	1 (1.7%)	1 (1.0%)
FECAL INCONTINENCE	0	1 (1.7%)	1 (1.0%)
INFECTION	0	1 (1.7%)	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (1.0%)
NAUSEA	0	1 (1.7%)	1 (1.0%)
TRAUMA	0	1 (1.7%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.7%)	1 (1.0%)
VOMITING	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=45)	 Placebo (N=59)	 Total (N=104)
TOTAL	5 (11.1%)	9 (15.3%)	14 (13.5%)
ABDOMINAL PAIN	2 (4.4%)	0	2 (1.9%)
HEADACHE	1 (2.2%)	1 (1.7%)	2 (1.9%)
NAUSEA	1 (2.2%)	1 (1.7%)	2 (1.9%)
RESPIRATORY DISORDER	0	2 (3.4%)	2 (1.9%)
ANXIETY	1 (2.2%)	0	1 (1.0%)
ASTHMA	1 (2.2%)	0	1 (1.0%)
INCREASED APPETITE	1 (2.2%)	0	1 (1.0%)
NERVOUSNESS	1 (2.2%)	0	1 (1.0%)
PARESTHESIA	1 (2.2%)	0	1 (1.0%)
SINUSITIS	1 (2.2%)	0	1 (1.0%)
THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (1.0%)
COUGH INCREASED	0	1 (1.7%)	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.7%)	1 (1.0%)
HOSTILITY	0	1 (1.7%)	1 (1.0%)
LYMPHOCYTOSIS	0	1 (1.7%)	1 (1.0%)
SGOT INCREASED	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=45)	 Placebo (N=59)	 Total (N=104)
TOTAL	0	1 (1.7%)	1 (1.0%)
INFECTION	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	14 (56.0%)	14 (38.9%)	28 (45.9%)
Nervous System	TOTAL	6 (24.0%)	5 (13.9%)	11 (18.0%)
	HOSTILITY	2 (8.0%)	0	2 (3.3%)
	NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
	AGITATION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	ANXIETY	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
	INSOMNIA	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	4 (16.0%)	4 (11.1%)	8 (13.1%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	DYSPEPSIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	NAUSEA	0	1 (2.8%)	1 (1.6%)
	VOMITING	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	4 (16.0%)	2 (5.6%)	6 (9.8%)
	WEIGHT GAIN	4 (16.0%)	2 (5.6%)	6 (9.8%)
Body as a Whole	TOTAL	3 (12.0%)	2 (5.6%)	5 (8.2%)
	ABDOMINAL PAIN	2 (8.0%)	1 (2.8%)	3 (4.9%)
	HEADACHE	1 (4.0%)	0	1 (1.6%)
	ASTHENIA	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	LEUKOPENIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
Urogenital System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.6%)
	YAWN	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Special Senses	TOTAL	0	1 (2.8%)	1 (1.6%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	14 (58.3%)	19 (55.9%)	33 (56.9%)
Body as a Whole	TOTAL	9 (37.5%)	5 (14.7%)	14 (24.1%)
	HEADACHE	7 (29.2%)	4 (11.8%)	11 (19.0%)
	FEVER	1 (4.2%)	0	1 (1.7%)
	PAIN	1 (4.2%)	0	1 (1.7%)
	TRAUMA	1 (4.2%)	0	1 (1.7%)
	ABDOMINAL PAIN	0	1 (2.9%)	1 (1.7%)
Nervous System	TOTAL	7 (29.2%)	15 (44.1%)	22 (37.9%)
	NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
	HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	HOSTILITY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	DIZZINESS	1 (4.2%)	0	1 (1.7%)
	MYOCLONUS	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	6 (25.0%)	2 (5.9%)	8 (13.8%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	NAUSEA	3 (12.5%)	0	3 (5.2%)
	DYSPEPSIA	2 (8.3%)	0	2 (3.4%)
	DIARRHEA	1 (4.2%)	0	1 (1.7%)
Cardiovascular System	TOTAL	0	3 (8.8%)	3 (5.2%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

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Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	28 (57.1%)	33 (47.1%)	61 (51.3%)
Nervous System	TOTAL	13 (26.5%)	20 (28.6%)	33 (27.7%)
	NERVOUSNESS	3 (6.1%)	9 (12.9%)	12 (10.1%)
	HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	HOSTILITY	3 (6.1%)	2 (2.9%)	5 (4.2%)
	INSOMNIA	2 (4.1%)	3 (4.3%)	5 (4.2%)
	ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
	AGITATION	1 (2.0%)	2 (2.9%)	3 (2.5%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	DIZZINESS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	MYOCLONUS	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
Body as a Whole	TOTAL	12 (24.5%)	7 (10.0%)	19 (16.0%)
	HEADACHE	8 (16.3%)	4 (5.7%)	12 (10.1%)
	ABDOMINAL PAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
	FEVER	1 (2.0%)	0	1 (0.8%)
	PAIN	1 (2.0%)	0	1 (0.8%)
	TRAUMA	1 (2.0%)	0	1 (0.8%)
	ASTHENIA	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	10 (20.4%)	6 (8.6%)	16 (13.4%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	DYSPEPSIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
	NAUSEA	3 (6.1%)	1 (1.4%)	4 (3.4%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	DIARRHEA	1 (2.0%)	0	1 (0.8%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	VOMITING	0	1 (1.4%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.2%)	3 (4.3%)	7 (5.9%)
	WEIGHT GAIN	4 (8.2%)	3 (4.3%)	7 (5.9%)
Hemic and Lymphatic System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
Hemic and Lymphatic System	LEUKOPENIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Urogenital System	TOTAL	1 (2.0%)	3 (4.3%)	4 (3.4%)
	URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
Cardiovascular System	TOTAL	0	4 (5.7%)	4 (3.4%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	0	1 (1.4%)	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.8%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)

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Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	9 (36.0%)	13 (43.3%)	22 (40.0%)
Nervous System	TOTAL	5 (20.0%)	7 (23.3%)	12 (21.8%)
	SOMNOLENCE	2 (8.0%)	2 (6.7%)	4 (7.3%)
	NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
	EMOTIONAL LABILITY	1 (4.0%)	2 (6.7%)	3 (5.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	AGITATION	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	DIZZINESS	0	1 (3.3%)	1 (1.8%)
	HOSTILITY	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	4 (16.0%)	4 (13.3%)	8 (14.5%)
	NAUSEA	4 (16.0%)	0	4 (7.3%)
	VOMITING	2 (8.0%)	0	2 (3.6%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DIARRHEA	0	1 (3.3%)	1 (1.8%)
	INCREASED APPETITE	0	1 (3.3%)	1 (1.8%)
Body as a Whole	TOTAL	1 (4.0%)	5 (16.7%)	6 (10.9%)
	HEADACHE	1 (4.0%)	3 (10.0%)	4 (7.3%)
	ASTHENIA	0	2 (6.7%)	2 (3.6%)
	ABDOMINAL PAIN	0	1 (3.3%)	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	0	1 (1.8%)
	LEUKOPENIA	1 (4.0%)	0	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (4.0%)	3 (10.0%)	4 (7.3%)
	WEIGHT GAIN	1 (4.0%)	3 (10.0%)	4 (7.3%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.8%)
	ACNE	0	1 (3.3%)	1 (1.8%)

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Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (4.2%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	8 (40.0%)	13 (48.1%)	21 (44.7%)
Body as a Whole	TOTAL	5 (25.0%)	7 (25.9%)	12 (25.5%)
	HEADACHE	3 (15.0%)	4 (14.8%)	7 (14.9%)
	ASTHENIA	2 (10.0%)	2 (7.4%)	4 (8.5%)
	ABDOMINAL PAIN	0	2 (7.4%)	2 (4.3%)
Nervous System	TOTAL	5 (25.0%)	7 (25.9%)	12 (25.5%)
	NEUROSIS	3 (15.0%)	0	3 (6.4%)
	HOSTILITY	1 (5.0%)	2 (7.4%)	3 (6.4%)
	INSOMNIA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	AGITATION	0	2 (7.4%)	2 (4.3%)
	NERVOUSNESS	0	2 (7.4%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	0	1 (2.1%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	ACNE	1 (5.0%)	0	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
Digestive System	TOTAL	0	8 (29.6%)	8 (17.0%)
	NAUSEA	0	3 (11.1%)	3 (6.4%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	0	2 (7.4%)	2 (4.3%)
	RESPIRATORY DISORDER	0	2 (7.4%)	2 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	17 (37.8%)	26 (45.6%)	43 (42.2%)
Nervous System	TOTAL	10 (22.2%)	14 (24.6%)	24 (23.5%)
	INSOMNIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	NERVOUSNESS	2 (4.4%)	3 (5.3%)	5 (4.9%)
	EMOTIONAL LABILITY	2 (4.4%)	2 (3.5%)	4 (3.9%)
	SOMNOLENCE	2 (4.4%)	2 (3.5%)	4 (3.9%)
	HOSTILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
	NEUROSIS	3 (6.7%)	0	3 (2.9%)
	DIZZINESS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	AGITATION	0	3 (5.3%)	3 (2.9%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)	1 (1.0%)
Body as a Whole	TOTAL	6 (13.3%)	12 (21.1%)	18 (17.6%)
	HEADACHE	4 (8.9%)	7 (12.3%)	11 (10.8%)
	ASTHENIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	ABDOMINAL PAIN	0	3 (5.3%)	3 (2.9%)
Digestive System	TOTAL	4 (8.9%)	12 (21.1%)	16 (15.7%)
	NAUSEA	4 (8.9%)	3 (5.3%)	7 (6.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	VOMITING	2 (4.4%)	0	2 (2.0%)
	DRY MOUTH	0	2 (3.5%)	2 (2.0%)
	DYSPEPSIA	0	2 (3.5%)	2 (2.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	DIARRHEA	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	INCREASED APPETITE	0	1 (1.8%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.4%)	4 (7.0%)	6 (5.9%)
	WEIGHT GAIN	2 (4.4%)	3 (5.3%)	5 (4.9%)
	WEIGHT LOSS	0	1 (1.8%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0	1 (1.0%)
	LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.2%)	2 (3.5%)	3 (2.9%)
	ACNE	1 (2.2%)	1 (1.8%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
Skin and Appendages	SWEATING	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	0	2 (3.5%)	2 (2.0%)
	RESPIRATORY DISORDER	0	2 (3.5%)	2 (2.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.4%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.4%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	23 (46.0%)	27 (40.9%)	50 (43.1%)
Nervous System	TOTAL	11 (22.0%)	12 (18.2%)	23 (19.8%)
	NERVOUSNESS	4 (8.0%)	1 (1.5%)	5 (4.3%)
	SOMNOLENCE	2 (4.0%)	3 (4.5%)	5 (4.3%)
	INSOMNIA	1 (2.0%)	3 (4.5%)	4 (3.4%)
	HOSTILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
	AGITATION	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EMOTIONAL LABILITY	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	DIZZINESS	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	8 (16.0%)	8 (12.1%)	16 (13.8%)
	NAUSEA	4 (8.0%)	1 (1.5%)	5 (4.3%)
	VOMITING	2 (4.0%)	1 (1.5%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	DRY MOUTH	2 (4.0%)	0	2 (1.7%)
	DYSPEPSIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	INCREASED APPETITE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	DIARRHEA	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	5 (10.0%)	5 (7.6%)	10 (8.6%)
	WEIGHT GAIN	5 (10.0%)	5 (7.6%)	10 (8.6%)
Body as a Whole	TOTAL	4 (8.0%)	7 (10.6%)	11 (9.5%)
	HEADACHE	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
	ASTHENIA	0	3 (4.5%)	3 (2.6%)
Hemic and Lymphatic System	TOTAL	2 (4.0%)	1 (1.5%)	3 (2.6%)
	LEUKOPENIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
Urogenital System	TOTAL	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.9%)
	SYNCOPE	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.9%)
	ACNE	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.9%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.4%)	1 (1.9%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.9%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	22 (50.0%)	32 (52.5%)	54 (51.4%)
Body as a Whole	TOTAL	14 (31.8%)	12 (19.7%)	26 (24.8%)
	HEADACHE	10 (22.7%)	8 (13.1%)	18 (17.1%)
	ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ABDOMINAL PAIN	0	3 (4.9%)	3 (2.9%)
	FEVER	1 (2.3%)	0	1 (1.0%)
	PAIN	1 (2.3%)	0	1 (1.0%)
	TRAUMA	1 (2.3%)	0	1 (1.0%)
Nervous System	TOTAL	12 (27.3%)	22 (36.1%)	34 (32.4%)
	NERVOUSNESS	1 (2.3%)	11 (18.0%)	12 (11.4%)
	HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
	INSOMNIA	3 (6.8%)	4 (6.6%)	7 (6.7%)
	HOSTILITY	2 (4.5%)	4 (6.6%)	6 (5.7%)
	NEUROSIS	4 (9.1%)	0	4 (3.8%)
	DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ANXIETY	1 (2.3%)	2 (3.3%)	3 (2.9%)
	AGITATION	0	3 (4.9%)	3 (2.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	EMOTIONAL LABILITY	1 (2.3%)	0	1 (1.0%)
	MYOCLONUS	1 (2.3%)	0	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	6 (13.6%)	10 (16.4%)	16 (15.2%)
	NAUSEA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DYSPEPSIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	DIARRHEA	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	FLATULENCE	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ACNE	1 (2.3%)	0	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
Skin and Appendages	SWEATING	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	0	3 (4.9%)	3 (2.9%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
Respiratory System	TOTAL	0	2 (3.3%)	2 (1.9%)
	RESPIRATORY DISORDER	0	2 (3.3%)	2 (1.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	45 (47.9%)	59 (46.5%)	104 (47.1%)
Nervous System	TOTAL	23 (24.5%)	34 (26.8%)	57 (25.8%)
	NERVOUSNESS	5 (5.3%)	12 (9.4%)	17 (7.7%)
	HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
	INSOMNIA	4 (4.3%)	7 (5.5%)	11 (5.0%)
	HOSTILITY	4 (4.3%)	5 (3.9%)	9 (4.1%)
	SOMNOLENCE	3 (3.2%)	4 (3.1%)	7 (3.2%)
	AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
	DIZZINESS	2 (2.1%)	3 (2.4%)	5 (2.3%)
	NEUROSIS	4 (4.3%)	0	4 (1.8%)
	EMOTIONAL LABILITY	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	TREMOR	0	3 (2.4%)	3 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	MYOCLONUS	1 (1.1%)	0	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.5%)
Body as a Whole	TOTAL	18 (19.1%)	19 (15.0%)	37 (16.7%)
	HEADACHE	12 (12.8%)	11 (8.7%)	23 (10.4%)
	ABDOMINAL PAIN	2 (2.1%)	5 (3.9%)	7 (3.2%)
	ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
	FEVER	1 (1.1%)	0	1 (0.5%)
	PAIN	1 (1.1%)	0	1 (0.5%)
	TRAUMA	1 (1.1%)	0	1 (0.5%)
Digestive System	TOTAL	14 (14.9%)	18 (14.2%)	32 (14.5%)
	NAUSEA	7 (7.4%)	4 (3.1%)	11 (5.0%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DYSPEPSIA	3 (3.2%)	3 (2.4%)	6 (2.7%)
	DRY MOUTH	2 (2.1%)	2 (1.6%)	4 (1.8%)
	VOMITING	2 (2.1%)	1 (0.8%)	3 (1.4%)
	CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIARRHEA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	INCREASED APPETITE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FLATULENCE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	6 (6.4%)	7 (5.5%)	13 (5.9%)
	WEIGHT GAIN	6 (6.4%)	6 (4.7%)	12 (5.4%)
	WEIGHT LOSS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	2 (2.1%)	1 (0.8%)	3 (1.4%)
	LEUKOPENIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
Skin and Appendages	TOTAL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ACNE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	3 (2.4%)	4 (1.8%)
	URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
Cardiovascular System	TOTAL	0	4 (3.1%)	4 (1.8%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	0	3 (2.4%)	3 (1.4%)
	RESPIRATORY DISORDER	0	2 (1.6%)	2 (0.9%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.5%)
	ABNORMAL VISION	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (1.1%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (1.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
TOTAL	14 (56.0%)	12 (33.3%)	26 (42.6%)
WEIGHT GAIN	4 (16.0%)	2 (5.6%)	6 (9.8%)
ABDOMINAL PAIN	2 (8.0%)	1 (2.8%)	3 (4.9%)
URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
DRY MOUTH	2 (8.0%)	0	2 (3.3%)
HOSTILITY	2 (8.0%)	0	2 (3.3%)
NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
AGITATION	1 (4.0%)	1 (2.8%)	2 (3.3%)
DYSPEPSIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
LEUKOPENIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
CONSTIPATION	1 (4.0%)	0	1 (1.6%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
HEADACHE	1 (4.0%)	0	1 (1.6%)
INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
ANXIETY	0	1 (2.8%)	1 (1.6%)
ASTHENIA	0	1 (2.8%)	1 (1.6%)
DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
INSOMNIA	0	1 (2.8%)	1 (1.6%)
NAUSEA	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)
VOMITING	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
TOTAL	14 (58.3%)	19 (55.9%)	33 (56.9%)
HEADACHE	7 (29.2%)	4 (11.8%)	11 (19.0%)
NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
NAUSEA	3 (12.5%)	0	3 (5.2%)
ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
HOSTILITY	1 (4.2%)	2 (5.9%)	3 (5.2%)
VASODILATATION	0	3 (8.8%)	3 (5.2%)
DYSPEPSIA	2 (8.3%)	0	2 (3.4%)
SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
DIARRHEA	1 (4.2%)	0	1 (1.7%)
DIZZINESS	1 (4.2%)	0	1 (1.7%)
FEVER	1 (4.2%)	0	1 (1.7%)
MYOCLONUS	1 (4.2%)	0	1 (1.7%)
NEUROSIS	1 (4.2%)	0	1 (1.7%)
PAIN	1 (4.2%)	0	1 (1.7%)
TRAUMA	1 (4.2%)	0	1 (1.7%)
ABDOMINAL PAIN	0	1 (2.9%)	1 (1.7%)
AGITATION	0	1 (2.9%)	1 (1.7%)
MANIC REACTION	0	1 (2.9%)	1 (1.7%)
TREMOR	0	1 (2.9%)	1 (1.7%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)
WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
TOTAL	28 (57.1%)	31 (44.3%)	59 (49.6%)
HEADACHE	8 (16.3%)	4 (5.7%)	12 (10.1%)
NERVOUSNESS	3 (6.1%)	9 (12.9%)	12 (10.1%)
HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
WEIGHT GAIN	4 (8.2%)	3 (4.3%)	7 (5.9%)
HOSTILITY	3 (6.1%)	2 (2.9%)	5 (4.2%)
DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
INSOMNIA	2 (4.1%)	3 (4.3%)	5 (4.2%)
DYSPEPSIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
NAUSEA	3 (6.1%)	1 (1.4%)	4 (3.4%)
ABDOMINAL PAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
AGITATION	1 (2.0%)	2 (2.9%)	3 (2.5%)
SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
VASODILATATION	0	3 (4.3%)	3 (2.5%)
DRY MOUTH	2 (4.1%)	0	2 (1.7%)
DIZZINESS	1 (2.0%)	1 (1.4%)	2 (1.7%)
LEUKOPENIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
TREMOR	0	2 (2.9%)	2 (1.7%)
CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
CONSTIPATION	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
DIARRHEA	1 (2.0%)	0	1 (0.8%)
FEVER	1 (2.0%)	0	1 (0.8%)
INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
MYOCLONUS	1 (2.0%)	0	1 (0.8%)
NEUROSIS	1 (2.0%)	0	1 (0.8%)
PAIN	1 (2.0%)	0	1 (0.8%)
TRAUMA	1 (2.0%)	0	1 (0.8%)
ASTHENIA	0	1 (1.4%)	1 (0.8%)
MANIC REACTION	0	1 (1.4%)	1 (0.8%)
VOMITING	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
TOTAL	9 (36.0%)	12 (40.0%)	21 (38.2%)
NAUSEA	4 (16.0%)	0	4 (7.3%)
SOMNOLENCE	2 (8.0%)	2 (6.7%)	4 (7.3%)
HEADACHE	1 (4.0%)	3 (10.0%)	4 (7.3%)
WEIGHT GAIN	1 (4.0%)	3 (10.0%)	4 (7.3%)
NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
EMOTIONAL LABILITY	1 (4.0%)	2 (6.7%)	3 (5.5%)
INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
VOMITING	2 (8.0%)	0	2 (3.6%)
ASTHENIA	0	2 (6.7%)	2 (3.6%)
DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
LEUKOPENIA	1 (4.0%)	0	1 (1.8%)
ABDOMINAL PAIN	0	1 (3.3%)	1 (1.8%)
ACNE	0	1 (3.3%)	1 (1.8%)
AGITATION	0	1 (3.3%)	1 (1.8%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
DIARRHEA	0	1 (3.3%)	1 (1.8%)
DIZZINESS	0	1 (3.3%)	1 (1.8%)
HOSTILITY	0	1 (3.3%)	1 (1.8%)
INCREASED APPETITE	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Preferred Term			
TOTAL	8 (40.0%)	13 (48.1%)	21 (44.7%)
HEADACHE	3 (15.0%)	4 (14.8%)	7 (14.9%)
ASTHENIA	2 (10.0%)	2 (7.4%)	4 (8.5%)
NEUROSIS	3 (15.0%)	0	3 (6.4%)
HOSTILITY	1 (5.0%)	2 (7.4%)	3 (6.4%)
INSOMNIA	1 (5.0%)	2 (7.4%)	3 (6.4%)
NAUSEA	0	3 (11.1%)	3 (6.4%)
DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
ABDOMINAL PAIN	0	2 (7.4%)	2 (4.3%)
AGITATION	0	2 (7.4%)	2 (4.3%)
DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
DRY MOUTH	0	2 (7.4%)	2 (4.3%)
DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
NERVOUSNESS	0	2 (7.4%)	2 (4.3%)
RESPIRATORY DISORDER	0	2 (7.4%)	2 (4.3%)
ACNE	1 (5.0%)	0	1 (2.1%)
EMOTIONAL LABILITY	1 (5.0%)	0	1 (2.1%)
MANIC REACTION	1 (5.0%)	0	1 (2.1%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
CONSTIPATION	0	1 (3.7%)	1 (2.1%)
TREMOR	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	17 (37.8%)	25 (43.9%)	42 (41.2%)
HEADACHE	4 (8.9%)	7 (12.3%)	11 (10.8%)
NAUSEA	4 (8.9%)	3 (5.3%)	7 (6.9%)
ASTHENIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
INSOMNIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
NERVOUSNESS	2 (4.4%)	3 (5.3%)	5 (4.9%)
WEIGHT GAIN	2 (4.4%)	3 (5.3%)	5 (4.9%)
EMOTIONAL LABILITY	2 (4.4%)	2 (3.5%)	4 (3.9%)
SOMNOLENCE	2 (4.4%)	2 (3.5%)	4 (3.9%)
HOSTILITY	1 (2.2%)	3 (5.3%)	4 (3.9%)
DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
NEUROSIS	3 (6.7%)	0	3 (2.9%)
DIZZINESS	1 (2.2%)	2 (3.5%)	3 (2.9%)
ABDOMINAL PAIN	0	3 (5.3%)	3 (2.9%)
AGITATION	0	3 (5.3%)	3 (2.9%)
VOMITING	2 (4.4%)	0	2 (2.0%)
ACNE	1 (2.2%)	1 (1.8%)	2 (2.0%)
HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
DRY MOUTH	0	2 (3.5%)	2 (2.0%)
DYSPEPSIA	0	2 (3.5%)	2 (2.0%)
RESPIRATORY DISORDER	0	2 (3.5%)	2 (2.0%)
LEUKOPENIA	1 (2.2%)	0	1 (1.0%)
MANIC REACTION	1 (2.2%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
CONSTIPATION	0	1 (1.8%)	1 (1.0%)
DIARRHEA	0	1 (1.8%)	1 (1.0%)
INCREASED APPETITE	0	1 (1.8%)	1 (1.0%)
TREMOR	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
TOTAL	23 (46.0%)	24 (36.4%)	47 (40.5%)
WEIGHT GAIN	5 (10.0%)	5 (7.6%)	10 (8.6%)
NAUSEA	4 (8.0%)	1 (1.5%)	5 (4.3%)
NERVOUSNESS	4 (8.0%)	1 (1.5%)	5 (4.3%)
HEADACHE	2 (4.0%)	3 (4.5%)	5 (4.3%)
SOMNOLENCE	2 (4.0%)	3 (4.5%)	5 (4.3%)
ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
INSOMNIA	1 (2.0%)	3 (4.5%)	4 (3.4%)
HOSTILITY	2 (4.0%)	1 (1.5%)	3 (2.6%)
LEUKOPENIA	2 (4.0%)	1 (1.5%)	3 (2.6%)
VOMITING	2 (4.0%)	1 (1.5%)	3 (2.6%)
AGITATION	1 (2.0%)	2 (3.0%)	3 (2.6%)
EMOTIONAL LABILITY	1 (2.0%)	2 (3.0%)	3 (2.6%)
URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)
ASTHENIA	0	3 (4.5%)	3 (2.6%)
DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
DRY MOUTH	2 (4.0%)	0	2 (1.7%)
DYSPEPSIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
INCREASED APPETITE	1 (2.0%)	1 (1.5%)	2 (1.7%)
DIZZINESS	0	2 (3.0%)	2 (1.7%)
CONSTIPATION	1 (2.0%)	0	1 (0.9%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
ACNE	0	1 (1.5%)	1 (0.9%)
ANXIETY	0	1 (1.5%)	1 (0.9%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
DIARRHEA	0	1 (1.5%)	1 (0.9%)
TREMOR	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
TOTAL	22 (50.0%)	32 (52.5%)	54 (51.4%)
HEADACHE	10 (22.7%)	8 (13.1%)	18 (17.1%)
NERVOUSNESS	1 (2.3%)	11 (18.0%)	12 (11.4%)
HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
INSOMNIA	3 (6.8%)	4 (6.6%)	7 (6.7%)
NAUSEA	3 (6.8%)	3 (4.9%)	6 (5.7%)
DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
HOSTILITY	2 (4.5%)	4 (6.6%)	6 (5.7%)
NEUROSIS	4 (9.1%)	0	4 (3.8%)
ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
DYSPEPSIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
ANXIETY	1 (2.3%)	2 (3.3%)	3 (2.9%)
ABDOMINAL PAIN	0	3 (4.9%)	3 (2.9%)
AGITATION	0	3 (4.9%)	3 (2.9%)
VASODILATATION	0	3 (4.9%)	3 (2.9%)
MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)
DRY MOUTH	0	2 (3.3%)	2 (1.9%)
RESPIRATORY DISORDER	0	2 (3.3%)	2 (1.9%)
TREMOR	0	2 (3.3%)	2 (1.9%)
ACNE	1 (2.3%)	0	1 (1.0%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
DIARRHEA	1 (2.3%)	0	1 (1.0%)
EMOTIONAL LABILITY	1 (2.3%)	0	1 (1.0%)
FEVER	1 (2.3%)	0	1 (1.0%)
MYOCLONUS	1 (2.3%)	0	1 (1.0%)
PAIN	1 (2.3%)	0	1 (1.0%)
TRAUMA	1 (2.3%)	0	1 (1.0%)
CONSTIPATION	0	1 (1.6%)	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
TOTAL	45 (47.9%)	56 (44.1%)	101 (45.7%)
HEADACHE	12 (12.8%)	11 (8.7%)	23 (10.4%)
NERVOUSNESS	5 (5.3%)	12 (9.4%)	17 (7.7%)
HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
WEIGHT GAIN	6 (6.4%)	6 (4.7%)	12 (5.4%)
NAUSEA	7 (7.4%)	4 (3.1%)	11 (5.0%)
INSOMNIA	4 (4.3%)	7 (5.5%)	11 (5.0%)
HOSTILITY	4 (4.3%)	5 (3.9%)	9 (4.1%)
DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
SOMNOLENCE	3 (3.2%)	4 (3.1%)	7 (3.2%)
ABDOMINAL PAIN	2 (2.1%)	5 (3.9%)	7 (3.2%)
ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
DYSPEPSIA	3 (3.2%)	3 (2.4%)	6 (2.7%)
AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
DIZZINESS	2 (2.1%)	3 (2.4%)	5 (2.3%)
NEUROSIS	4 (4.3%)	0	4 (1.8%)
DRY MOUTH	2 (2.1%)	2 (1.6%)	4 (1.8%)
EMOTIONAL LABILITY	2 (2.1%)	2 (1.6%)	4 (1.8%)
ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
LEUKOPENIA	2 (2.1%)	1 (0.8%)	3 (1.4%)
VOMITING	2 (2.1%)	1 (0.8%)	3 (1.4%)
TREMOR	0	3 (2.4%)	3 (1.4%)
VASODILATATION	0	3 (2.4%)	3 (1.4%)
ACNE	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
DIARRHEA	1 (1.1%)	1 (0.8%)	2 (0.9%)
INCREASED APPETITE	1 (1.1%)	1 (0.8%)	2 (0.9%)
MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
RESPIRATORY DISORDER	0	2 (1.6%)	2 (0.9%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
FEVER	1 (1.1%)	0	1 (0.5%)
MYOCLONUS	1 (1.1%)	0	1 (0.5%)
PAIN	1 (1.1%)	0	1 (0.5%)
TRAUMA	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=13)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	1 (12.5%)	2 (15.4%)	3 (14.3%)
Nervous System	TOTAL	1 (12.5%)	0	1 (4.8%)
	DEPRESSION	1 (12.5%)	0	1 (4.8%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.8%)
	SYNCOPE	0	1 (7.7%)	1 (4.8%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.8%)
	NAUSEA	0	1 (7.7%)	1 (4.8%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (20.0%)	1 (12.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (20.0%)	1 (12.5%)
	WEIGHT GAIN	0	1 (20.0%)	1 (12.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=4)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	1 (9.1%)	3 (16.7%)	4 (13.8%)
Nervous System	TOTAL	1 (9.1%)	0	1 (3.4%)
	DEPRESSION	1 (9.1%)	0	1 (3.4%)
Cardiovascular System	TOTAL	0	1 (5.6%)	1 (3.4%)
	SYNCOPE	0	1 (5.6%)	1 (3.4%)
Digestive System	TOTAL	0	1 (5.6%)	1 (3.4%)
	NAUSEA	0	1 (5.6%)	1 (3.4%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.6%)	1 (3.4%)
	WEIGHT GAIN	0	1 (5.6%)	1 (3.4%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=14)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	3 (33.3%)	2 (22.2%)	5 (27.8%)
Hemic and Lymphatic System	TOTAL	1 (11.1%)	0	1 (5.6%)
	LEUKOPENIA	1 (11.1%)	0	1 (5.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (11.1%)	0	1 (5.6%)
	WEIGHT GAIN	1 (11.1%)	0	1 (5.6%)
Nervous System	TOTAL	1 (11.1%)	2 (22.2%)	3 (16.7%)
	HOSTILITY	1 (11.1%)	0	1 (5.6%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.6%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.6%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.6%)
	MYALGIA	0	1 (11.1%)	1 (5.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=2)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=3)	Total (N=5)
Body System	Preferred Term			
TOTAL	TOTAL	1 (50.0%)	0	1 (20.0%)
Cardiovascular System	TOTAL	1 (50.0%)	0	1 (20.0%)
	BRADYCARDIA	1 (50.0%)	0	1 (20.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=2)	Total (N=3)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=12)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	4 (36.4%)	2 (16.7%)	6 (26.1%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.3%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.3%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (4.3%)
	LEUKOPENIA	1 (9.1%)	0	1 (4.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (4.3%)
	WEIGHT GAIN	1 (9.1%)	0	1 (4.3%)
Nervous System	TOTAL	1 (9.1%)	2 (16.7%)	3 (13.0%)
	HOSTILITY	1 (9.1%)	0	1 (4.3%)
	SOMNOLENCE	0	1 (8.3%)	1 (4.3%)
	WITHDRAWAL SYNDROME	0	1 (8.3%)	1 (4.3%)
Musculoskeletal System	TOTAL	0	1 (8.3%)	1 (4.3%)
	MYALGIA	0	1 (8.3%)	1 (4.3%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=9)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=3)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=22)	Total (N=39)
Body System	Preferred Term			
TOTAL	TOTAL	4 (23.5%)	4 (18.2%)	8 (20.5%)
Nervous System	TOTAL	2 (11.8%)	2 (9.1%)	4 (10.3%)
	DEPRESSION	1 (5.9%)	0	1 (2.6%)
	HOSTILITY	1 (5.9%)	0	1 (2.6%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.6%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.6%)
Hemic and Lymphatic System	TOTAL	1 (5.9%)	0	1 (2.6%)
	LEUKOPENIA	1 (5.9%)	0	1 (2.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.9%)	0	1 (2.6%)
	WEIGHT GAIN	1 (5.9%)	0	1 (2.6%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.6%)
	SYNCOPE	0	1 (4.5%)	1 (2.6%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.6%)
	NAUSEA	0	1 (4.5%)	1 (2.6%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.6%)
	MYALGIA	0	1 (4.5%)	1 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=5)	Total (N=12)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=8)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	1 (20.0%)	1 (12.5%)	2 (15.4%)
Cardiovascular System	TOTAL	1 (20.0%)	0	1 (7.7%)
	BRADYCARDIA	1 (20.0%)	0	1 (7.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (7.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (7.7%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=6)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=2)	Placebo (N=2)	Total (N=4)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=30)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	5 (22.7%)	5 (16.7%)	10 (19.2%)
Nervous System	TOTAL	2 (9.1%)	2 (6.7%)	4 (7.7%)
	DEPRESSION	1 (4.5%)	0	1 (1.9%)
	HOSTILITY	1 (4.5%)	0	1 (1.9%)
	SOMNOLENCE	0	1 (3.3%)	1 (1.9%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	BRADYCARDIA	1 (4.5%)	0	1 (1.9%)
	SYNCOPE	0	1 (3.3%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	1 (4.5%)	0	1 (1.9%)
	LEUKOPENIA	1 (4.5%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (4.5%)	1 (3.3%)	2 (3.8%)
	WEIGHT GAIN	1 (4.5%)	1 (3.3%)	2 (3.8%)
Digestive System	TOTAL	0	1 (3.3%)	1 (1.9%)
	NAUSEA	0	1 (3.3%)	1 (1.9%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.9%)
	MYALGIA	0	1 (3.3%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=23)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=7)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	14 (56.0%)	15 (41.7%)	29 (47.5%)
Nervous System	TOTAL	6 (24.0%)	5 (13.9%)	11 (18.0%)
	HOSTILITY	2 (8.0%)	0	2 (3.3%)
	NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
	AGITATION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	HYPERKINESIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.6%)
	ANXIETY	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.6%)
	INSOMNIA	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	4 (16.0%)	5 (13.9%)	9 (14.8%)
	DRY MOUTH	2 (8.0%)	0	2 (3.3%)
	DYSPEPSIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	NAUSEA	0	2 (5.6%)	2 (3.3%)
	CONSTIPATION	1 (4.0%)	0	1 (1.6%)
	INCREASED APPETITE	1 (4.0%)	0	1 (1.6%)
	DECREASED APPETITE	0	1 (2.8%)	1 (1.6%)
	VOMITING	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	4 (16.0%)	2 (5.6%)	6 (9.8%)
	WEIGHT GAIN	4 (16.0%)	2 (5.6%)	6 (9.8%)
Body as a Whole	TOTAL	3 (12.0%)	2 (5.6%)	5 (8.2%)
	ABDOMINAL PAIN	2 (8.0%)	1 (2.8%)	3 (4.9%)
	HEADACHE	1 (4.0%)	0	1 (1.6%)
	ASTHENIA	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	LEUKOPENIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
Urogenital System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	URINARY INCONTINENCE	1 (4.0%)	2 (5.6%)	3 (4.9%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.6%)
	SYNCOPE	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
Respiratory System	YAWN	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	0	1 (2.8%)	1 (1.6%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	14 (58.3%)	19 (55.9%)	33 (56.9%)
Body as a Whole	TOTAL	9 (37.5%)	5 (14.7%)	14 (24.1%)
	HEADACHE	7 (29.2%)	4 (11.8%)	11 (19.0%)
	FEVER	1 (4.2%)	0	1 (1.7%)
	PAIN	1 (4.2%)	0	1 (1.7%)
	TRAUMA	1 (4.2%)	0	1 (1.7%)
	ABDOMINAL PAIN	0	1 (2.9%)	1 (1.7%)
Nervous System	TOTAL	7 (29.2%)	15 (44.1%)	22 (37.9%)
	NERVOUSNESS	1 (4.2%)	9 (26.5%)	10 (17.2%)
	HYPERKINESIA	5 (20.8%)	4 (11.8%)	9 (15.5%)
	INSOMNIA	2 (8.3%)	2 (5.9%)	4 (6.9%)
	ANXIETY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	HOSTILITY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	SOMNOLENCE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	DIZZINESS	1 (4.2%)	0	1 (1.7%)
	MYOCLONUS	1 (4.2%)	0	1 (1.7%)
	NEUROSIS	1 (4.2%)	0	1 (1.7%)
	AGITATION	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
Digestive System	TOTAL	6 (25.0%)	2 (5.9%)	8 (13.8%)
	DECREASED APPETITE	2 (8.3%)	2 (5.9%)	4 (6.9%)
	NAUSEA	3 (12.5%)	0	3 (5.2%)
	DYSPEPSIA	2 (8.3%)	0	2 (3.4%)
	DIARRHEA	1 (4.2%)	0	1 (1.7%)
Cardiovascular System	TOTAL	0	3 (8.8%)	3 (5.2%)
	VASODILATATION	0	3 (8.8%)	3 (5.2%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)
Urogenital System	TOTAL	0	1 (2.9%)	1 (1.7%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.7%)

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	28 (57.1%)	34 (48.6%)	62 (52.1%)
Nervous System	TOTAL	13 (26.5%)	20 (28.6%)	33 (27.7%)
	NERVOUSNESS	3 (6.1%)	9 (12.9%)	12 (10.1%)
	HYPERKINESIA	6 (12.2%)	5 (7.1%)	11 (9.2%)
	HOSTILITY	3 (6.1%)	2 (2.9%)	5 (4.2%)
	INSOMNIA	2 (4.1%)	3 (4.3%)	5 (4.2%)
	ANXIETY	1 (2.0%)	3 (4.3%)	4 (3.4%)
	AGITATION	1 (2.0%)	2 (2.9%)	3 (2.5%)
	SOMNOLENCE	1 (2.0%)	2 (2.9%)	3 (2.5%)
	DIZZINESS	1 (2.0%)	1 (1.4%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	DEPRESSION	1 (2.0%)	0	1 (0.8%)
	MYOCLONUS	1 (2.0%)	0	1 (0.8%)
	NEUROSIS	1 (2.0%)	0	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
Body as a Whole	TOTAL	12 (24.5%)	7 (10.0%)	19 (16.0%)
	HEADACHE	8 (16.3%)	4 (5.7%)	12 (10.1%)
	ABDOMINAL PAIN	2 (4.1%)	2 (2.9%)	4 (3.4%)
	FEVER	1 (2.0%)	0	1 (0.8%)
	PAIN	1 (2.0%)	0	1 (0.8%)
	TRAUMA	1 (2.0%)	0	1 (0.8%)
	ASTHENIA	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	10 (20.4%)	7 (10.0%)	17 (14.3%)
	NAUSEA	3 (6.1%)	2 (2.9%)	5 (4.2%)
	DECREASED APPETITE	2 (4.1%)	3 (4.3%)	5 (4.2%)
	DYSPEPSIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
	DRY MOUTH	2 (4.1%)	0	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.8%)
	DIARRHEA	1 (2.0%)	0	1 (0.8%)
	INCREASED APPETITE	1 (2.0%)	0	1 (0.8%)
	VOMITING	0	1 (1.4%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (8.2%)	3 (4.3%)	7 (5.9%)
	WEIGHT GAIN	4 (8.2%)	3 (4.3%)	7 (5.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Hemic and Lymphatic System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	LEUKOPENIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
Urogenital System	TOTAL	1 (2.0%)	3 (4.3%)	4 (3.4%)
	URINARY INCONTINENCE	1 (2.0%)	3 (4.3%)	4 (3.4%)
Cardiovascular System	TOTAL	0	4 (5.7%)	4 (3.4%)
	VASODILATATION	0	3 (4.3%)	3 (2.5%)
	SYNCOPE	0	1 (1.4%)	1 (0.8%)
Respiratory System	TOTAL	0	1 (1.4%)	1 (0.8%)
	YAWN	0	1 (1.4%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.8%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	11 (44.0%)	14 (46.7%)	25 (45.5%)
Nervous System	TOTAL	5 (20.0%)	8 (26.7%)	13 (23.6%)
	SOMNOLENCE	2 (8.0%)	3 (10.0%)	5 (9.1%)
	NERVOUSNESS	2 (8.0%)	1 (3.3%)	3 (5.5%)
	EMOTIONAL LABILITY	1 (4.0%)	2 (6.7%)	3 (5.5%)
	INSOMNIA	1 (4.0%)	2 (6.7%)	3 (5.5%)
	HOSTILITY	1 (4.0%)	1 (3.3%)	2 (3.6%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (3.6%)
	AGITATION	0	1 (3.3%)	1 (1.8%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.8%)
	DIZZINESS	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	4 (16.0%)	4 (13.3%)	8 (14.5%)
	NAUSEA	4 (16.0%)	0	4 (7.3%)
	VOMITING	2 (8.0%)	0	2 (3.6%)
	DECREASED APPETITE	0	2 (6.7%)	2 (3.6%)
	DIARRHEA	0	1 (3.3%)	1 (1.8%)
	INCREASED APPETITE	0	1 (3.3%)	1 (1.8%)
Hemic and Lymphatic System	TOTAL	2 (8.0%)	0	2 (3.6%)
	LEUKOPENIA	2 (8.0%)	0	2 (3.6%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.0%)	3 (10.0%)	5 (9.1%)
	WEIGHT GAIN	2 (8.0%)	3 (10.0%)	5 (9.1%)
Body as a Whole	TOTAL	1 (4.0%)	5 (16.7%)	6 (10.9%)
	HEADACHE	1 (4.0%)	3 (10.0%)	4 (7.3%)
	ASTHENIA	0	2 (6.7%)	2 (3.6%)
	ABDOMINAL PAIN	0	1 (3.3%)	1 (1.8%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.8%)
	MYALGIA	0	1 (3.3%)	1 (1.8%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.8%)
	ACNE	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (4.2%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	9 (45.0%)	13 (48.1%)	22 (46.8%)
Body as a Whole	TOTAL	5 (25.0%)	7 (25.9%)	12 (25.5%)
	HEADACHE	3 (15.0%)	4 (14.8%)	7 (14.9%)
	ASTHENIA	2 (10.0%)	2 (7.4%)	4 (8.5%)
	ABDOMINAL PAIN	0	2 (7.4%)	2 (4.3%)
Nervous System	TOTAL	5 (25.0%)	7 (25.9%)	12 (25.5%)
	NEUROSIS	3 (15.0%)	0	3 (6.4%)
	HOSTILITY	1 (5.0%)	2 (7.4%)	3 (6.4%)
	INSOMNIA	1 (5.0%)	2 (7.4%)	3 (6.4%)
	DIZZINESS	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	AGITATION	0	2 (7.4%)	2 (4.3%)
	NERVOUSNESS	0	2 (7.4%)	2 (4.3%)
	EMOTIONAL LABILITY	1 (5.0%)	0	1 (2.1%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	TREMOR	0	1 (3.7%)	1 (2.1%)
Cardiovascular System	TOTAL	1 (5.0%)	0	1 (2.1%)
	BRADYCARDIA	1 (5.0%)	0	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.1%)
	WEIGHT LOSS	0	1 (3.7%)	1 (2.1%)
Skin and Appendages	TOTAL	1 (5.0%)	1 (3.7%)	2 (4.3%)
	ACNE	1 (5.0%)	0	1 (2.1%)
	SWEATING	0	1 (3.7%)	1 (2.1%)
Digestive System	TOTAL	0	8 (29.6%)	8 (17.0%)
	NAUSEA	0	3 (11.1%)	3 (6.4%)
	DECREASED APPETITE	0	2 (7.4%)	2 (4.3%)
	DRY MOUTH	0	2 (7.4%)	2 (4.3%)
	DYSPEPSIA	0	2 (7.4%)	2 (4.3%)
	CONSTIPATION	0	1 (3.7%)	1 (2.1%)
	FLATULENCE	0	1 (3.7%)	1 (2.1%)
Respiratory System	TOTAL	0	2 (7.4%)	2 (4.3%)
	RESPIRATORY DISORDER	0	2 (7.4%)	2 (4.3%)

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	TOTAL	20 (44.4%)	27 (47.4%)	47 (46.1%)
Nervous System	TOTAL	10 (22.2%)	15 (26.3%)	25 (24.5%)
	INSOMNIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	HOSTILITY	2 (4.4%)	3 (5.3%)	5 (4.9%)
	NERVOUSNESS	2 (4.4%)	3 (5.3%)	5 (4.9%)
	SOMNOLENCE	2 (4.4%)	3 (5.3%)	5 (4.9%)
	EMOTIONAL LABILITY	2 (4.4%)	2 (3.5%)	4 (3.9%)
	NEUROSIS	3 (6.7%)	0	3 (2.9%)
	DIZZINESS	1 (2.2%)	2 (3.5%)	3 (2.9%)
	AGITATION	0	3 (5.3%)	3 (2.9%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	WITHDRAWAL SYNDROME	0	2 (3.5%)	2 (2.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	CONCENTRATION IMPAIRED	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
	TREMOR	0	1 (1.8%)	1 (1.0%)
Body as a Whole	TOTAL	6 (13.3%)	12 (21.1%)	18 (17.6%)
	HEADACHE	4 (8.9%)	7 (12.3%)	11 (10.8%)
	ASTHENIA	2 (4.4%)	4 (7.0%)	6 (5.9%)
	ABDOMINAL PAIN	0	3 (5.3%)	3 (2.9%)
Digestive System	TOTAL	4 (8.9%)	12 (21.1%)	16 (15.7%)
	NAUSEA	4 (8.9%)	3 (5.3%)	7 (6.9%)
	DECREASED APPETITE	0	4 (7.0%)	4 (3.9%)
	VOMITING	2 (4.4%)	0	2 (2.0%)
	DRY MOUTH	0	2 (3.5%)	2 (2.0%)
	DYSPEPSIA	0	2 (3.5%)	2 (2.0%)
	CONSTIPATION	0	1 (1.8%)	1 (1.0%)
	DIARRHEA	0	1 (1.8%)	1 (1.0%)
	FLATULENCE	0	1 (1.8%)	1 (1.0%)
	INCREASED APPETITE	0	1 (1.8%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	3 (6.7%)	4 (7.0%)	7 (6.9%)
	WEIGHT GAIN	3 (6.7%)	3 (5.3%)	6 (5.9%)
	WEIGHT LOSS	0	1 (1.8%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	2 (4.4%)	0	2 (2.0%)
	LEUKOPENIA	2 (4.4%)	0	2 (2.0%)
Cardiovascular System	TOTAL	1 (2.2%)	0	1 (1.0%)
	BRADYCARDIA	1 (2.2%)	0	1 (1.0%)

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Skin and Appendages	TOTAL	1 (2.2%)	2 (3.5%)	3 (2.9%)
	ACNE	1 (2.2%)	1 (1.8%)	2 (2.0%)
	SWEATING	0	1 (1.8%)	1 (1.0%)
Musculoskeletal System	TOTAL	0	1 (1.8%)	1 (1.0%)
	MYALGIA	0	1 (1.8%)	1 (1.0%)
Respiratory System	TOTAL	0	2 (3.5%)	2 (2.0%)
	RESPIRATORY DISORDER	0	2 (3.5%)	2 (2.0%)

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.4%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.4%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)

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Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	25 (50.0%)	29 (43.9%)	54 (46.6%)
Nervous System	TOTAL	11 (22.0%)	13 (19.7%)	24 (20.7%)
	SOMNOLENCE	2 (4.0%)	4 (6.1%)	6 (5.2%)
	NERVOUSNESS	4 (8.0%)	1 (1.5%)	5 (4.3%)
	HOSTILITY	3 (6.0%)	1 (1.5%)	4 (3.4%)
	INSOMNIA	1 (2.0%)	3 (4.5%)	4 (3.4%)
	AGITATION	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EMOTIONAL LABILITY	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HYPERKINESIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	DIZZINESS	0	2 (3.0%)	2 (1.7%)
	WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	DEPRESSION	1 (2.0%)	0	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.9%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	8 (16.0%)	9 (13.6%)	17 (14.7%)
	NAUSEA	4 (8.0%)	2 (3.0%)	6 (5.2%)
	VOMITING	2 (4.0%)	1 (1.5%)	3 (2.6%)
	DECREASED APPETITE	0	3 (4.5%)	3 (2.6%)
	DRY MOUTH	2 (4.0%)	0	2 (1.7%)
	DYSPEPSIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	INCREASED APPETITE	1 (2.0%)	1 (1.5%)	2 (1.7%)
	CONSTIPATION	1 (2.0%)	0	1 (0.9%)
	DIARRHEA	0	1 (1.5%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	6 (12.0%)	5 (7.6%)	11 (9.5%)
	WEIGHT GAIN	6 (12.0%)	5 (7.6%)	11 (9.5%)
Body as a Whole	TOTAL	4 (8.0%)	7 (10.6%)	11 (9.5%)
	HEADACHE	2 (4.0%)	3 (4.5%)	5 (4.3%)
	ABDOMINAL PAIN	2 (4.0%)	2 (3.0%)	4 (3.4%)
	ASTHENIA	0	3 (4.5%)	3 (2.6%)
Hemic and Lymphatic System	TOTAL	3 (6.0%)	1 (1.5%)	4 (3.4%)
	LEUKOPENIA	3 (6.0%)	1 (1.5%)	4 (3.4%)
Urogenital System	TOTAL	1 (2.0%)	2 (3.0%)	3 (2.6%)
	URINARY INCONTINENCE	1 (2.0%)	2 (3.0%)	3 (2.6%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.9%)
	SYNCOPE	0	1 (1.5%)	1 (0.9%)
Musculoskeletal System	TOTAL	0	1 (1.5%)	1 (0.9%)
	MYALGIA	0	1 (1.5%)	1 (0.9%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.9%)
	YAWN	0	1 (1.5%)	1 (0.9%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.9%)
	ACNE	0	1 (1.5%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.9%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
TOTAL	TOTAL	0	1 (3.4%)	1 (1.9%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.9%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	23 (52.3%)	32 (52.5%)	55 (52.4%)
Body as a Whole	TOTAL	14 (31.8%)	12 (19.7%)	26 (24.8%)
	HEADACHE	10 (22.7%)	8 (13.1%)	18 (17.1%)
	ASTHENIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	ABDOMINAL PAIN	0	3 (4.9%)	3 (2.9%)
	FEVER	1 (2.3%)	0	1 (1.0%)
	PAIN	1 (2.3%)	0	1 (1.0%)
	TRAUMA	1 (2.3%)	0	1 (1.0%)
Nervous System	TOTAL	12 (27.3%)	22 (36.1%)	34 (32.4%)
	NERVOUSNESS	1 (2.3%)	11 (18.0%)	12 (11.4%)
	HYPERKINESIA	6 (13.6%)	5 (8.2%)	11 (10.5%)
	INSOMNIA	3 (6.8%)	4 (6.6%)	7 (6.7%)
	HOSTILITY	2 (4.5%)	4 (6.6%)	6 (5.7%)
	NEUROSIS	4 (9.1%)	0	4 (3.8%)
	DIZZINESS	2 (4.5%)	1 (1.6%)	3 (2.9%)
	ANXIETY	1 (2.3%)	2 (3.3%)	3 (2.9%)
	AGITATION	0	3 (4.9%)	3 (2.9%)
	MANIC REACTION	1 (2.3%)	1 (1.6%)	2 (1.9%)
	SOMNOLENCE	1 (2.3%)	1 (1.6%)	2 (1.9%)
	TREMOR	0	2 (3.3%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	EMOTIONAL LABILITY	1 (2.3%)	0	1 (1.0%)
	MYOCLONUS	1 (2.3%)	0	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	6 (13.6%)	10 (16.4%)	16 (15.2%)
	NAUSEA	3 (6.8%)	3 (4.9%)	6 (5.7%)
	DECREASED APPETITE	2 (4.5%)	4 (6.6%)	6 (5.7%)
	DYSPEPSIA	2 (4.5%)	2 (3.3%)	4 (3.8%)
	DRY MOUTH	0	2 (3.3%)	2 (1.9%)
	DIARRHEA	1 (2.3%)	0	1 (1.0%)
	CONSTIPATION	0	1 (1.6%)	1 (1.0%)
	FLATULENCE	0	1 (1.6%)	1 (1.0%)
Cardiovascular System	TOTAL	1 (2.3%)	3 (4.9%)	4 (3.8%)
	VASODILATATION	0	3 (4.9%)	3 (2.9%)
	BRADYCARDIA	1 (2.3%)	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.3%)	2 (3.3%)	3 (2.9%)
	WEIGHT GAIN	1 (2.3%)	1 (1.6%)	2 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Metabolic and Nutritional Disorders	WEIGHT LOSS	0	1 (1.6%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ACNE	1 (2.3%)	0	1 (1.0%)
	SWEATING	0	1 (1.6%)	1 (1.0%)
Respiratory System	TOTAL	0	2 (3.3%)	2 (1.9%)
	RESPIRATORY DISORDER	0	2 (3.3%)	2 (1.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	48 (51.1%)	61 (48.0%)	109 (49.3%)
Nervous System	TOTAL	23 (24.5%)	35 (27.6%)	58 (26.2%)
	NERVOUSNESS	5 (5.3%)	12 (9.4%)	17 (7.7%)
	HYPERKINESIA	7 (7.4%)	6 (4.7%)	13 (5.9%)
	INSOMNIA	4 (4.3%)	7 (5.5%)	11 (5.0%)
	HOSTILITY	5 (5.3%)	5 (3.9%)	10 (4.5%)
	SOMNOLENCE	3 (3.2%)	5 (3.9%)	8 (3.6%)
	AGITATION	1 (1.1%)	5 (3.9%)	6 (2.7%)
	DIZZINESS	2 (2.1%)	3 (2.4%)	5 (2.3%)
	NEUROSIS	4 (4.3%)	0	4 (1.8%)
	EMOTIONAL LABILITY	2 (2.1%)	2 (1.6%)	4 (1.8%)
	ANXIETY	1 (1.1%)	3 (2.4%)	4 (1.8%)
	TREMOR	0	3 (2.4%)	3 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.1%)	1 (0.8%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	WITHDRAWAL SYNDROME	0	2 (1.6%)	2 (0.9%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	DEPRESSION	1 (1.1%)	0	1 (0.5%)
	MYOCLONUS	1 (1.1%)	0	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.5%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
Body as a Whole	TOTAL	18 (19.1%)	19 (15.0%)	37 (16.7%)
	HEADACHE	12 (12.8%)	11 (8.7%)	23 (10.4%)
	ABDOMINAL PAIN	2 (2.1%)	5 (3.9%)	7 (3.2%)
	ASTHENIA	2 (2.1%)	5 (3.9%)	7 (3.2%)
	FEVER	1 (1.1%)	0	1 (0.5%)
	PAIN	1 (1.1%)	0	1 (0.5%)
	TRAUMA	1 (1.1%)	0	1 (0.5%)
Digestive System	TOTAL	14 (14.9%)	19 (15.0%)	33 (14.9%)
	NAUSEA	7 (7.4%)	5 (3.9%)	12 (5.4%)
	DECREASED APPETITE	2 (2.1%)	7 (5.5%)	9 (4.1%)
	DYSPEPSIA	3 (3.2%)	3 (2.4%)	6 (2.7%)
	DRY MOUTH	2 (2.1%)	2 (1.6%)	4 (1.8%)
	VOMITING	2 (2.1%)	1 (0.8%)	3 (1.4%)
	CONSTIPATION	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DIARRHEA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	INCREASED APPETITE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	FLATULENCE	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Metabolic and Nutritional Disorders	TOTAL	7 (7.4%)	7 (5.5%)	14 (6.3%)
	WEIGHT GAIN	7 (7.4%)	6 (4.7%)	13 (5.9%)
	WEIGHT LOSS	0	1 (0.8%)	1 (0.5%)
Hemic and Lymphatic System	TOTAL	3 (3.2%)	1 (0.8%)	4 (1.8%)
	LEUKOPENIA	3 (3.2%)	1 (0.8%)	4 (1.8%)
Cardiovascular System	TOTAL	1 (1.1%)	4 (3.1%)	5 (2.3%)
	VASODILATATION	0	3 (2.4%)	3 (1.4%)
	BRADYCARDIA	1 (1.1%)	0	1 (0.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.5%)
Skin and Appendages	TOTAL	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ACNE	1 (1.1%)	1 (0.8%)	2 (0.9%)
	SWEATING	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	3 (2.4%)	4 (1.8%)
	URINARY INCONTINENCE	1 (1.1%)	3 (2.4%)	4 (1.8%)
Musculoskeletal System	TOTAL	0	1 (0.8%)	1 (0.5%)
	MYALGIA	0	1 (0.8%)	1 (0.5%)
Respiratory System	TOTAL	0	3 (2.4%)	3 (1.4%)
	RESPIRATORY DISORDER	0	2 (1.6%)	2 (0.9%)
	YAWN	0	1 (0.8%)	1 (0.5%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.5%)
	ABNORMAL VISION	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (1.1%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (1.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=34)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	3 (9.1%)	2 (5.9%)	5 (7.5%)
Nervous System	TOTAL	2 (6.1%)	0	2 (3.0%)
	ANXIETY	1 (3.0%)	0	1 (1.5%)
	INSOMNIA	1 (3.0%)	0	1 (1.5%)
	NERVOUSNESS	1 (3.0%)	0	1 (1.5%)
	WITHDRAWAL SYNDROME	1 (3.0%)	0	1 (1.5%)
Body as a Whole	TOTAL	1 (3.0%)	0	1 (1.5%)
	HEADACHE	1 (3.0%)	0	1 (1.5%)
Digestive System	TOTAL	1 (3.0%)	0	1 (1.5%)
	INCREASED APPETITE	1 (3.0%)	0	1 (1.5%)
Musculoskeletal System	TOTAL	1 (3.0%)	0	1 (1.5%)
	MYALGIA	1 (3.0%)	0	1 (1.5%)
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.5%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.5%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.5%)

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=18)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=16)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=25)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	2 (16.7%)	2 (8.0%)	4 (10.8%)
Nervous System	TOTAL	1 (8.3%)	0	1 (2.7%)
	PARESTHESIA	1 (8.3%)	0	1 (2.7%)
	THINKING ABNORMAL	1 (8.3%)	0	1 (2.7%)
Respiratory System	TOTAL	1 (8.3%)	0	1 (2.7%)
	RESPIRATORY DISORDER	1 (8.3%)	0	1 (2.7%)
Body as a Whole	TOTAL	0	1 (4.0%)	1 (2.7%)
	HEADACHE	0	1 (4.0%)	1 (2.7%)
Digestive System	TOTAL	0	1 (4.0%)	1 (2.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (4.0%)	1 (2.7%)

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=18)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=59)	Total (N=104)
Body System	Preferred Term			
TOTAL	TOTAL	5 (11.1%)	4 (6.8%)	9 (8.7%)
Nervous System	TOTAL	3 (6.7%)	0	3 (2.9%)
	ANXIETY	1 (2.2%)	0	1 (1.0%)
	INSOMNIA	1 (2.2%)	0	1 (1.0%)
	NERVOUSNESS	1 (2.2%)	0	1 (1.0%)
	PARESTHESIA	1 (2.2%)	0	1 (1.0%)
	THINKING ABNORMAL	1 (2.2%)	0	1 (1.0%)
	WITHDRAWAL SYNDROME	1 (2.2%)	0	1 (1.0%)
Body as a Whole	TOTAL	1 (2.2%)	1 (1.7%)	2 (1.9%)
	HEADACHE	1 (2.2%)	1 (1.7%)	2 (1.9%)
Digestive System	TOTAL	1 (2.2%)	1 (1.7%)	2 (1.9%)
	INCREASED APPETITE	1 (2.2%)	0	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (1.0%)
Musculoskeletal System	TOTAL	1 (2.2%)	0	1 (1.0%)
	MYALGIA	1 (2.2%)	0	1 (1.0%)
Respiratory System	TOTAL	1 (2.2%)	0	1 (1.0%)
	RESPIRATORY DISORDER	1 (2.2%)	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.7%)	1 (1.0%)
	LYMPHOCYTOSIS	0	1 (1.7%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.7%)	1 (1.0%)
	SGOT INCREASED	0	1 (1.7%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=23)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	4 (16.0%)	4 (11.1%)	8 (13.1%)
Nervous System	TOTAL	3 (12.0%)	3 (8.3%)	6 (9.8%)
	HOSTILITY	1 (4.0%)	1 (2.8%)	2 (3.3%)
	CONVULSION	1 (4.0%)	0	1 (1.6%)
	DEPRESSION	1 (4.0%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
	AGITATION	0	1 (2.8%)	1 (1.6%)
	HALLUCINATIONS	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	1 (4.0%)	0	1 (1.6%)
	VOMITING	1 (4.0%)	0	1 (1.6%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.6%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	1 (4.2%)	6 (17.6%)	7 (12.1%)
Nervous System	TOTAL	1 (4.2%)	6 (17.6%)	7 (12.1%)
	HYPERKINESIA	1 (4.2%)	3 (8.8%)	4 (6.9%)
	HOSTILITY	1 (4.2%)	2 (5.9%)	3 (5.2%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
	MANIC REACTION	0	1 (2.9%)	1 (1.7%)
	NERVOUSNESS	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	5 (10.2%)	10 (14.3%)	15 (12.6%)
Nervous System	TOTAL	4 (8.2%)	9 (12.9%)	13 (10.9%)
	HOSTILITY	2 (4.1%)	3 (4.3%)	5 (4.2%)
	HYPERKINESIA	1 (2.0%)	3 (4.3%)	4 (3.4%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
	CONVULSION	1 (2.0%)	0	1 (0.8%)
	DEPRESSION	1 (2.0%)	0	1 (0.8%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
	AGITATION	0	1 (1.4%)	1 (0.8%)
	HALLUCINATIONS	0	1 (1.4%)	1 (0.8%)
	MANIC REACTION	0	1 (1.4%)	1 (0.8%)
	NERVOUSNESS	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	1 (2.0%)	0	1 (0.8%)
	VOMITING	1 (2.0%)	0	1 (0.8%)
Cardiovascular System	TOTAL	0	1 (1.4%)	1 (0.8%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	2 (8.0%)	4 (13.3%)	6 (10.9%)
Digestive System	TOTAL	1 (4.0%)	0	1 (1.8%)
	NAUSEA	1 (4.0%)	0	1 (1.8%)
Nervous System	TOTAL	1 (4.0%)	4 (13.3%)	5 (9.1%)
	EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.8%)
	ANXIETY	0	1 (3.3%)	1 (1.8%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
	HOSTILITY	0	1 (3.3%)	1 (1.8%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (4.2%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (4.2%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (4.2%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	1 (5.0%)	5 (18.5%)	6 (12.8%)
Nervous System	TOTAL	1 (5.0%)	4 (14.8%)	5 (10.6%)
	EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HOSTILITY	0	2 (7.4%)	2 (4.3%)
	NERVOUSNESS	0	2 (7.4%)	2 (4.3%)
	AGITATION	0	1 (3.7%)	1 (2.1%)
	ANXIETY	0	1 (3.7%)	1 (2.1%)
Body as a Whole	TOTAL	0	1 (3.7%)	1 (2.1%)
	ASTHENIA	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.7%)	9 (15.8%)	12 (11.8%)
Nervous System	TOTAL	2 (4.4%)	8 (14.0%)	10 (9.8%)
	EMOTIONAL LABILITY	2 (4.4%)	1 (1.8%)	3 (2.9%)
	HOSTILITY	0	3 (5.3%)	3 (2.9%)
	ANXIETY	0	2 (3.5%)	2 (2.0%)
	NERVOUSNESS	0	2 (3.5%)	2 (2.0%)
	AGITATION	0	1 (1.8%)	1 (1.0%)
	HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)
	LIBIDO DECREASED	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	1 (2.2%)	0	1 (1.0%)
	NAUSEA	1 (2.2%)	0	1 (1.0%)
Body as a Whole	TOTAL	0	1 (1.8%)	1 (1.0%)
	ASTHENIA	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.4%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.4%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.4%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	6 (12.0%)	8 (12.1%)	14 (12.1%)
Nervous System	TOTAL	4 (8.0%)	7 (10.6%)	11 (9.5%)
	HOSTILITY	1 (2.0%)	2 (3.0%)	3 (2.6%)
	EMOTIONAL LABILITY	2 (4.0%)	0	2 (1.7%)
	HALLUCINATIONS	0	2 (3.0%)	2 (1.7%)
	CONVULSION	1 (2.0%)	0	1 (0.9%)
	DEPRESSION	1 (2.0%)	0	1 (0.9%)
	AGITATION	0	1 (1.5%)	1 (0.9%)
	ANXIETY	0	1 (1.5%)	1 (0.9%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	2 (4.0%)	0	2 (1.7%)
	NAUSEA	1 (2.0%)	0	1 (0.9%)
	VOMITING	1 (2.0%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.9%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.4%)	1 (1.9%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.9%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.9%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	2 (4.5%)	11 (18.0%)	13 (12.4%)
Nervous System	TOTAL	2 (4.5%)	10 (16.4%)	12 (11.4%)
	HOSTILITY	1 (2.3%)	4 (6.6%)	5 (4.8%)
	HYPERKINESIA	1 (2.3%)	3 (4.9%)	4 (3.8%)
	NERVOUSNESS	0	3 (4.9%)	3 (2.9%)
	EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
	AGITATION	0	1 (1.6%)	1 (1.0%)
	ANXIETY	0	1 (1.6%)	1 (1.0%)
	MANIC REACTION	0	1 (1.6%)	1 (1.0%)
Body as a Whole	TOTAL	0	1 (1.6%)	1 (1.0%)
	ASTHENIA	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	8 (8.5%)	19 (15.0%)	27 (12.2%)
Nervous System	TOTAL	6 (6.4%)	17 (13.4%)	23 (10.4%)
	HOSTILITY	2 (2.1%)	6 (4.7%)	8 (3.6%)
	EMOTIONAL LABILITY	3 (3.2%)	1 (0.8%)	4 (1.8%)
	HYPERKINESIA	1 (1.1%)	3 (2.4%)	4 (1.8%)
	NERVOUSNESS	0	3 (2.4%)	3 (1.4%)
	AGITATION	0	2 (1.6%)	2 (0.9%)
	ANXIETY	0	2 (1.6%)	2 (0.9%)
	HALLUCINATIONS	0	2 (1.6%)	2 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.1%)	0	1 (0.5%)
	CONVULSION	1 (1.1%)	0	1 (0.5%)
	DEPRESSION	1 (1.1%)	0	1 (0.5%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.5%)
	MANIC REACTION	0	1 (0.8%)	1 (0.5%)
Digestive System	TOTAL	2 (2.1%)	0	2 (0.9%)
	NAUSEA	1 (1.1%)	0	1 (0.5%)
	VOMITING	1 (1.1%)	0	1 (0.5%)
Body as a Whole	TOTAL	0	1 (0.8%)	1 (0.5%)
	ASTHENIA	0	1 (0.8%)	1 (0.5%)
Cardiovascular System	TOTAL	0	1 (0.8%)	1 (0.5%)
	ELECTROCARDIOGRAM ABNORMAL	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (1.1%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (1.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (1.1%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=25)	 Placebo (N=36)	 Total (N=61)
TOTAL	4 (16.0%)	3 (8.3%)	7 (11.5%)
HOSTILITY	1 (4.0%)	1 (2.8%)	2 (3.3%)
CONVULSION	1 (4.0%)	0	1 (1.6%)
DEPRESSION	1 (4.0%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.6%)
VOMITING	1 (4.0%)	0	1 (1.6%)
AGITATION	0	1 (2.8%)	1 (1.6%)
HALLUCINATIONS	0	1 (2.8%)	1 (1.6%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=24)	 Placebo (N=34)	 Total (N=58)
TOTAL	1 (4.2%)	6 (17.6%)	7 (12.1%)
HYPERKINESIA	1 (4.2%)	3 (8.8%)	4 (6.9%)
HOSTILITY	1 (4.2%)	2 (5.9%)	3 (5.2%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.7%)
NERVOUSNESS	0	1 (2.9%)	1 (1.7%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Preferred Term			
TOTAL	5 (10.2%)	9 (12.9%)	14 (11.8%)
HOSTILITY	2 (4.1%)	3 (4.3%)	5 (4.2%)
HYPERKINESIA	1 (2.0%)	3 (4.3%)	4 (3.4%)
CONCENTRATION IMPAIRED	1 (2.0%)	0	1 (0.8%)
CONVULSION	1 (2.0%)	0	1 (0.8%)
DEPRESSION	1 (2.0%)	0	1 (0.8%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (0.8%)
VOMITING	1 (2.0%)	0	1 (0.8%)
AGITATION	0	1 (1.4%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.4%)	1 (0.8%)
NERVOUSNESS	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Preferred Term			
TOTAL	2 (8.0%)	3 (10.0%)	5 (9.1%)
EMOTIONAL LABILITY	1 (4.0%)	0	1 (1.8%)
NAUSEA	1 (4.0%)	0	1 (1.8%)
ANXIETY	0	1 (3.3%)	1 (1.8%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.8%)
HOSTILITY	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Preferred Term			
TOTAL	1 (5.0%)	4 (14.8%)	5 (10.6%)
EMOTIONAL LABILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
HOSTILITY	0	2 (7.4%)	2 (4.3%)
NERVOUSNESS	0	2 (7.4%)	2 (4.3%)
AGITATION	0	1 (3.7%)	1 (2.1%)
ANXIETY	0	1 (3.7%)	1 (2.1%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
TOTAL	3 (6.7%)	7 (12.3%)	10 (9.8%)
EMOTIONAL LABILITY	2 (4.4%)	1 (1.8%)	3 (2.9%)
HOSTILITY	0	3 (5.3%)	3 (2.9%)
ANXIETY	0	2 (3.5%)	2 (2.0%)
NERVOUSNESS	0	2 (3.5%)	2 (2.0%)
NAUSEA	1 (2.2%)	0	1 (1.0%)
AGITATION	0	1 (1.8%)	1 (1.0%)
HALLUCINATIONS	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=50)	 Placebo (N=66)	 Total (N=116)
TOTAL	6 (12.0%)	6 (9.1%)	12 (10.3%)
HOSTILITY	1 (2.0%)	2 (3.0%)	3 (2.6%)
EMOTIONAL LABILITY	2 (4.0%)	0	2 (1.7%)
HALLUCINATIONS	0	2 (3.0%)	2 (1.7%)
CONVULSION	1 (2.0%)	0	1 (0.9%)
DEPRESSION	1 (2.0%)	0	1 (0.9%)
NAUSEA	1 (2.0%)	0	1 (0.9%)
VOMITING	1 (2.0%)	0	1 (0.9%)
AGITATION	0	1 (1.5%)	1 (0.9%)
ANXIETY	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Preferred Term			
TOTAL	2 (4.5%)	10 (16.4%)	12 (11.4%)
HOSTILITY	1 (2.3%)	4 (6.6%)	5 (4.8%)
HYPERKINESIA	1 (2.3%)	3 (4.9%)	4 (3.8%)
NERVOUSNESS	0	3 (4.9%)	3 (2.9%)
EMOTIONAL LABILITY	1 (2.3%)	1 (1.6%)	2 (1.9%)
CONCENTRATION IMPAIRED	1 (2.3%)	0	1 (1.0%)
AGITATION	0	1 (1.6%)	1 (1.0%)
ANXIETY	0	1 (1.6%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=94)	 Placebo (N=127)	 Total (N=221)
TOTAL	8 (8.5%)	16 (12.6%)	24 (10.9%)
HOSTILITY	2 (2.1%)	6 (4.7%)	8 (3.6%)
EMOTIONAL LABILITY	3 (3.2%)	1 (0.8%)	4 (1.8%)
HYPERKINESIA	1 (1.1%)	3 (2.4%)	4 (1.8%)
NERVOUSNESS	0	3 (2.4%)	3 (1.4%)
AGITATION	0	2 (1.6%)	2 (0.9%)
ANXIETY	0	2 (1.6%)	2 (0.9%)
HALLUCINATIONS	0	2 (1.6%)	2 (0.9%)
CONCENTRATION IMPAIRED	1 (1.1%)	0	1 (0.5%)
CONVULSION	1 (1.1%)	0	1 (0.5%)
DEPRESSION	1 (1.1%)	0	1 (0.5%)
NAUSEA	1 (1.1%)	0	1 (0.5%)
VOMITING	1 (1.1%)	0	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=25)	RESPIRATORY DISORDER	2	8.0	0	0.0	1	4.0	0	0.0	1	4.0	0	0.0	0	0.0	1	4.0	1	4.0	2	8.0	0	0.0	0	0.0	8	32.0
	HEADACHE	3	12.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	20.0
	ABDOMINAL PAIN	0	0.0	1	4.0	2	8.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	16.0
	FEVER	0	0.0	0	0.0	1	4.0	1	4.0	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	16.0
	INFECTION	0	0.0	0	0.0	0	0.0	2	8.0	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	16.0
	PHARYNGITIS	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	4	16.0
	TRAUMA	0	0.0	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	4	16.0
	VOMITING	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	0	0.0	4	16.0
	WEIGHT GAIN	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	0	0.0	0	0.0	1	4.0	0	0.0	4	16.0
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	3	12.0
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	3	12.0
	NERVOUSNESS	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	12.0
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0	0	0.0	0	0.0	2	8.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	2	8.0
	DIARRHEA	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=25)	DRY MOUTH	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	2	8.0
	SINUSITIS	1	4.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	1	4.0
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0
	CONSTIPATION	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	CONVULSION	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0
	FACE EDEMA	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	HALLUCINATIONS	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	INCREASED APPETITE	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	NAUSEA	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0

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BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=25)	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	1	4.0
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	INFECTION	0	0.0	2	5.6	2	5.6	0	0.0	1	2.8	1	2.8	0	0.0	2	5.6	1	2.8	0	0.0	0	0.0	0	0.0	9	25.0
	RESPIRATORY DISORDER	2	5.6	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	6	16.7
	HEADACHE	1	2.8	1	2.8	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	PHARYNGITIS	2	5.6	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	TRAUMA	1	2.8	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	VOMITING	2	5.6	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	ABDOMINAL PAIN	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	3	8.3
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	3	8.3
	DYSPEPSIA	2	5.6	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	INSOMNIA	2	5.6	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	RHINITIS	1	2.8	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	3	8.3
	AGITATION	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ASTHENIA	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	FEVER	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	HYPESTHESIA	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	2	5.6
	NAUSEA	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	RASH	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ABNORMAL VISION	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ANXIETY	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8
	BRONCHITIS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8
	COUGH INCREASED	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	DECREASED APPETITE	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DIARRHEA	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	GASTROENTERITIS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HYPERKINESIA	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=36)	MIGRAINE	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MYALGIA	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	OTITIS MEDIA	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PAIN	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SINUSITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TOOTH CARIES	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TREMOR	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	YAWN	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=11)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=22)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=14)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=14)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=24)	HEADACHE	2	8.3	1	4.2	3	12.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	8	33.3
	HYPERKINESIA	1	4.2	0	0.0	1	4.2	1	4.2	1	4.2	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	5	20.8
	NAUSEA	0	0.0	1	4.2	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	4	16.7
	TRAUMA	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	4	16.7
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	3	12.5
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	3	12.5
	RHINITIS	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	12.5
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	DECREASED APPETITE	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	DIARRHEA	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	2	8.3
	DYSPEPSIA	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	INSOMNIA	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	2	8.3
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	SINUSITIS	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=24)	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ANXIETY	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	DIZZINESS	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MYOCLONUS	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	NERVOUSNESS	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2
	PAIN	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	RESPIRATORY DISORDER	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=24)	SOMNOLENCE	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=34)	NERVOUSNESS	2	5.9	0	0.0	3	8.8	0	0.0	2	5.9	1	2.9	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	9	26.5
	RESPIRATORY DISORDER	0	0.0	1	2.9	1	2.9	1	2.9	1	2.9	2	5.9	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	7	20.6
	HEADACHE	2	5.9	1	2.9	1	2.9	0	0.0	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	17.6
	ABDOMINAL PAIN	1	2.9	2	5.9	2	5.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	14.7
	HOSTILITY	0	0.0	0	0.0	2	5.9	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	4	11.8
	HYPERKINESIA	0	0.0	1	2.9	0	0.0	2	5.9	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	4	11.8
	PHARYNGITIS	0	0.0	2	5.9	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.8
	RHINITIS	0	0.0	1	2.9	0	0.0	1	2.9	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.8
	TRAUMA	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	3	8.8
	VASODILATATION	0	0.0	1	2.9	1	2.9	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.8
	ANXIETY	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	CONTACT DERMATITIS	1	2.9	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	DECREASED APPETITE	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	DIZZINESS	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	INSOMNIA	0	0.0	1	2.9	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	2	5.9

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=34)	RASH	0	0.0	0	0.0	1	2.9	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.9
	AGITATION	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	COUGH INCREASED	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	DYSKINESIA	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	EAR PAIN	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	FLATULENCE	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	GASTROENTERITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	1	2.9
	HERPES SIMPLEX	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	MANIC REACTION	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	MYOCLONUS	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=34)	NAUSEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	OTITIS EXTERNA	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	SINUSITIS	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	TREMOR	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	VERTIGO	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=11)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=22)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=13)	DYSMENORRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	7.7

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=12)	DYSMENORRHEA	0	0.0	1	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	8.3

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=49)	HEADACHE	5	10.2	2	4.1	4	8.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	13	26.5
	RESPIRATORY DISORDER	2	4.1	0	0.0	1	2.0	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	2	4.1	0	0.0	0	0.0	9	18.4
	TRAUMA	0	0.0	2	4.1	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	4	8.2	0	0.0	0	0.0	0	0.0	0	0.0	8	16.3
	FEVER	0	0.0	0	0.0	1	2.0	1	2.0	3	6.1	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	7	14.3
	INFECTION	0	0.0	0	0.0	0	0.0	2	4.1	3	6.1	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	7	14.3
	HYPERKINESIA	1	2.0	0	0.0	1	2.0	1	2.0	2	4.1	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	6	12.2
	PHARYNGITIS	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0	2	4.1	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	6	12.2
	ABDOMINAL PAIN	0	0.0	1	2.0	2	4.1	0	0.0	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	10.2
	DYSPEPSIA	0	0.0	1	2.0	0	0.0	2	4.1	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	5	10.2
	NAUSEA	0	0.0	1	2.0	2	4.1	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	5	10.2
	RHINITIS	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	5	10.2
	DIARRHEA	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	4	8.2
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	2.0	2	4.1	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.2
	NERVOUSNESS	1	2.0	0	0.0	1	2.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.2
	SINUSITIS	1	2.0	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.2
	VOMITING	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1	0	0.0	4	8.2
	WEIGHT GAIN	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1	0	0.0	0	0.0	1	2.0	0	0.0	4	8.2

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=49)	COUGH INCREASED	0	0.0	0	0.0	0	0.0	2	4.1	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.1
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	3	6.1
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	2	4.1
	DECREASED APPETITE	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.1
	DRY MOUTH	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	INSOMNIA	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ANXIETY	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=49)	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONSTIPATION	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONVULSION	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	DIZZINESS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	FACE EDEMA	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HALLUCINATIONS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	INCREASED APPETITE	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MYOCLONUS	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=49)	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	PAIN	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	SOMNOLENCE	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=70)	RESPIRATORY DISORDER	2	2.9	1	1.4	1	1.4	1	1.4	3	4.3	2	2.9	0	0.0	1	1.4	0	0.0	2	2.9	0	0.0	0	0.0	13	18.6
	HEADACHE	3	4.3	2	2.9	2	2.9	1	1.4	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	10	14.3
	INFECTION	0	0.0	2	2.9	2	2.9	0	0.0	1	1.4	2	2.9	0	0.0	2	2.9	1	1.4	0	0.0	0	0.0	0	0.0	10	14.3
	NERVOUSNESS	2	2.9	0	0.0	3	4.3	0	0.0	2	2.9	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	9	12.9
	ABDOMINAL PAIN	1	1.4	3	4.3	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9	0	0.0	0	0.0	0	0.0	8	11.4
	PHARYNGITIS	2	2.9	3	4.3	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	10.0
	TRAUMA	2	2.9	1	1.4	0	0.0	0	0.0	2	2.9	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	7	10.0
	RHINITIS	1	1.4	1	1.4	0	0.0	1	1.4	2	2.9	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	8.6
	HOSTILITY	0	0.0	0	0.0	2	2.9	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	5	7.1
	HYPERKINESIA	0	0.0	2	2.9	0	0.0	2	2.9	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	5	7.1
	INSOMNIA	2	2.9	2	2.9	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	7.1
	DYSPEPSIA	2	2.9	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	4	5.7
	RASH	2	2.9	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	5.7
	VOMITING	2	2.9	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	5.7
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	2	2.9	0	0.0	1	1.4	0	0.0	0	0.0	4	5.7
	AGITATION	1	1.4	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	2	2.9	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=70)	ANXIETY	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	3	4.3
	CONTACT DERMATITIS	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	3	4.3
	DECREASED APPETITE	2	2.9	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	DIZZINESS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	3	4.3
	FEVER	1	1.4	0	0.0	0	0.0	0	0.0	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	NAUSEA	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	OTITIS MEDIA	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	3	4.3
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	VASODILATATION	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.3
	ASTHENIA	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	COUGH INCREASED	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	GASTROENTERITIS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	HYPESTHESIA	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	2	2.9

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=70)	PAIN	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	SINUSITIS	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	TOOTH CARIES	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	TREMOR	0	0.0	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9
	ABNORMAL VISION	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4
	BRONCHITIS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DIARRHEA	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DYSKINESIA	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	EAR PAIN	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=70)	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	FLATULENCE	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	HERPES SIMPLEX	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MANIC REACTION	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MIGRAINE	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MYALGIA	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MYOCLONUS	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=70)	OTITIS EXTERNA	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	VERTIGO	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	YAWN	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=22)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=44)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=27)	DYSMENORRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=26)	DYSMENORRHEA	0	0.0	1	3.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.8

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=25)	NAUSEA	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	2	8.0	0	0.0	1	4.0	0	0.0	0	0.0	5	20.0
	HEADACHE	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	4	16.0
	RESPIRATORY DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	4	16.0
	TRAUMA	0	0.0	1	4.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	4	16.0
	SOMNOLENCE	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	3	12.0
	ALLERGIC REACTION	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	2	8.0
	BACK PAIN	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	2	8.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	2	8.0
	NERVOUSNESS	1	4.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0
	ABDOMINAL PAIN	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	ASTHMA	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	BRONCHITIS	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=25)	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	1	4.0
	DRY MOUTH	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	INSOMNIA	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	1	4.0
	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	SINUSITIS	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	VERTIGO	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0
	WEIGHT LOSS	0	0.0	1	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=30)	RESPIRATORY DISORDER	2	6.7	0	0.0	1	3.3	0	0.0	2	6.7	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	7	23.3
	HEADACHE	1	3.3	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	1	3.3	1	3.3	0	0.0	1	3.3	0	0.0	6	20.0
	ASTHENIA	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	3	10.0
	EMOTIONAL LABILITY	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	3	10.0
	WEIGHT GAIN	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	3	10.0
	ASTHMA	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	2	6.7
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	2	6.7
	DECREASED APPETITE	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INCREASED APPETITE	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INSOMNIA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	2	6.7
	NAUSEA	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	SOMNOLENCE	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	2	6.7
	TRAUMA	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3
	ACNE	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=30)	AGITATION	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3
	ANXIETY	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	COUGH INCREASED	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DIARRHEA	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DYSPEPSIA	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	FEVER	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	GASTROINTEST-INAL DISORDER	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3
	HALLUCINATIO-NS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	1	3.3
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	NERVOUSNESS	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	PAIN	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=30)	PHARYNGITIS	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	RHINITIS	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	WITHDRAWAL SYNDROME	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=16)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=15)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=9)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=15)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=20)	HEADACHE	3	15.0	0	0.0	0	0.0	0	0.0	1	5.0	2	10.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	7	35.0
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0	0	0.0	1	5.0	0	0.0	0	0.0	1	5.0	0	0.0	4	20.0
	ALLERGIC REACTION	0	0.0	1	5.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	3	15.0
	ASTHENIA	1	5.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	3	15.0
	NEUROSIS	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	3	15.0
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0
	ARTHRALGIA	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0
	RESPIRATORY DISORDER	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0
	SINUSITIS	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	2	10.0
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	ANXIETY	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=20)	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	INSOMNIA	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	MANIC REACTION	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	NERVOUSNESS	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	1	5.0
	RHINITIS	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=27)	HEADACHE	2	7.4	2	7.4	1	3.7	0	0.0	1	3.7	2	7.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	29.6
	NAUSEA	1	3.7	1	3.7	0	0.0	0	0.0	1	3.7	1	3.7	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	5	18.5
	RESPIRATORY DISORDER	1	3.7	1	3.7	1	3.7	1	3.7	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	18.5
	ABDOMINAL PAIN	1	3.7	0	0.0	1	3.7	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	11.1
	ALLERGIC REACTION	0	0.0	1	3.7	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	3	11.1
	ASTHENIA	1	3.7	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	3	11.1
	HOSTILITY	0	0.0	0	0.0	1	3.7	1	3.7	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	11.1
	INFECTION	1	3.7	2	7.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	11.1
	INSOMNIA	1	3.7	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	3	11.1
	NERVOUSNESS	0	0.0	0	0.0	1	3.7	1	3.7	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	11.1
	ACNE	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4
	AGITATION	1	3.7	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4
	ASTHMA	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4
	DECREASED APPETITE	1	3.7	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4
	DRY MOUTH	2	7.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4
	DYSPEPSIA	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=27)	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	1	3.7
	ARTHRALGIA	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	BACK PAIN	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	CONSTIPATION	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	CONTACT DERMATITIS	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	DIZZINESS	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	EOSINOPHILIA	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	EPISTAXIS	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	FEVER	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	FLATULENCE	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	1	3.7
	MONOCYTOSIS	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=27)	OTITIS MEDIA	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	1	3.7
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	RASH	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	SWEATING	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	TREMOR	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	URTICARIA	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	WEIGHT LOSS	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=11)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=18)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=9)	DYSMENORRHEA	1	11.1	0	0.0	0	0.0	0	0.0	1	11.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	22.2

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=9)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=45)	HEADACHE	4	8.9	1	2.2	0	0.0	0	0.0	1	2.2	3	6.7	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	11	24.4
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	0	0.0	2	4.4	1	2.2	0	0.0	1	2.2	0	0.0	6	13.3
	RESPIRATORY DISORDER	1	2.2	0	0.0	0	0.0	0	0.0	2	4.4	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	6	13.3
	ALLERGIC REACTION	0	0.0	2	4.4	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	5	11.1
	NAUSEA	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	2	4.4	0	0.0	1	2.2	0	0.0	0	0.0	5	11.1
	SOMNOLENCE	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	4	8.9
	TRAUMA	0	0.0	1	2.2	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	4	8.9
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	2.2	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	ASTHENIA	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	NERVOUSNESS	1	2.2	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	NEUROSIS	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	3	6.7
	SINUSITIS	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	ABDOMINAL PAIN	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	ARTHRALGIA	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	ASTHMA	0	0.0	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	BACK PAIN	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=45)	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	2	4.4
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	2	4.4
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	2	4.4
	INSOMNIA	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	RHINITIS	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	ANXIETY	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	BRONCHITIS	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	DRY MOUTH	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=45)	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	MANIC REACTION	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	VERTIGO	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	WEIGHT LOSS	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=57)	HEADACHE	3	5.3	2	3.5	1	1.8	1	1.8	1	1.8	3	5.3	0	0.0	1	1.8	1	1.8	0	0.0	1	1.8	0	0.0	14	24.6
	RESPIRATORY DISORDER	3	5.3	1	1.8	2	3.5	1	1.8	3	5.3	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	12	21.1
	NAUSEA	2	3.5	1	1.8	1	1.8	0	0.0	1	1.8	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	7	12.3
	ASTHENIA	1	1.8	2	3.5	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	6	10.5
	INFECTION	1	1.8	2	3.5	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	5	8.8
	INSOMNIA	1	1.8	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	2	3.5	0	0.0	0	0.0	0	0.0	5	8.8
	ABDOMINAL PAIN	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	4	7.0
	ASTHMA	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	4	7.0
	DECREASED APPETITE	2	3.5	0	0.0	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	EMOTIONAL LABILITY	0	0.0	1	1.8	0	0.0	2	3.5	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	HOSTILITY	0	0.0	0	0.0	1	1.8	1	1.8	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	NERVOUSNESS	1	1.8	0	0.0	1	1.8	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	ACNE	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3
	AGITATION	2	3.5	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3
	ALLERGIC REACTION	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	3	5.3
	DYSPEPSIA	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=57)	TRAUMA	0	0.0	0	0.0	1	1.8	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3
	WEIGHT GAIN	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	3	5.3
	ANXIETY	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	2	3.5
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	2	3.5
	DIARRHEA	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	DIZZINESS	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	DRY MOUTH	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	FEVER	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	INCREASED APPETITE	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	PHARYNGITIS	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	2	3.5
	RHINITIS	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	SOMNOLENCE	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	2	3.5
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8
	ARTHRALGIA	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	BACK PAIN	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=57)	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	CONSTIPATION	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	CONTACT DERMATITIS	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	COUGH INCREASED	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	EOSINOPHILIA	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	EPISTAXIS	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	FLATULENCE	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	GASTROINTEST-INAL DISORDER	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8
	HALLUCINATIO-NS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	MONOCYTOSIS	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	OTITIS MEDIA	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=57)	PAIN	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	RASH	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	SWEATING	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	TREMOR	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	URTICARIA	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	WEIGHT LOSS	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	WITHDRAWAL SYNDROME	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=27)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=33)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=18)	DYSMENORRHEA	1	5.6	0	0.0	0	0.0	0	0.0	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	11.1

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=24)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=50)	RESPIRATORY DISORDER	2	4.0	0	0.0	1	2.0	0	0.0	3	6.0	1	2.0	0	0.0	1	2.0	1	2.0	2	4.0	1	2.0	0	0.0	12	24.0
	HEADACHE	4	8.0	2	4.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	9	18.0
	TRAUMA	0	0.0	3	6.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.0	1	2.0	0	0.0	0	0.0	0	0.0	8	16.0
	INFECTION	0	0.0	0	0.0	0	0.0	2	4.0	2	4.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	6	12.0
	NAUSEA	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	2	4.0	0	0.0	1	2.0	0	0.0	0	0.0	6	12.0
	VOMITING	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	2	4.0	0	0.0	0	0.0	2	4.0	0	0.0	6	12.0
	ABDOMINAL PAIN	1	2.0	1	2.0	2	4.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	10.0
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	2	4.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.0	0	0.0	0	0.0	5	10.0
	NERVOUSNESS	1	2.0	1	2.0	1	2.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	10.0
	WEIGHT GAIN	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.0	0	0.0	0	0.0	1	2.0	0	0.0	5	10.0
	ALLERGIC REACTION	0	0.0	1	2.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	4	8.0
	FEVER	0	0.0	0	0.0	1	2.0	1	2.0	2	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.0
	PHARYNGITIS	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	4	8.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	3	6.0
	DIARRHEA	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	3	6.0
	DRY MOUTH	3	6.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	3	6.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=50)	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	2	4.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.0
	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	3	6.0
	SINUSITIS	1	2.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.0
	SOMNOLENCE	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.0
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.0
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	2	4.0
	BACK PAIN	2	4.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	2	4.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.0
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	ASTHMA	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	BRONCHITIS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONSTIPATION	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONVULSION	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=50)	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0
	FACE EDEMA	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HALLUCINATIONS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	INCREASED APPETITE	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	INSOMNIA	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	VERTIGO	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	WEIGHT LOSS	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

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Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	RESPIRATORY DISORDER	4	6.1	0	0.0	1	1.5	0	0.0	4	6.1	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5	0	0.0	0	0.0	13	19.7
	INFECTION	0	0.0	2	3.0	2	3.0	0	0.0	2	3.0	1	1.5	0	0.0	3	4.5	1	1.5	0	0.0	0	0.0	0	0.0	11	16.7
	HEADACHE	2	3.0	1	1.5	1	1.5	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	10	15.2
	TRAUMA	1	1.5	0	0.0	1	1.5	1	1.5	2	3.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	6	9.1
	WEIGHT GAIN	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	6	9.1
	ASTHENIA	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	5	7.6
	INSOMNIA	2	3.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	5	7.6
	PHARYNGITIS	3	4.5	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	7.6
	ABDOMINAL PAIN	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5	0	0.0	0	0.0	0	0.0	4	6.1
	DYSPEPSIA	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	NAUSEA	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	RHINITIS	1	1.5	1	1.5	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	VOMITING	2	3.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	AGITATION	1	1.5	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	ASTHMA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	3	4.5
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	BRONCHITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	DECREASED APPETITE	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	EMOTIONAL LABILITY	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	FEVER	1	1.5	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	SOMNOLENCE	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ANXIETY	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	COUGH INCREASED	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	DIARRHEA	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	HYPESTHESIA	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	INCREASED APPETITE	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	PAIN	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	RASH	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	TOOTH CARIES	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ABNORMAL VISION	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=66)	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HYPERKINESIA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MIGRAINE	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MYALGIA	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	NERVOUSNESS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	OTITIS MEDIA	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	SINUSITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	TREMOR	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	WITHDRAWAL SYNDROME	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	YAWN	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=27)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=37)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=23)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=29)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=44)	HEADACHE	5	11.4	1	2.3	3	6.8	0	0.0	1	2.3	2	4.5	0	0.0	0	0.0	1	2.3	1	2.3	1	2.3	0	0.0	15	34.1
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	3	6.8	0	0.0	1	2.3	0	0.0	0	0.0	2	4.5	0	0.0	7	15.9
	HYPERKINESIA	1	2.3	0	0.0	1	2.3	1	2.3	1	2.3	0	0.0	0	0.0	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0	6	13.6
	NAUSEA	0	0.0	1	2.3	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	4	9.1
	NEUROSIS	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5	0	0.0	4	9.1
	RHINITIS	1	2.3	0	0.0	1	2.3	0	0.0	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	9.1
	SINUSITIS	0	0.0	2	4.5	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	4	9.1
	TRAUMA	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0	4	9.1
	ALLERGIC REACTION	0	0.0	1	2.3	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	3	6.8
	ASTHENIA	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	3	6.8
	DIARRHEA	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	3	6.8
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	3	6.8
	INSOMNIA	1	2.3	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.8
	RESPIRATORY DISORDER	1	2.3	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	3	6.8
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	ANXIETY	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=44)	ARTHRALGIA	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	2	4.5
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	DECREASED APPETITE	2	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	DIZZINESS	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	DYSPEPSIA	0	0.0	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	NERVOUSNESS	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	2	4.5
	PAIN	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	2	4.5
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	SOMNOLENCE	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	4.5
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=44)	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	1	2.3
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	MANIC REACTION	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	MYOCLONUS	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3	0	0.0	0	0.0	0	0.0	0	0.0	1	2.3

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Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=61)	HEADACHE	4	6.6	3	4.9	2	3.3	0	0.0	2	3.3	3	4.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	14	23.0
	NERVOUSNESS	2	3.3	0	0.0	4	6.6	1	1.6	3	4.9	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	12	19.7
	RESPIRATORY DISORDER	1	1.6	2	3.3	2	3.3	2	3.3	2	3.3	2	3.3	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	12	19.7
	ABDOMINAL PAIN	2	3.3	2	3.3	3	4.9	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	13.1
	HOSTILITY	0	0.0	0	0.0	3	4.9	2	3.3	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	7	11.5
	NAUSEA	1	1.6	1	1.6	0	0.0	0	0.0	1	1.6	1	1.6	0	0.0	2	3.3	0	0.0	0	0.0	0	0.0	0	0.0	6	9.8
	HYPERKINESIA	0	0.0	1	1.6	0	0.0	2	3.3	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	5	8.2
	INSOMNIA	1	1.6	2	3.3	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	5	8.2
	ALLERGIC REACTION	0	0.0	1	1.6	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	4	6.6
	DECREASED APPETITE	2	3.3	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.6
	INFECTION	1	1.6	2	3.3	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.6
	PHARYNGITIS	0	0.0	2	3.3	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	4	6.6
	RHINITIS	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	2	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.6
	TRAUMA	1	1.6	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	4	6.6
	AGITATION	2	3.3	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	ANXIETY	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	3	4.9
	ASTHENIA	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	3	4.9

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=61)	CONTACT DERMATITIS	1	1.6	0	0.0	2	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	DIZZINESS	2	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	DYSPEPSIA	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	OTITIS MEDIA	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	3	4.9
	RASH	1	1.6	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	VASODILATATION	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.9
	ACNE	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	ASTHMA	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	DRY MOUTH	2	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	FEVER	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	FLATULENCE	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	TREMOR	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.3
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	ARTHRALGIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	BACK PAIN	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	CONSTIPATION	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	COUGH INCREASED	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=61)	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	DYSKINESIA	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EAR PAIN	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EPISTAXIS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	GASTROENTERITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6
	HERPES SIMPLEX	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6
	MANIC REACTION	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	MYOCLONUS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	OTITIS EXTERNA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=61)	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SINUSITIS	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SWEATING	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	URTICARIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	VERTIGO	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	WEIGHT LOSS	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=22)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=40)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=22)	DYSMENORRHEA	1	4.5	0	0.0	0	0.0	0	0.0	1	4.5	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	13.6

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=21)	DYSMENORRHEA	0	0.0	1	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.8

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=94)	HEADACHE	9	9.6	3	3.2	4	4.3	0	0.0	1	1.1	3	3.2	0	0.0	0	0.0	1	1.1	2	2.1	1	1.1	0	0.0	24	25.5
	RESPIRATORY DISORDER	3	3.2	0	0.0	1	1.1	1	1.1	3	3.2	1	1.1	0	0.0	2	2.1	1	1.1	2	2.1	1	1.1	0	0.0	15	16.0
	INFECTION	0	0.0	0	0.0	0	0.0	2	2.1	3	3.2	3	3.2	0	0.0	2	2.1	1	1.1	0	0.0	2	2.1	0	0.0	13	13.8
	TRAUMA	0	0.0	3	3.2	2	2.1	1	1.1	1	1.1	0	0.0	0	0.0	4	4.3	1	1.1	0	0.0	0	0.0	0	0.0	12	12.8
	NAUSEA	1	1.1	1	1.1	2	2.1	1	1.1	0	0.0	1	1.1	0	0.0	3	3.2	0	0.0	1	1.1	0	0.0	0	0.0	10	10.6
	ABDOMINAL PAIN	1	1.1	1	1.1	2	2.1	0	0.0	2	2.1	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	7.4
	ALLERGIC REACTION	0	0.0	2	2.1	0	0.0	1	1.1	2	2.1	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	7	7.4
	DYSPEPSIA	0	0.0	1	1.1	0	0.0	3	3.2	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	7	7.4
	FEVER	0	0.0	0	0.0	1	1.1	1	1.1	3	3.2	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	7	7.4
	HYPERKINESIA	1	1.1	0	0.0	1	1.1	1	1.1	2	2.1	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	7	7.4
	NERVOUSNESS	2	2.1	2	2.1	1	1.1	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	7.4
	RHINITIS	1	1.1	0	0.0	1	1.1	0	0.0	1	1.1	2	2.1	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	7	7.4
	SINUSITIS	1	1.1	3	3.2	1	1.1	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	7	7.4
	DIARRHEA	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	6	6.4
	PHARYNGITIS	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	2	2.1	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	6	6.4
	VOMITING	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	2	2.1	0	0.0	0	0.0	2	2.1	0	0.0	6	6.4
	WEIGHT GAIN	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.3	0	0.0	0	0.0	1	1.1	0	0.0	6	6.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=94)	HOSTILITY	0	0.0	0	0.0	0	0.0	1	1.1	2	2.1	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	5	5.3
	SOMNOLENCE	2	2.1	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	5	5.3
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1	1	1.1	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	4	4.3
	INSOMNIA	1	1.1	3	3.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.3
	NEUROSIS	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1	0	0.0	4	4.3
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	4	4.3
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.1	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	ARTHRALGIA	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	3	3.2
	ASTHENIA	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	ASTHMA	0	0.0	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	3	3.2
	BACK PAIN	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	2	2.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	3	3.2
	DIZZINESS	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	3	3.2
	DRY MOUTH	3	3.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.2
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	2	2.1
	ANXIETY	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=94)	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	2	2.1
	DECREASED APPETITE	2	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1
	PAIN	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	2	2.1
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	BRONCHITIS	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	CONSTIPATION	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	CONVULSION	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=94)	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	FACE EDEMA	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	HALLUCINATIONS	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	INCREASED APPETITE	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	MANIC REACTION	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	MYOCLONUS	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	1	1.1
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	1	1.1
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=94)	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	VERTIGO	0	0.0	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
	WEIGHT LOSS	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1

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Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=127)	RESPIRATORY DISORDER	5	3.9	2	1.6	3	2.4	2	1.6	6	4.7	3	2.4	0	0.0	1	0.8	0	0.0	3	2.4	0	0.0	0	0.0	25	19.7
	HEADACHE	6	4.7	4	3.1	3	2.4	2	1.6	2	1.6	4	3.1	0	0.0	1	0.8	1	0.8	0	0.0	1	0.8	0	0.0	24	18.9
	INFECTION	1	0.8	4	3.1	2	1.6	0	0.0	2	1.6	2	1.6	0	0.0	3	2.4	1	0.8	0	0.0	0	0.0	0	0.0	15	11.8
	NERVOUSNESS	3	2.4	0	0.0	4	3.1	1	0.8	3	2.4	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	13	10.2
	ABDOMINAL PAIN	2	1.6	3	2.4	3	2.4	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	3	2.4	0	0.0	0	0.0	0	0.0	12	9.4
	INSOMNIA	3	2.4	3	2.4	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	10	7.9
	NAUSEA	3	2.4	1	0.8	1	0.8	0	0.0	2	1.6	1	0.8	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	10	7.9
	TRAUMA	2	1.6	1	0.8	1	0.8	1	0.8	3	2.4	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	10	7.9
	HOSTILITY	0	0.0	0	0.0	3	2.4	3	2.4	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	9	7.1
	PHARYNGITIS	3	2.4	3	2.4	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	9	7.1
	ASTHENIA	2	1.6	2	1.6	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	1	0.8	0	0.0	8	6.3
	RHINITIS	1	0.8	2	1.6	0	0.0	1	0.8	2	1.6	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	6.3
	DECREASED APPETITE	4	3.1	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	5.5
	DYSPEPSIA	2	1.6	1	0.8	2	1.6	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	7	5.5
	WEIGHT GAIN	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	3	2.4	1	0.8	1	0.8	0	0.0	0	0.0	7	5.5
	AGITATION	3	2.4	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4.7
	ALLERGIC REACTION	0	0.0	1	0.8	0	0.0	2	1.6	2	1.6	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	6	4.7

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=127)	HYPERKINESIA	0	0.0	2	1.6	0	0.0	2	1.6	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	6	4.7
	ANXIETY	2	1.6	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	5	3.9
	ASTHMA	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	5	3.9
	DIZZINESS	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6	0	0.0	1	0.8	0	0.0	0	0.0	5	3.9
	FEVER	1	0.8	1	0.8	1	0.8	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3.9
	RASH	3	2.4	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3.9
	BACK PAIN	0	0.0	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	4	3.1
	CONTACT DERMATITIS	1	0.8	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	4	3.1
	EMOTIONAL LABILITY	0	0.0	1	0.8	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	OTITIS MEDIA	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	4	3.1
	SOMNOLENCE	0	0.0	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	4	3.1
	VOMITING	2	1.6	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	ACNE	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	BRONCHITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	3	2.4
	COUGH INCREASED	1	0.8	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	DIARRHEA	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	EPISTAXIS	0	0.0	1	0.8	0	0.0	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=127)	PAIN	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	TOOTH CARIES	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	TREMOR	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	VASODILATATION	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4
	ABNORMAL VISION	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	2	1.6
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	DRY MOUTH	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	FLATULENCE	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	GASTROENTERITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	2	1.6
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	2	1.6
	HYPESTHESIA	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=127)	INCREASED APPETITE	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	2	1.6
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	SINUSITIS	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.6
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ARTHRALGIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	CONSTIPATION	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DYSKINESIA	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	EAR PAIN	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ELECTROCARDIOGRAM ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8
	EOSINOPHILIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GASTROINTESTINAL DISORDER	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=127)	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8
	HERPES SIMPLEX	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MANIC REACTION	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MIGRAINE	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MYALGIA	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MYOCLONUS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	OTITIS EXTERNA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=127)	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	SWEATING	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	URTICARIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	VERTIGO	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	WEIGHT LOSS	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	WITHDRAWAL SYNDROME	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	YAWN	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=49)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=77)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=45)	DYSMENORRHEA	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7

BRL 29060 - 716
Interim Output
Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=50)	DYSMENORRHEA	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	27	54.0	29	58.0	5	10.0
Body as a Whole	TOTAL	10	20.0	15	30.0	2	4.0
	ABDOMINAL PAIN	3	6.0	2	4.0	0	0.0
	ALLERGIC REACTION	3	6.0	1	2.0	0	0.0
	BACK PAIN	0	0.0	2	4.0	0	0.0
	CHEST PAIN	1	2.0	0	0.0	0	0.0
	FACE EDEMA	1	2.0	0	0.0	0	0.0
	FEVER	1	2.0	3	6.0	0	0.0
	HEADACHE	3	6.0	6	12.0	0	0.0
	INFECTION	1	2.0	4	8.0	1	2.0
	TRAUMA	2	4.0	5	10.0	1	2.0
Digestive System	TOTAL	10	20.0	9	18.0	0	0.0
	CONSTIPATION	0	0.0	1	2.0	0	0.0
	DIARRHEA	0	0.0	3	6.0	0	0.0
	DRY MOUTH	3	6.0	0	0.0	0	0.0
	DYSPEPSIA	5	10.0	0	0.0	0	0.0
	INCREASED APPETITE	1	2.0	0	0.0	0	0.0
	NAUSEA	4	8.0	2	4.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	STOMATITIS	0	0.0	1	2.0	0	0.0
	VOMITING	1	2.0	5	10.0	0	0.0
Hemic and Lymphatic System	TOTAL	2	4.0	0	0.0	0	0.0
	LEUKOPENIA	2	4.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	2	4.0	4	8.0	0	0.0
	WEIGHT GAIN	2	4.0	3	6.0	0	0.0
	WEIGHT LOSS	0	0.0	1	2.0	0	0.0
Musculoskeletal System	TOTAL	1	2.0	0	0.0	0	0.0
	ARTHRALGIA	1	2.0	0	0.0	0	0.0
Nervous System	TOTAL	11	22.0	8	16.0	3	6.0
	AGITATION	0	0.0	1	2.0	1	2.0
	CONVULSION	0	0.0	1	2.0	0	0.0
	DEPRESSION	0	0.0	2	4.0	1	2.0
	DIZZINESS	1	2.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	2.0	0	0.0	2	4.0
	HALLUCINATIONS	1	2.0	0	0.0	0	0.0
	HOSTILITY	0	0.0	2	4.0	1	2.0
	HYPERKINESIA	1	2.0	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	INSOMNIA	1	2.0	0	0.0	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	2.0
	NERVOUSNESS	3	6.0	2	4.0	0	0.0
	SOMNOLENCE	2	4.0	1	2.0	0	0.0
	VERTIGO	1	2.0	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	2.0	0	0.0
Respiratory System	TOTAL	11	22.0	10	20.0	0	0.0
	ASTHMA	0	0.0	1	2.0	0	0.0
	BRONCHITIS	0	0.0	1	2.0	0	0.0
	COUGH INCREASED	1	2.0	0	0.0	0	0.0
	PHARYNGITIS	2	4.0	2	4.0	0	0.0
	RESPIRATORY DISORDER	5	10.0	7	14.0	0	0.0
	RHINITIS	3	6.0	0	0.0	0	0.0
	SINUSITIS	2	4.0	1	2.0	0	0.0
Skin and Appendages	TOTAL	3	6.0	3	6.0	0	0.0
	ACNE	1	2.0	1	2.0	0	0.0
	CONTACT DERMATITIS	1	2.0	1	2.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	2.0	0	0.0
	RASH	1	2.0	0	0.0	0	0.0
Special Senses	TOTAL	1	2.0	1	2.0	0	0.0
	OTITIS MEDIA	1	2.0	1	2.0	0	0.0
Urogenital System	TOTAL	1	2.0	1	2.0	0	0.0
	ALBUMINURIA	1	2.0	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	2.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=27), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=23), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	26	59.1	23	52.3	4	9.1
Body as a Whole	TOTAL	15	34.1	15	34.1	2	4.5
	ABDOMINAL PAIN	1	2.3	1	2.3	0	0.0
	ABNORMAL LABORATORY VALUE	1	2.3	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	2.3
	ALLERGIC REACTION	2	4.5	1	2.3	0	0.0
	ASTHENIA	1	2.3	2	4.5	0	0.0
	BACK PAIN	1	2.3	0	0.0	0	0.0
	FEVER	2	4.5	1	2.3	0	0.0
	HEADACHE	8	18.2	7	15.9	0	0.0
	INFECTION	2	4.5	4	9.1	1	2.3
	PAIN	1	2.3	1	2.3	0	0.0
	TRAUMA	1	2.3	3	6.8	0	0.0
Cardiovascular System	TOTAL	1	2.3	0	0.0	0	0.0
	HAEMATOMA	1	2.3	0	0.0	0	0.0
Digestive System	TOTAL	7	15.9	2	4.5	0	0.0
	DECREASED APPETITE	2	4.5	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	2	4.5	1	2.3	0	0.0
	DYSPEPSIA	2	4.5	0	0.0	0	0.0
	NAUSEA	4	9.1	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	2.3	0	0.0
Hemic and Lymphatic System	TOTAL	1	2.3	0	0.0	0	0.0
	ANEMIA	1	2.3	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	2.3	0	0.0
	WEIGHT GAIN	0	0.0	1	2.3	0	0.0
Musculoskeletal System	TOTAL	2	4.5	1	2.3	0	0.0
	ARTHRALGIA	1	2.3	1	2.3	0	0.0
	MYALGIA	1	2.3	0	0.0	0	0.0
Nervous System	TOTAL	7	15.9	9	20.5	2	4.5
	ANXIETY	1	2.3	1	2.3	0	0.0
	CONCENTRATION IMPAIRED	1	2.3	0	0.0	0	0.0
	DIZZINESS	2	4.5	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	2.3	0	0.0
	HOSTILITY	1	2.3	1	2.3	0	0.0
	HYPERKINESIA	2	4.5	4	9.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	INSOMNIA	3	6.8	1	2.3	0	0.0
	MANIC REACTION	0	0.0	1	2.3	0	0.0
	MYOCLONUS	1	2.3	0	0.0	0	0.0
	NERVOUSNESS	1	2.3	1	2.3	0	0.0
	NEUROSIS	3	6.8	0	0.0	1	2.3
	SOMNOLENCE	0	0.0	1	2.3	1	2.3
Respiratory System	TOTAL	7	15.9	4	9.1	1	2.3
	ASTHMA	1	2.3	1	2.3	0	0.0
	COUGH INCREASED	1	2.3	1	2.3	0	0.0
	PHARYNGITIS	1	2.3	0	0.0	1	2.3
	RESPIRATORY DISORDER	1	2.3	2	4.5	0	0.0
	RHINITIS	4	9.1	0	0.0	0	0.0
	SINUSITIS	2	4.5	2	4.5	0	0.0
Skin and Appendages	TOTAL	1	2.3	1	2.3	0	0.0
	ACNE	0	0.0	1	2.3	0	0.0
	MACULOPAPULAR RASH	1	2.3	0	0.0	0	0.0
Special Senses	TOTAL	3	6.8	3	6.8	0	0.0
	BLEPHARITIS	1	2.3	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	EAR PAIN	0	0.0	1	2.3	0	0.0
	EYE PAIN	1	2.3	0	0.0	0	0.0
	OTITIS EXTERNA	1	2.3	1	2.3	0	0.0
	OTITIS MEDIA	0	0.0	2	4.5	0	0.0
Urogenital System	TOTAL	3	6.8	0	0.0	0	0.0
	ALBUMINURIA	2	4.5	0	0.0	0	0.0
	DYSURIA	1	2.3	0	0.0	0	0.0
	HAEMATURIA	1	2.3	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	3	13.6	0	0.0
Urogenital System	TOTAL	0	0.0	3	13.6	0	0.0
	DYSMENORRHEA	0	0.0	3	13.6	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	53	56.4	52	55.3	9	9.6
Body as a Whole	TOTAL	25	26.6	30	31.9	4	4.3
	ABDOMINAL PAIN	4	4.3	3	3.2	0	0.0
	ABNORMAL LABORATORY VALUE	1	1.1	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	1.1
	ALLERGIC REACTION	5	5.3	2	2.1	0	0.0
	ASTHENIA	1	1.1	2	2.1	0	0.0
	BACK PAIN	1	1.1	2	2.1	0	0.0
	CHEST PAIN	1	1.1	0	0.0	0	0.0
	FACE EDEMA	1	1.1	0	0.0	0	0.0
	FEVER	3	3.2	4	4.3	0	0.0
	HEADACHE	11	11.7	13	13.8	0	0.0
	INFECTION	3	3.2	8	8.5	2	2.1
	PAIN	1	1.1	1	1.1	0	0.0
	TRAUMA	3	3.2	8	8.5	1	1.1
Cardiovascular System	TOTAL	1	1.1	0	0.0	0	0.0
	HAEMATOMA	1	1.1	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	TOTAL	17	18.1	11	11.7	0	0.0
	CONSTIPATION	0	0.0	1	1.1	0	0.0
	DECREASED APPETITE	2	2.1	0	0.0	0	0.0
	DIARRHEA	2	2.1	4	4.3	0	0.0
	DRY MOUTH	3	3.2	0	0.0	0	0.0
	DYSPEPSIA	7	7.4	0	0.0	0	0.0
	INCREASED APPETITE	1	1.1	0	0.0	0	0.0
	NAUSEA	8	8.5	2	2.1	0	0.0
	STOMATITIS	0	0.0	1	1.1	0	0.0
	TOOTH DISORDER	0	0.0	1	1.1	0	0.0
	VOMITING	1	1.1	5	5.3	0	0.0
Hemic and Lymphatic System	TOTAL	3	3.2	0	0.0	0	0.0
	ANEMIA	1	1.1	0	0.0	0	0.0
	LEUKOPENIA	2	2.1	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	2	2.1	5	5.3	0	0.0
	WEIGHT GAIN	2	2.1	4	4.3	0	0.0
	WEIGHT LOSS	0	0.0	1	1.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	TOTAL	3	3.2	1	1.1	0	0.0
	ARTHRALGIA	2	2.1	1	1.1	0	0.0
	MYALGIA	1	1.1	0	0.0	0	0.0
Nervous System	TOTAL	18	19.1	17	18.1	5	5.3
	AGITATION	0	0.0	1	1.1	1	1.1
	ANXIETY	1	1.1	1	1.1	0	0.0
	CONCENTRATION IMPAIRED	1	1.1	0	0.0	0	0.0
	CONVULSION	0	0.0	1	1.1	0	0.0
	DEPRESSION	0	0.0	2	2.1	1	1.1
	DIZZINESS	3	3.2	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.1	1	1.1	2	2.1
	HALLUCINATIONS	1	1.1	0	0.0	0	0.0
	HOSTILITY	1	1.1	3	3.2	1	1.1
	HYPERKINESIA	3	3.2	4	4.3	0	0.0
	INSOMNIA	4	4.3	1	1.1	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	1.1
	MANIC REACTION	0	0.0	1	1.1	0	0.0
	MYOCLONUS	1	1.1	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	NERVOUSNESS	4	4.3	3	3.2	0	0.0
	NEUROSIS	3	3.2	0	0.0	1	1.1
	SOMNOLENCE	2	2.1	2	2.1	1	1.1
	VERTIGO	1	1.1	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	1.1	0	0.0
Respiratory System	TOTAL	18	19.1	14	14.9	1	1.1
	ASTHMA	1	1.1	2	2.1	0	0.0
	BRONCHITIS	0	0.0	1	1.1	0	0.0
	COUGH INCREASED	2	2.1	1	1.1	0	0.0
	PHARYNGITIS	3	3.2	2	2.1	1	1.1
	RESPIRATORY DISORDER	6	6.4	9	9.6	0	0.0
	RHINITIS	7	7.4	0	0.0	0	0.0
	SINUSITIS	4	4.3	3	3.2	0	0.0
Skin and Appendages	TOTAL	4	4.3	4	4.3	0	0.0
	ACNE	1	1.1	2	2.1	0	0.0
	CONTACT DERMATITIS	1	1.1	1	1.1	0	0.0
	HERPES ZOSTER	0	0.0	1	1.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	MACULOPAPULAR RASH	1	1.1	0	0.0	0	0.0
	RASH	1	1.1	0	0.0	0	0.0
Special Senses	TOTAL	4	4.3	4	4.3	0	0.0
	BLEPHARITIS	1	1.1	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	1.1	0	0.0
	EYE PAIN	1	1.1	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.1	1	1.1	0	0.0
	OTITIS MEDIA	1	1.1	3	3.2	0	0.0
Urogenital System	TOTAL	4	4.3	1	1.1	0	0.0
	ALBUMINURIA	3	3.2	0	0.0	0	0.0
	DYSURIA	1	1.1	0	0.0	0	0.0
	HAEMATURIA	1	1.1	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	1.1	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=49), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=45), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	3	6.7	0	0.0
Urogenital System	TOTAL	0	0.0	3	6.7	0	0.0
	DYSMENORRHEA	0	0.0	3	6.7	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	39	59.1	28	42.4	11	16.7
Body as a Whole	TOTAL	18	27.3	14	21.2	1	1.5
	ABDOMINAL PAIN	2	3.0	2	3.0	0	0.0
	ALLERGIC REACTION	1	1.5	1	1.5	0	0.0
	ASTHENIA	4	6.1	1	1.5	0	0.0
	BACK PAIN	3	4.5	0	0.0	0	0.0
	FEVER	1	1.5	2	3.0	0	0.0
	HEADACHE	8	12.1	2	3.0	0	0.0
	INFECTION	5	7.6	6	9.1	0	0.0
	PAIN	1	1.5	1	1.5	0	0.0
	TRAUMA	2	3.0	3	4.5	1	1.5
Cardiovascular System	TOTAL	2	3.0	1	1.5	1	1.5
	ELECTROCARDIOGRAM ABNORMAL	1	1.5	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	1.5
	SYNCOPE	1	1.5	1	1.5	0	0.0
Digestive System	TOTAL	15	22.7	5	7.6	1	1.5
	DECREASED APPETITE	3	4.5	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	2	3.0	0	0.0	0	0.0
	DYSPEPSIA	3	4.5	1	1.5	0	0.0
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0
	INCREASED APPETITE	2	3.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.5	0	0.0	0	0.0
	NAUSEA	3	4.5	1	1.5	0	0.0
	TOOTH CARIES	1	1.5	1	1.5	1	1.5
	VOMITING	2	3.0	2	3.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.5	1	1.5	0	0.0
	ANEMIA	1	1.5	0	0.0	0	0.0
	LEUKOPENIA	1	1.5	1	1.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	7.6	2	3.0	0	0.0
	DEHYDRATION	0	0.0	1	1.5	0	0.0
	WEIGHT GAIN	5	7.6	1	1.5	0	0.0
Musculoskeletal System	TOTAL	0	0.0	1	1.5	0	0.0
	ARTHROSIS	0	0.0	1	1.5	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	0	0.0	1	1.5	0	0.0
Nervous System	TOTAL	8	12.1	11	16.7	6	9.1
	AGITATION	0	0.0	2	3.0	1	1.5
	ANXIETY	1	1.5	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	1	1.5	1	1.5	0	0.0
	DEPRESSION	1	1.5	0	0.0	0	0.0
	DIZZINESS	2	3.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	3.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	1	1.5
	HALLUCINATIONS	0	0.0	1	1.5	1	1.5
	HOSTILITY	0	0.0	1	1.5	1	1.5
	HYPERKINESIA	1	1.5	0	0.0	0	0.0
	HYPESTHESIA	1	1.5	1	1.5	0	0.0
	INSOMNIA	4	6.1	1	1.5	0	0.0
	LIBIDO DECREASED	1	1.5	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.5	0	0.0
	PARALYSIS	0	0.0	0	0.0	1	1.5

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	0	0.0	3	4.5	0	0.0
	TREMOR	0	0.0	1	1.5	0	0.0
	WITHDRAWAL SYNDROME	0	0.0	1	1.5	0	0.0
Respiratory System	TOTAL	18	27.3	10	15.2	1	1.5
	ASTHMA	2	3.0	0	0.0	1	1.5
	BRONCHITIS	0	0.0	3	4.5	0	0.0
	COUGH INCREASED	2	3.0	0	0.0	0	0.0
	EPISTAXIS	2	3.0	0	0.0	0	0.0
	PHARYNGITIS	5	7.6	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	1.5	0	0.0
	RESPIRATORY DISORDER	8	12.1	5	7.6	0	0.0
	RHINITIS	4	6.1	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	1.5	0	0.0
	YAWN	1	1.5	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	4.5	2	3.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0
	CONTACT DERMATITIS	0	0.0	1	1.5	0	0.0

(CONTINUED)

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	MACULOPAPULAR RASH	1	1.5	0	0.0	0	0.0
	PRURITUS	2	3.0	0	0.0	0	0.0
	RASH	1	1.5	0	0.0	1	1.5
Special Senses	TOTAL	1	1.5	0	0.0	1	1.5
	ABNORMAL VISION	1	1.5	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	1	1.5
Urogenital System	TOTAL	4	6.1	0	0.0	1	1.5
	ALBUMINURIA	2	3.0	0	0.0	0	0.0
	CYSTITIS	1	1.5	0	0.0	0	0.0
	HAEMATURIA	2	3.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.5	0	0.0	1	1.5

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=37), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=29), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	6.9	0	0.0	0	0.0
Urogenital System	TOTAL	2	6.9	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	3.4	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	3.4	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	35	57.4	34	55.7	5	8.2
Body as a Whole	TOTAL	17	27.9	11	18.0	1	1.6
	ABDOMINAL PAIN	4	6.6	3	4.9	1	1.6
	ALLERGIC REACTION	3	4.9	1	1.6	0	0.0
	ASTHENIA	1	1.6	2	3.3	0	0.0
	BACK PAIN	0	0.0	1	1.6	0	0.0
	FEVER	2	3.3	0	0.0	0	0.0
	HEADACHE	9	14.8	5	8.2	0	0.0
	INFECTION	1	1.6	2	3.3	1	1.6
	PAIN	0	0.0	1	1.6	0	0.0
	TRAUMA	4	6.6	0	0.0	0	0.0
Cardiovascular System	TOTAL	3	4.9	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	1	1.6
	VASODILATATION	3	4.9	0	0.0	0	0.0
Digestive System	TOTAL	10	16.4	6	9.8	1	1.6
	CONSTIPATION	1	1.6	0	0.0	0	0.0
	DECREASED APPETITE	4	6.6	0	0.0	0	0.0
	DIARRHEA	0	0.0	1	1.6	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	2	3.3	0	0.0	0	0.0
	DYSPEPSIA	0	0.0	3	4.9	0	0.0
	FLATULENCE	2	3.3	0	0.0	0	0.0
	GASTROENTERITIS	1	1.6	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.6	0	0.0
	NAUSEA	2	3.3	3	4.9	1	1.6
	TOOTH CARIES	1	1.6	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	1	1.6	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.6	1	1.6	0	0.0
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0
	LEUKOCYTOSIS	1	1.6	0	0.0	0	0.0
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	2	3.3	0	0.0
	WEIGHT GAIN	0	0.0	1	1.6	0	0.0
	WEIGHT LOSS	0	0.0	1	1.6	0	0.0
Musculoskeletal System	TOTAL	1	1.6	0	0.0	0	0.0
	ARTHRALGIA	1	1.6	0	0.0	0	0.0
Nervous System	TOTAL	12	19.7	21	34.4	4	6.6

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	AGITATION	1	1.6	2	3.3	0	0.0
	ANXIETY	0	0.0	3	4.9	0	0.0
	DEPRESSION	0	0.0	1	1.6	0	0.0
	DIZZINESS	1	1.6	2	3.3	0	0.0
	DYSKINESIA	1	1.6	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	1.6	0	0.0
	HOSTILITY	2	3.3	3	4.9	2	3.3
	HYPERKINESIA	0	0.0	4	6.6	1	1.6
	INSOMNIA	3	4.9	2	3.3	0	0.0
	LACK OF EMOTION	0	0.0	1	1.6	0	0.0
	MANIC REACTION	0	0.0	1	1.6	0	0.0
	MYOCLONUS	1	1.6	0	0.0	0	0.0
	NERVOUSNESS	3	4.9	8	13.1	1	1.6
	PSYCHOSIS	0	0.0	1	1.6	0	0.0
	SOMNOLENCE	0	0.0	1	1.6	0	0.0
	TREMOR	2	3.3	0	0.0	0	0.0
	VERTIGO	1	1.6	0	0.0	0	0.0
Respiratory System	TOTAL	12	19.7	7	11.5	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	ASTHMA	0	0.0	2	3.3	0	0.0
	COUGH INCREASED	0	0.0	1	1.6	0	0.0
	EPISTAXIS	1	1.6	0	0.0	0	0.0
	PHARYNGITIS	3	4.9	1	1.6	0	0.0
	PNEUMONIA	0	0.0	1	1.6	0	0.0
	RESPIRATORY DISORDER	8	13.1	4	6.6	0	0.0
	RHINITIS	3	4.9	1	1.6	0	0.0
	SINUSITIS	1	1.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	6	9.8	1	1.6	0	0.0
	ACNE	2	3.3	0	0.0	0	0.0
	CONTACT DERMATITIS	2	3.3	1	1.6	0	0.0
	HERPES SIMPLEX	1	1.6	0	0.0	0	0.0
	RASH	3	4.9	0	0.0	0	0.0
	SWEATING	1	1.6	0	0.0	0	0.0
	URTICARIA	1	1.6	0	0.0	0	0.0
Special Senses	TOTAL	4	6.6	2	3.3	0	0.0
	ABNORMAL VISION	1	1.6	0	0.0	0	0.0
	EAR PAIN	1	1.6	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	OTITIS EXTERNA	1	1.6	0	0.0	0	0.0
	OTITIS MEDIA	1	1.6	2	3.3	0	0.0
Urogenital System	TOTAL	1	1.6	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.6	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=40), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=21), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	4.8	0	0.0	0	0.0
Urogenital System	TOTAL	1	4.8	0	0.0	0	0.0
	DYSMENORRHEA	1	4.8	0	0.0	0	0.0

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Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	74	58.3	62	48.8	16	12.6
Body as a Whole	TOTAL	35	27.6	25	19.7	2	1.6
	ABDOMINAL PAIN	6	4.7	5	3.9	1	0.8
	ALLERGIC REACTION	4	3.1	2	1.6	0	0.0
	ASTHENIA	5	3.9	3	2.4	0	0.0
	BACK PAIN	3	2.4	1	0.8	0	0.0
	FEVER	3	2.4	2	1.6	0	0.0
	HEADACHE	17	13.4	7	5.5	0	0.0
	INFECTION	6	4.7	8	6.3	1	0.8
	PAIN	1	0.8	2	1.6	0	0.0
	TRAUMA	6	4.7	3	2.4	1	0.8
Cardiovascular System	TOTAL	5	3.9	1	0.8	2	1.6
	ELECTROCARDIOGRAM ABNORMAL	1	0.8	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	0.8
	SYNCOPE	1	0.8	1	0.8	1	0.8
	VASODILATATION	3	2.4	0	0.0	0	0.0
Digestive System	TOTAL	25	19.7	11	8.7	2	1.6
	CONSTIPATION	1	0.8	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	7	5.5	0	0.0	0	0.0
	DIARRHEA	2	1.6	1	0.8	0	0.0
	DRY MOUTH	2	1.6	0	0.0	0	0.0
	DYSPEPSIA	3	2.4	4	3.1	0	0.0
	FLATULENCE	2	1.6	0	0.0	0	0.0
	GASTROENTERITIS	2	1.6	0	0.0	0	0.0
	GASTROINTESTIN-AL DISORDER	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	2	1.6	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.8	0	0.0	0	0.0
	NAUSEA	5	3.9	4	3.1	1	0.8
	TOOTH CARIES	2	1.6	1	0.8	1	0.8
	ULCERATIVE STOMATITIS	1	0.8	0	0.0	0	0.0
	VOMITING	2	1.6	2	1.6	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.6	2	1.6	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Hemic and Lymphatic System	EOSINOPHILIA	0	0.0	1	0.8	0	0.0
	LEUKOCYTOSIS	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	1	0.8	1	0.8	0	0.0
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	3.9	4	3.1	0	0.0
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	5	3.9	2	1.6	0	0.0
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	1	0.8	1	0.8	0	0.0
	ARTHRALGIA	1	0.8	0	0.0	0	0.0
	ARTHROSIS	0	0.0	1	0.8	0	0.0
	MYALGIA	0	0.0	1	0.8	0	0.0
Nervous System	TOTAL	20	15.7	32	25.2	10	7.9
	AGITATION	1	0.8	4	3.1	1	0.8
	ANXIETY	1	0.8	3	2.4	1	0.8
	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	DEPRESSION	1	0.8	1	0.8	0	0.0
	DIZZINESS	3	2.4	2	1.6	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DYSKINESIA	1	0.8	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	3	2.4	1	0.8
	EUPHORIA	0	0.0	0	0.0	1	0.8
	HALLUCINATIONS	0	0.0	1	0.8	1	0.8
	HOSTILITY	2	1.6	4	3.1	3	2.4
	HYPERKINESIA	1	0.8	4	3.1	1	0.8
	HYPESTHESIA	1	0.8	1	0.8	0	0.0
	INSOMNIA	7	5.5	3	2.4	0	0.0
	LACK OF EMOTION	0	0.0	1	0.8	0	0.0
	LIBIDO DECREASED	1	0.8	0	0.0	0	0.0
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	3	2.4	9	7.1	1	0.8
	PARALYSIS	0	0.0	0	0.0	1	0.8
	PSYCHOSIS	0	0.0	1	0.8	0	0.0
	SOMNOLENCE	0	0.0	4	3.1	0	0.0
	TREMOR	2	1.6	1	0.8	0	0.0
	VERTIGO	1	0.8	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	WITHDRAWAL SYNDROME	0	0.0	1	0.8	0	0.0
Respiratory System	TOTAL	30	23.6	17	13.4	1	0.8
	ASTHMA	2	1.6	2	1.6	1	0.8
	BRONCHITIS	0	0.0	3	2.4	0	0.0
	COUGH INCREASED	2	1.6	1	0.8	0	0.0
	EPISTAXIS	3	2.4	0	0.0	0	0.0
	PHARYNGITIS	8	6.3	1	0.8	0	0.0
	PNEUMONIA	0	0.0	2	1.6	0	0.0
	RESPIRATORY DISORDER	16	12.6	9	7.1	0	0.0
	RHINITIS	7	5.5	1	0.8	0	0.0
	SINUSITIS	1	0.8	1	0.8	0	0.0
	YAWN	1	0.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	9	7.1	3	2.4	1	0.8
	ACNE	2	1.6	1	0.8	0	0.0
	CONTACT DERMATITIS	2	1.6	2	1.6	0	0.0
	HERPES SIMPLEX	1	0.8	0	0.0	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	PRURITUS	2	1.6	0	0.0	0	0.0
	RASH	4	3.1	0	0.0	1	0.8
	SWEATING	1	0.8	0	0.0	0	0.0
	URTICARIA	1	0.8	0	0.0	0	0.0
Special Senses	TOTAL	5	3.9	2	1.6	1	0.8
	ABNORMAL VISION	2	1.6	0	0.0	0	0.0
	EAR PAIN	1	0.8	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.8	0	0.0	0	0.0
	OTITIS MEDIA	1	0.8	2	1.6	1	0.8
Urogenital System	TOTAL	5	3.9	0	0.0	1	0.8
	ALBUMINURIA	2	1.6	0	0.0	0	0.0
	CYSTITIS	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.6	0	0.0	0	0.0
	URINARY INCONTINENCE	2	1.6	0	0.0	1	0.8

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=77), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=50), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	6.0	0	0.0	0	0.0
Urogenital System	TOTAL	3	6.0	0	0.0	0	0.0
	DYSMENORRHEA	1	2.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	2.0	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=17), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	23.5	2	11.8	1	5.9
Body as a Whole	TOTAL	0	0.0	0	0.0	1	5.9
	FEVER	0	0.0	0	0.0	1	5.9
Hemic and Lymphatic System	TOTAL	1	5.9	0	0.0	0	0.0
	LEUKOPENIA	1	5.9	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	5.9	0	0.0	0	0.0
	WEIGHT GAIN	1	5.9	0	0.0	0	0.0
Nervous System	TOTAL	1	5.9	2	11.8	0	0.0
	DEPRESSION	1	5.9	1	5.9	0	0.0
	HOSTILITY	0	0.0	1	5.9	0	0.0
Respiratory System	TOTAL	1	5.9	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	5.9	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=10), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=7), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=5), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	20.0	2	40.0	0	0.0
Body as a Whole	TOTAL	1	20.0	0	0.0	0	0.0
	ABDOMINAL PAIN	1	20.0	0	0.0	0	0.0
	HEADACHE	1	20.0	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	20.0	0	0.0
	BRADYCARDIA	0	0.0	1	20.0	0	0.0
Respiratory System	TOTAL	0	0.0	1	20.0	0	0.0
	SINUSITIS	0	0.0	1	20.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=3), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=2), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=22), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	5	22.7	4	18.2	1	4.5
Body as a Whole	TOTAL	1	4.5	0	0.0	1	4.5
	ABDOMINAL PAIN	1	4.5	0	0.0	0	0.0
	FEVER	0	0.0	0	0.0	1	4.5
	HEADACHE	1	4.5	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	4.5	0	0.0
	BRADYCARDIA	0	0.0	1	4.5	0	0.0
Hemic and Lymphatic System	TOTAL	1	4.5	0	0.0	0	0.0
	LEUKOPENIA	1	4.5	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	4.5	0	0.0	0	0.0
	WEIGHT GAIN	1	4.5	0	0.0	0	0.0
Nervous System	TOTAL	1	4.5	2	9.1	0	0.0
	DEPRESSION	1	4.5	1	4.5	0	0.0
	HOSTILITY	0	0.0	1	4.5	0	0.0
Respiratory System	TOTAL	1	4.5	1	4.5	0	0.0
	RESPIRATORY DISORDER	1	4.5	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	4.5	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=13), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=9), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=22), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	13.6	4	18.2	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	4.5	0	0.0
	SYNCOPE	0	0.0	1	4.5	0	0.0
Digestive System	TOTAL	1	4.5	0	0.0	0	0.0
	NAUSEA	1	4.5	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	4.5	0	0.0	0	0.0
	MYALGIA	1	4.5	0	0.0	0	0.0
Nervous System	TOTAL	2	9.1	2	9.1	0	0.0
	DEPRESSION	0	0.0	1	4.5	0	0.0
	HYSTERIA	0	0.0	1	4.5	0	0.0
	SOMNOLENCE	1	4.5	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	4.5	0	0.0	0	0.0
Special Searches	TOTAL	0	0.0	1	4.5	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	4.5	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=17), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=5), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=8), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	12.5	2	25.0	1	12.5
Body as a Whole	TOTAL	0	0.0	0	0.0	1	12.5
	INFECTION	0	0.0	0	0.0	1	12.5
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	12.5	0	0.0
	WEIGHT GAIN	0	0.0	1	12.5	0	0.0
Nervous System	TOTAL	1	12.5	1	12.5	0	0.0
	ABNORMAL DREAMS	1	12.5	0	0.0	0	0.0
	INSOMNIA	0	0.0	1	12.5	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=6), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=2), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=30), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	13.3	6	20.0	1	3.3
Body as a Whole	TOTAL	0	0.0	0	0.0	1	3.3
	INFECTION	0	0.0	0	0.0	1	3.3
Cardiovascular System	TOTAL	0	0.0	1	3.3	0	0.0
	SYNCOPE	0	0.0	1	3.3	0	0.0
Digestive System	TOTAL	1	3.3	0	0.0	0	0.0
	NAUSEA	1	3.3	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	3.3	0	0.0
	WEIGHT GAIN	0	0.0	1	3.3	0	0.0
Musculoskeletal System	TOTAL	1	3.3	0	0.0	0	0.0
	MYALGIA	1	3.3	0	0.0	0	0.0
Nervous System	TOTAL	3	10.0	3	10.0	0	0.0
	ABNORMAL DREAMS	1	3.3	0	0.0	0	0.0
	DEPRESSION	0	0.0	1	3.3	0	0.0
	HYSTERIA	0	0.0	1	3.3	0	0.0
	INSOMNIA	0	0.0	1	3.3	0	0.0
	SOMNOLENCE	1	3.3	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	3.3	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=30), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Searches	TOTAL	0	0.0	1	3.3	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	3.3	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=23), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=7), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	28	56.0	30	60.0	6	12.0
Body as a Whole	TOTAL	10	20.0	15	30.0	3	6.0
	ABDOMINAL PAIN	3	6.0	2	4.0	0	0.0
	ALLERGIC REACTION	3	6.0	1	2.0	0	0.0
	BACK PAIN	0	0.0	2	4.0	0	0.0
	CHEST PAIN	1	2.0	0	0.0	0	0.0
	FACE EDEMA	1	2.0	0	0.0	0	0.0
	FEVER	1	2.0	3	6.0	1	2.0
	HEADACHE	3	6.0	6	12.0	0	0.0
	INFECTION	1	2.0	4	8.0	1	2.0
	TRAUMA	2	4.0	5	10.0	1	2.0
Digestive System	TOTAL	10	20.0	9	18.0	0	0.0
	CONSTIPATION	0	0.0	1	2.0	0	0.0
	DIARRHEA	0	0.0	3	6.0	0	0.0
	DRY MOUTH	3	6.0	0	0.0	0	0.0
	DYSPEPSIA	5	10.0	0	0.0	0	0.0
	INCREASED APPETITE	1	2.0	0	0.0	0	0.0
	NAUSEA	4	8.0	2	4.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	STOMATITIS	0	0.0	1	2.0	0	0.0
	VOMITING	1	2.0	5	10.0	0	0.0
Hemic and Lymphatic System	TOTAL	3	6.0	0	0.0	0	0.0
	LEUKOPENIA	3	6.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	6.0	4	8.0	0	0.0
	WEIGHT GAIN	3	6.0	3	6.0	0	0.0
	WEIGHT LOSS	0	0.0	1	2.0	0	0.0
Musculoskeletal System	TOTAL	1	2.0	0	0.0	0	0.0
	ARTHRALGIA	1	2.0	0	0.0	0	0.0
Nervous System	TOTAL	12	24.0	9	18.0	3	6.0
	AGITATION	0	0.0	1	2.0	1	2.0
	CONVULSION	0	0.0	1	2.0	0	0.0
	DEPRESSION	1	2.0	2	4.0	1	2.0
	DIZZINESS	1	2.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	2.0	0	0.0	2	4.0
	HALLUCINATIONS	1	2.0	0	0.0	0	0.0
	HOSTILITY	0	0.0	3	6.0	1	2.0
	HYPERKINESIA	1	2.0	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	INSOMNIA	1	2.0	0	0.0	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	2.0
	NERVOUSNESS	3	6.0	2	4.0	0	0.0
	SOMNOLENCE	2	4.0	1	2.0	0	0.0
	VERTIGO	1	2.0	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	2.0	0	0.0
Respiratory System	TOTAL	11	22.0	10	20.0	0	0.0
	ASTHMA	0	0.0	1	2.0	0	0.0
	BRONCHITIS	0	0.0	1	2.0	0	0.0
	COUGH INCREASED	1	2.0	0	0.0	0	0.0
	PHARYNGITIS	2	4.0	2	4.0	0	0.0
	RESPIRATORY DISORDER	6	12.0	7	14.0	0	0.0
	RHINITIS	3	6.0	0	0.0	0	0.0
	SINUSITIS	2	4.0	1	2.0	0	0.0
Skin and Appendages	TOTAL	3	6.0	3	6.0	0	0.0
	ACNE	1	2.0	1	2.0	0	0.0
	CONTACT DERMATITIS	1	2.0	1	2.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=50), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	2.0	0	0.0
	RASH	1	2.0	0	0.0	0	0.0
Special Senses	TOTAL	1	2.0	1	2.0	0	0.0
	OTITIS MEDIA	1	2.0	1	2.0	0	0.0
Urogenital System	TOTAL	1	2.0	1	2.0	0	0.0
	ALBUMINURIA	1	2.0	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	2.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=27), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=23), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	26	59.1	23	52.3	4	9.1
Body as a Whole	TOTAL	15	34.1	15	34.1	2	4.5
	ABDOMINAL PAIN	2	4.5	1	2.3	0	0.0
	ABNORMAL LABORATORY VALUE	1	2.3	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	2.3
	ALLERGIC REACTION	2	4.5	1	2.3	0	0.0
	ASTHENIA	1	2.3	2	4.5	0	0.0
	BACK PAIN	1	2.3	0	0.0	0	0.0
	FEVER	2	4.5	1	2.3	0	0.0
	HEADACHE	8	18.2	7	15.9	0	0.0
	INFECTION	2	4.5	4	9.1	1	2.3
	PAIN	1	2.3	1	2.3	0	0.0
	TRAUMA	1	2.3	3	6.8	0	0.0
Cardiovascular System	TOTAL	1	2.3	1	2.3	0	0.0
	BRADYCARDIA	0	0.0	1	2.3	0	0.0
	HAEMATOMA	1	2.3	0	0.0	0	0.0
Digestive System	TOTAL	7	15.9	2	4.5	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	2	4.5	0	0.0	0	0.0
	DIARRHEA	2	4.5	1	2.3	0	0.0
	DYSPEPSIA	2	4.5	0	0.0	0	0.0
	NAUSEA	4	9.1	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	2.3	0	0.0
Hemic and Lymphatic System	TOTAL	1	2.3	0	0.0	0	0.0
	ANEMIA	1	2.3	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	2.3	0	0.0
	WEIGHT GAIN	0	0.0	1	2.3	0	0.0
Musculoskeletal System	TOTAL	2	4.5	1	2.3	0	0.0
	ARTHRALGIA	1	2.3	1	2.3	0	0.0
	MYALGIA	1	2.3	0	0.0	0	0.0
Nervous System	TOTAL	7	15.9	9	20.5	2	4.5
	ANXIETY	1	2.3	1	2.3	0	0.0
	CONCENTRATION IMPAIRED	1	2.3	0	0.0	0	0.0
	DIZZINESS	2	4.5	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	2.3	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	HOSTILITY	1	2.3	1	2.3	0	0.0
	HYPERKINESIA	2	4.5	4	9.1	0	0.0
	INSOMNIA	3	6.8	1	2.3	0	0.0
	MANIC REACTION	0	0.0	1	2.3	0	0.0
	MYOCLONUS	1	2.3	0	0.0	0	0.0
	NERVOUSNESS	1	2.3	1	2.3	0	0.0
	NEUROSIS	3	6.8	0	0.0	1	2.3
	SOMNOLENCE	0	0.0	1	2.3	1	2.3
Respiratory System	TOTAL	7	15.9	5	11.4	1	2.3
	ASTHMA	1	2.3	1	2.3	0	0.0
	COUGH INCREASED	1	2.3	1	2.3	0	0.0
	PHARYNGITIS	1	2.3	0	0.0	1	2.3
	RESPIRATORY DISORDER	1	2.3	2	4.5	0	0.0
	RHINITIS	4	9.1	0	0.0	0	0.0
	SINUSITIS	2	4.5	3	6.8	0	0.0
Skin and Appendages	TOTAL	1	2.3	1	2.3	0	0.0
	ACNE	0	0.0	1	2.3	0	0.0
	MACULOPAPULAR RASH	1	2.3	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=44), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	TOTAL	3	6.8	3	6.8	0	0.0
	BLEPHARITIS	1	2.3	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	2.3	0	0.0
	EYE PAIN	1	2.3	0	0.0	0	0.0
	OTITIS EXTERNA	1	2.3	1	2.3	0	0.0
	OTITIS MEDIA	0	0.0	2	4.5	0	0.0
Urogenital System	TOTAL	3	6.8	0	0.0	0	0.0
	ALBUMINURIA	2	4.5	0	0.0	0	0.0
	DYSURIA	1	2.3	0	0.0	0	0.0
	HAEMATURIA	1	2.3	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	3	13.6	0	0.0
Urogenital System	TOTAL	0	0.0	3	13.6	0	0.0
	DYSMENORRHEA	0	0.0	3	13.6	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	54	57.4	53	56.4	10	10.6
Body as a Whole	TOTAL	25	26.6	30	31.9	5	5.3
	ABDOMINAL PAIN	5	5.3	3	3.2	0	0.0
	ABNORMAL LABORATORY VALUE	1	1.1	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	1.1
	ALLERGIC REACTION	5	5.3	2	2.1	0	0.0
	ASTHENIA	1	1.1	2	2.1	0	0.0
	BACK PAIN	1	1.1	2	2.1	0	0.0
	CHEST PAIN	1	1.1	0	0.0	0	0.0
	FACE EDEMA	1	1.1	0	0.0	0	0.0
	FEVER	3	3.2	4	4.3	1	1.1
	HEADACHE	11	11.7	13	13.8	0	0.0
	INFECTION	3	3.2	8	8.5	2	2.1
	PAIN	1	1.1	1	1.1	0	0.0
	TRAUMA	3	3.2	8	8.5	1	1.1
Cardiovascular System	TOTAL	1	1.1	1	1.1	0	0.0
	BRADYCARDIA	0	0.0	1	1.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	HAEMATOMA	1	1.1	0	0.0	0	0.0
Digestive System	TOTAL	17	18.1	11	11.7	0	0.0
	CONSTIPATION	0	0.0	1	1.1	0	0.0
	DECREASED APPETITE	2	2.1	0	0.0	0	0.0
	DIARRHEA	2	2.1	4	4.3	0	0.0
	DRY MOUTH	3	3.2	0	0.0	0	0.0
	DYSPEPSIA	7	7.4	0	0.0	0	0.0
	INCREASED APPETITE	1	1.1	0	0.0	0	0.0
	NAUSEA	8	8.5	2	2.1	0	0.0
	STOMATITIS	0	0.0	1	1.1	0	0.0
	TOOTH DISORDER	0	0.0	1	1.1	0	0.0
	VOMITING	1	1.1	5	5.3	0	0.0
Hemic and Lymphatic System	TOTAL	4	4.3	0	0.0	0	0.0
	ANEMIA	1	1.1	0	0.0	0	0.0
	LEUKOPENIA	3	3.2	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	3.2	5	5.3	0	0.0
	WEIGHT GAIN	3	3.2	4	4.3	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Metabolic and Nutritional Disorders	WEIGHT LOSS	0	0.0	1	1.1	0	0.0
Musculoskeletal System	TOTAL	3	3.2	1	1.1	0	0.0
	ARTHRALGIA	2	2.1	1	1.1	0	0.0
	MYALGIA	1	1.1	0	0.0	0	0.0
Nervous System	TOTAL	19	20.2	18	19.1	5	5.3
	AGITATION	0	0.0	1	1.1	1	1.1
	ANXIETY	1	1.1	1	1.1	0	0.0
	CONCENTRATION IMPAIRED	1	1.1	0	0.0	0	0.0
	CONVULSION	0	0.0	1	1.1	0	0.0
	DEPRESSION	1	1.1	2	2.1	1	1.1
	DIZZINESS	3	3.2	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.1	1	1.1	2	2.1
	HALLUCINATIONS	1	1.1	0	0.0	0	0.0
	HOSTILITY	1	1.1	4	4.3	1	1.1
	HYPERKINESIA	3	3.2	4	4.3	0	0.0
	INSOMNIA	4	4.3	1	1.1	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	1.1

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	MANIC REACTION	0	0.0	1	1.1	0	0.0
	MYOCLONUS	1	1.1	0	0.0	0	0.0
	NERVOUSNESS	4	4.3	3	3.2	0	0.0
	NEUROSIS	3	3.2	0	0.0	1	1.1
	SOMNOLENCE	2	2.1	2	2.1	1	1.1
	VERTIGO	1	1.1	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	1.1	0	0.0
Respiratory System	TOTAL	18	19.1	15	16.0	1	1.1
	ASTHMA	1	1.1	2	2.1	0	0.0
	BRONCHITIS	0	0.0	1	1.1	0	0.0
	COUGH INCREASED	2	2.1	1	1.1	0	0.0
	PHARYNGITIS	3	3.2	2	2.1	1	1.1
	RESPIRATORY DISORDER	7	7.4	9	9.6	0	0.0
	RHINITIS	7	7.4	0	0.0	0	0.0
	SINUSITIS	4	4.3	4	4.3	0	0.0
Skin and Appendages	TOTAL	4	4.3	4	4.3	0	0.0
	ACNE	1	1.1	2	2.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=94), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	CONTACT DERMATITIS	1	1.1	1	1.1	0	0.0
	HERPES ZOSTER	0	0.0	1	1.1	0	0.0
	MACULOPAPULAR RASH	1	1.1	0	0.0	0	0.0
	RASH	1	1.1	0	0.0	0	0.0
Special Senses	TOTAL	4	4.3	4	4.3	0	0.0
	BLEPHARITIS	1	1.1	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	1.1	0	0.0
	EYE PAIN	1	1.1	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.1	1	1.1	0	0.0
	OTITIS MEDIA	1	1.1	3	3.2	0	0.0
Urogenital System	TOTAL	4	4.3	1	1.1	0	0.0
	ALBUMINURIA	3	3.2	0	0.0	0	0.0
	DYSURIA	1	1.1	0	0.0	0	0.0
	HAEMATURIA	1	1.1	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	1.1	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=49), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=45), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	3	6.7	0	0.0
Urogenital System	TOTAL	0	0.0	3	6.7	0	0.0
	DYSMENORRHEA	0	0.0	3	6.7	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	39	59.1	28	42.4	11	16.7
Body as a Whole	TOTAL	18	27.3	14	21.2	1	1.5
	ABDOMINAL PAIN	2	3.0	2	3.0	0	0.0
	ALLERGIC REACTION	1	1.5	1	1.5	0	0.0
	ASTHENIA	4	6.1	1	1.5	0	0.0
	BACK PAIN	3	4.5	0	0.0	0	0.0
	FEVER	1	1.5	2	3.0	0	0.0
	HEADACHE	8	12.1	2	3.0	0	0.0
	INFECTION	5	7.6	6	9.1	0	0.0
	PAIN	1	1.5	1	1.5	0	0.0
	TRAUMA	2	3.0	3	4.5	1	1.5
Cardiovascular System	TOTAL	2	3.0	1	1.5	1	1.5
	ELECTROCARDIOGRAM ABNORMAL	1	1.5	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	1.5
	SYNCOPE	1	1.5	1	1.5	0	0.0
Digestive System	TOTAL	16	24.2	5	7.6	1	1.5
	DECREASED APPETITE	3	4.5	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	2	3.0	0	0.0	0	0.0
	DYSPEPSIA	3	4.5	1	1.5	0	0.0
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0
	INCREASED APPETITE	2	3.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.5	0	0.0	0	0.0
	NAUSEA	4	6.1	1	1.5	0	0.0
	TOOTH CARIES	1	1.5	1	1.5	1	1.5
	VOMITING	2	3.0	2	3.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.5	1	1.5	0	0.0
	ANEMIA	1	1.5	0	0.0	0	0.0
	LEUKOPENIA	1	1.5	1	1.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	7.6	2	3.0	0	0.0
	DEHYDRATION	0	0.0	1	1.5	0	0.0
	WEIGHT GAIN	5	7.6	1	1.5	0	0.0
Musculoskeletal System	TOTAL	1	1.5	1	1.5	0	0.0
	ARTHROSIS	0	0.0	1	1.5	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	1	1.5	1	1.5	0	0.0
Nervous System	TOTAL	8	12.1	13	19.7	6	9.1
	AGITATION	0	0.0	2	3.0	1	1.5
	ANXIETY	1	1.5	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	1	1.5	1	1.5	0	0.0
	DEPRESSION	0	0.0	1	1.5	0	0.0
	DIZZINESS	2	3.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	3.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	1	1.5
	HALLUCINATIONS	0	0.0	1	1.5	1	1.5
	HOSTILITY	0	0.0	1	1.5	1	1.5
	HYPERKINESIA	1	1.5	0	0.0	0	0.0
	HYPESTHESIA	1	1.5	1	1.5	0	0.0
	HYSTERIA	0	0.0	1	1.5	0	0.0
	INSOMNIA	4	6.1	1	1.5	0	0.0
	LIBIDO DECREASED	1	1.5	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.5	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	PARALYSIS	0	0.0	0	0.0	1	1.5
	SOMNOLENCE	1	1.5	3	4.5	0	0.0
	TREMOR	0	0.0	1	1.5	0	0.0
	WITHDRAWAL SYNDROME	1	1.5	1	1.5	0	0.0
Respiratory System	TOTAL	18	27.3	10	15.2	1	1.5
	ASTHMA	2	3.0	0	0.0	1	1.5
	BRONCHITIS	0	0.0	3	4.5	0	0.0
	COUGH INCREASED	2	3.0	0	0.0	0	0.0
	EPISTAXIS	2	3.0	0	0.0	0	0.0
	PHARYNGITIS	5	7.6	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	1.5	0	0.0
	RESPIRATORY DISORDER	8	12.1	5	7.6	0	0.0
	RHINITIS	4	6.1	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	1.5	0	0.0
	YAWN	1	1.5	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	4.5	2	3.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	CONTACT DERMATITIS	0	0.0	1	1.5	0	0.0
	MACULOPAPULAR RASH	1	1.5	0	0.0	0	0.0
	PRURITUS	2	3.0	0	0.0	0	0.0
	RASH	1	1.5	0	0.0	1	1.5
Special Searches	TOTAL	0	0.0	1	1.5	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	1.5	0	0.0
Special Senses	TOTAL	1	1.5	0	0.0	1	1.5
	ABNORMAL VISION	1	1.5	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	1	1.5
Urogenital System	TOTAL	4	6.1	0	0.0	1	1.5
	ALBUMINURIA	2	3.0	0	0.0	0	0.0
	CYSTITIS	1	1.5	0	0.0	0	0.0
	HAEMATURIA	2	3.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.5	0	0.0	1	1.5

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=37), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=29), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	6.9	0	0.0	0	0.0
Urogenital System	TOTAL	2	6.9	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	3.4	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	3.4	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	35	57.4	35	57.4	6	9.8
Body as a Whole	TOTAL	17	27.9	11	18.0	2	3.3
	ABDOMINAL PAIN	4	6.6	3	4.9	1	1.6
	ALLERGIC REACTION	3	4.9	1	1.6	0	0.0
	ASTHENIA	1	1.6	2	3.3	0	0.0
	BACK PAIN	0	0.0	1	1.6	0	0.0
	FEVER	2	3.3	0	0.0	0	0.0
	HEADACHE	9	14.8	5	8.2	0	0.0
	INFECTION	1	1.6	2	3.3	2	3.3
	PAIN	0	0.0	1	1.6	0	0.0
	TRAUMA	4	6.6	0	0.0	0	0.0
Cardiovascular System	TOTAL	3	4.9	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	1	1.6
	VASODILATATION	3	4.9	0	0.0	0	0.0
Digestive System	TOTAL	10	16.4	6	9.8	1	1.6
	CONSTIPATION	1	1.6	0	0.0	0	0.0
	DECREASED APPETITE	4	6.6	0	0.0	0	0.0
	DIARRHEA	0	0.0	1	1.6	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	2	3.3	0	0.0	0	0.0
	DYSPEPSIA	0	0.0	3	4.9	0	0.0
	FLATULENCE	2	3.3	0	0.0	0	0.0
	GASTROENTERITIS	1	1.6	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.6	0	0.0
	NAUSEA	2	3.3	3	4.9	1	1.6
	TOOTH CARIES	1	1.6	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	1	1.6	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.6	1	1.6	0	0.0
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0
	LEUKOCYTOSIS	1	1.6	0	0.0	0	0.0
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	2	3.3	0	0.0
	WEIGHT GAIN	0	0.0	1	1.6	0	0.0
	WEIGHT LOSS	0	0.0	1	1.6	0	0.0
Musculoskeletal System	TOTAL	1	1.6	0	0.0	0	0.0
	ARTHRALGIA	1	1.6	0	0.0	0	0.0
Nervous System	TOTAL	13	21.3	22	36.1	4	6.6

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ABNORMAL DREAMS	1	1.6	0	0.0	0	0.0
	AGITATION	1	1.6	2	3.3	0	0.0
	ANXIETY	0	0.0	3	4.9	0	0.0
	DEPRESSION	0	0.0	1	1.6	0	0.0
	DIZZINESS	1	1.6	2	3.3	0	0.0
	DYSKINESIA	1	1.6	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	1.6	0	0.0
	HOSTILITY	2	3.3	3	4.9	2	3.3
	HYPERKINESIA	0	0.0	4	6.6	1	1.6
	INSOMNIA	3	4.9	3	4.9	0	0.0
	LACK OF EMOTION	0	0.0	1	1.6	0	0.0
	MANIC REACTION	0	0.0	1	1.6	0	0.0
	MYOCLONUS	1	1.6	0	0.0	0	0.0
	NERVOUSNESS	3	4.9	8	13.1	1	1.6
	PSYCHOSIS	0	0.0	1	1.6	0	0.0
	SOMNOLENCE	0	0.0	1	1.6	0	0.0
	TREMOR	2	3.3	0	0.0	0	0.0
	VERTIGO	1	1.6	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	TOTAL	12	19.7	7	11.5	0	0.0
	ASTHMA	0	0.0	2	3.3	0	0.0
	COUGH INCREASED	0	0.0	1	1.6	0	0.0
	EPISTAXIS	1	1.6	0	0.0	0	0.0
	PHARYNGITIS	3	4.9	1	1.6	0	0.0
	PNEUMONIA	0	0.0	1	1.6	0	0.0
	RESPIRATORY DISORDER	8	13.1	4	6.6	0	0.0
	RHINITIS	3	4.9	1	1.6	0	0.0
	SINUSITIS	1	1.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	6	9.8	1	1.6	0	0.0
	ACNE	2	3.3	0	0.0	0	0.0
	CONTACT DERMATITIS	2	3.3	1	1.6	0	0.0
	HERPES SIMPLEX	1	1.6	0	0.0	0	0.0
	RASH	3	4.9	0	0.0	0	0.0
	SWEATING	1	1.6	0	0.0	0	0.0
	URTICARIA	1	1.6	0	0.0	0	0.0
Special Senses	TOTAL	4	6.6	2	3.3	0	0.0
	ABNORMAL VISION	1	1.6	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=61), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	EAR PAIN	1	1.6	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.6	0	0.0	0	0.0
	OTITIS MEDIA	1	1.6	2	3.3	0	0.0
Urogenital System	TOTAL	1	1.6	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.6	0	0.0	0	0.0

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Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=40), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=21), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	4.8	0	0.0	0	0.0
Urogenital System	TOTAL	1	4.8	0	0.0	0	0.0
	DYSMENORRHEA	1	4.8	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	74	58.3	63	49.6	17	13.4
Body as a Whole	TOTAL	35	27.6	25	19.7	3	2.4
	ABDOMINAL PAIN	6	4.7	5	3.9	1	0.8
	ALLERGIC REACTION	4	3.1	2	1.6	0	0.0
	ASTHENIA	5	3.9	3	2.4	0	0.0
	BACK PAIN	3	2.4	1	0.8	0	0.0
	FEVER	3	2.4	2	1.6	0	0.0
	HEADACHE	17	13.4	7	5.5	0	0.0
	INFECTION	6	4.7	8	6.3	2	1.6
	PAIN	1	0.8	2	1.6	0	0.0
	TRAUMA	6	4.7	3	2.4	1	0.8
Cardiovascular System	TOTAL	5	3.9	1	0.8	2	1.6
	ELECTROCARDIOGRAM ABNORMAL	1	0.8	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	0.8
	SYNCOPE	1	0.8	1	0.8	1	0.8
	VASODILATATION	3	2.4	0	0.0	0	0.0
Digestive System	TOTAL	26	20.5	11	8.7	2	1.6
	CONSTIPATION	1	0.8	0	0.0	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	7	5.5	0	0.0	0	0.0
	DIARRHEA	2	1.6	1	0.8	0	0.0
	DRY MOUTH	2	1.6	0	0.0	0	0.0
	DYSPEPSIA	3	2.4	4	3.1	0	0.0
	FLATULENCE	2	1.6	0	0.0	0	0.0
	GASTROENTERITIS	2	1.6	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	2	1.6	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.8	0	0.0	0	0.0
	NAUSEA	6	4.7	4	3.1	1	0.8
	TOOTH CARIES	2	1.6	1	0.8	1	0.8
	ULCERATIVE STOMATITIS	1	0.8	0	0.0	0	0.0
	VOMITING	2	1.6	2	1.6	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.6	2	1.6	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Hemic and Lymphatic System	EOSINOPHILIA	0	0.0	1	0.8	0	0.0
	LEUKOCYTOSIS	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	1	0.8	1	0.8	0	0.0
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	3.9	4	3.1	0	0.0
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	5	3.9	2	1.6	0	0.0
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	2	1.6	1	0.8	0	0.0
	ARTHRALGIA	1	0.8	0	0.0	0	0.0
	ARTHROSIS	0	0.0	1	0.8	0	0.0
	MYALGIA	1	0.8	1	0.8	0	0.0
Nervous System	TOTAL	21	16.5	35	27.6	10	7.9
	ABNORMAL DREAMS	1	0.8	0	0.0	0	0.0
	AGITATION	1	0.8	4	3.1	1	0.8
	ANXIETY	1	0.8	3	2.4	1	0.8
	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	DEPRESSION	0	0.0	2	1.6	0	0.0

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BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DIZZINESS	3	2.4	2	1.6	0	0.0
	DYSKINESIA	1	0.8	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	3	2.4	1	0.8
	EUPHORIA	0	0.0	0	0.0	1	0.8
	HALLUCINATIONS	0	0.0	1	0.8	1	0.8
	HOSTILITY	2	1.6	4	3.1	3	2.4
	HYPERKINESIA	1	0.8	4	3.1	1	0.8
	HYPESTHESIA	1	0.8	1	0.8	0	0.0
	HYSTERIA	0	0.0	1	0.8	0	0.0
	INSOMNIA	7	5.5	4	3.1	0	0.0
	LACK OF EMOTION	0	0.0	1	0.8	0	0.0
	LIBIDO DECREASED	1	0.8	0	0.0	0	0.0
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	3	2.4	9	7.1	1	0.8
	PARALYSIS	0	0.0	0	0.0	1	0.8
	PSYCHOSIS	0	0.0	1	0.8	0	0.0
	SOMNOLENCE	1	0.8	4	3.1	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	TREMOR	2	1.6	1	0.8	0	0.0
	VERTIGO	1	0.8	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	0.8	1	0.8	0	0.0
Respiratory System	TOTAL	30	23.6	17	13.4	1	0.8
	ASTHMA	2	1.6	2	1.6	1	0.8
	BRONCHITIS	0	0.0	3	2.4	0	0.0
	COUGH INCREASED	2	1.6	1	0.8	0	0.0
	EPISTAXIS	3	2.4	0	0.0	0	0.0
	PHARYNGITIS	8	6.3	1	0.8	0	0.0
	PNEUMONIA	0	0.0	2	1.6	0	0.0
	RESPIRATORY DISORDER	16	12.6	9	7.1	0	0.0
	RHINITIS	7	5.5	1	0.8	0	0.0
	SINUSITIS	1	0.8	1	0.8	0	0.0
	YAWN	1	0.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	9	7.1	3	2.4	1	0.8
	ACNE	2	1.6	1	0.8	0	0.0
	CONTACT DERMATITIS	2	1.6	2	1.6	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES SIMPLEX	1	0.8	0	0.0	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0
	PRURITUS	2	1.6	0	0.0	0	0.0
	RASH	4	3.1	0	0.0	1	0.8
	SWEATING	1	0.8	0	0.0	0	0.0
	URTICARIA	1	0.8	0	0.0	0	0.0
Special Searches	TOTAL	0	0.0	1	0.8	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	0.8	0	0.0
Special Senses	TOTAL	5	3.9	2	1.6	1	0.8
	ABNORMAL VISION	2	1.6	0	0.0	0	0.0
	EAR PAIN	1	0.8	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.8	0	0.0	0	0.0
	OTITIS MEDIA	1	0.8	2	1.6	1	0.8
Urogenital System	TOTAL	5	3.9	0	0.0	1	0.8
	ALBUMINURIA	2	1.6	0	0.0	0	0.0
	CYSTITIS	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.6	0	0.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=127), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	URINARY INCONTINENCE	2	1.6	0	0.0	1	0.8

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=77), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=50), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	6.0	0	0.0	0	0.0
Urogenital System	TOTAL	3	6.0	0	0.0	0	0.0
	DYSMENORRHEA	1	2.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	2.0	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=33), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	7	21.2	3	9.1	0	0.0
Body as a Whole	TOTAL	1	3.0	2	6.1	0	0.0
	ABDOMINAL PAIN	1	3.0	2	6.1	0	0.0
	HEADACHE	1	3.0	1	3.0	0	0.0
Digestive System	TOTAL	1	3.0	1	3.0	0	0.0
	DIARRHEA	1	3.0	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	1	3.0	0	0.0
	NAUSEA	0	0.0	1	3.0	0	0.0
Musculoskeletal System	TOTAL	1	3.0	0	0.0	0	0.0
	MYALGIA	1	3.0	0	0.0	0	0.0
Nervous System	TOTAL	3	9.1	1	3.0	0	0.0
	ANXIETY	0	0.0	1	3.0	0	0.0
	DEPRESSION	1	3.0	0	0.0	0	0.0
	INSOMNIA	1	3.0	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	3.0	0	0.0
	WITHDRAWAL SYNDROME	1	3.0	0	0.0	0	0.0
Respiratory System	TOTAL	3	9.1	1	3.0	0	0.0
	ASTHMA	0	0.0	1	3.0	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=33), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	PHARYNGITIS	1	3.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	3.0	0	0.0	0	0.0
	SINUSITIS	1	3.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=19), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=14), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=12), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	33.3	2	16.7	0	0.0
Body as a Whole	TOTAL	3	25.0	0	0.0	0	0.0
	FEVER	1	8.3	0	0.0	0	0.0
	HEADACHE	1	8.3	0	0.0	0	0.0
	PAIN	1	8.3	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	1	8.3	0	0.0
	PARESTHESIA	0	0.0	1	8.3	0	0.0
	THINKING ABNORMAL	0	0.0	1	8.3	0	0.0
Respiratory System	TOTAL	1	8.3	1	8.3	0	0.0
	RESPIRATORY DISORDER	1	8.3	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	8.3	0	0.0
Special Senses	TOTAL	1	8.3	0	0.0	0	0.0
	EAR PAIN	1	8.3	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=6), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=6), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=45), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	11	24.4	5	11.1	0	0.0
Body as a Whole	TOTAL	4	8.9	2	4.4	0	0.0
	ABDOMINAL PAIN	1	2.2	2	4.4	0	0.0
	FEVER	1	2.2	0	0.0	0	0.0
	HEADACHE	2	4.4	1	2.2	0	0.0
	PAIN	1	2.2	0	0.0	0	0.0
Digestive System	TOTAL	1	2.2	1	2.2	0	0.0
	DIARRHEA	1	2.2	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	1	2.2	0	0.0
	NAUSEA	0	0.0	1	2.2	0	0.0
Musculoskeletal System	TOTAL	1	2.2	0	0.0	0	0.0
	MYALGIA	1	2.2	0	0.0	0	0.0
Nervous System	TOTAL	3	6.7	2	4.4	0	0.0
	ANXIETY	0	0.0	1	2.2	0	0.0
	DEPRESSION	1	2.2	0	0.0	0	0.0
	INSOMNIA	1	2.2	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	2.2	0	0.0
	PARESTHESIA	0	0.0	1	2.2	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=45), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	THINKING ABNORMAL	0	0.0	1	2.2	0	0.0
	WITHDRAWAL SYNDROME	1	2.2	0	0.0	0	0.0
Respiratory System	TOTAL	4	8.9	2	4.4	0	0.0
	ASTHMA	0	0.0	1	2.2	0	0.0
	PHARYNGITIS	1	2.2	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	4.4	0	0.0	0	0.0
	SINUSITIS	1	2.2	1	2.2	0	0.0
Special Senses	TOTAL	1	2.2	0	0.0	0	0.0
	EAR PAIN	1	2.2	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=25), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=20), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=34), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	11.8	5	14.7	0	0.0
Body as a Whole	TOTAL	2	5.9	0	0.0	0	0.0
	ALLERGIC REACTION	1	2.9	0	0.0	0	0.0
	INFECTION	1	2.9	0	0.0	0	0.0
Digestive System	TOTAL	2	5.9	0	0.0	0	0.0
	DIARRHEA	1	2.9	0	0.0	0	0.0
	FECAL INCONTINENCE	1	2.9	0	0.0	0	0.0
	NAUSEA	1	2.9	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	1	2.9	0	0.0
	LYMPHOCYTOSIS	0	0.0	1	2.9	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	2.9	0	0.0
	SGOT INCREASED	0	0.0	1	2.9	0	0.0
Nervous System	TOTAL	0	0.0	2	5.9	0	0.0
	CONCENTRATION IMPAIRED	0	0.0	1	2.9	0	0.0
	HOSTILITY	0	0.0	1	2.9	0	0.0
Respiratory System	TOTAL	1	2.9	2	5.9	0	0.0
	RESPIRATORY DISORDER	1	2.9	2	5.9	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=34), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
Urogenital System	TOTAL	1	2.9	0	0.0	0	0.0
	URINARY INCONTINENCE	1	2.9	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=18), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=16), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=25), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	8.0	4	16.0	1	4.0
Body as a Whole	TOTAL	1	4.0	1	4.0	1	4.0
	HEADACHE	0	0.0	1	4.0	0	0.0
	INFECTION	0	0.0	0	0.0	1	4.0
	TRAUMA	1	4.0	0	0.0	0	0.0
Digestive System	TOTAL	1	4.0	1	4.0	0	0.0
	DIARRHEA	1	4.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	4.0	0	0.0	0	0.0
	NAUSEA	0	0.0	1	4.0	0	0.0
	VOMITING	1	4.0	0	0.0	0	0.0
Respiratory System	TOTAL	0	0.0	1	4.0	0	0.0
	COUGH INCREASED	0	0.0	1	4.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	1	4.0	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	4.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=18), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=7), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=59), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	6	10.2	9	15.3	1	1.7
Body as a Whole	TOTAL	3	5.1	1	1.7	1	1.7
	ALLERGIC REACTION	1	1.7	0	0.0	0	0.0
	HEADACHE	0	0.0	1	1.7	0	0.0
	INFECTION	1	1.7	0	0.0	1	1.7
	TRAUMA	1	1.7	0	0.0	0	0.0
Digestive System	TOTAL	3	5.1	1	1.7	0	0.0
	DIARRHEA	2	3.4	0	0.0	0	0.0
	FECAL INCONTINENCE	1	1.7	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.7	0	0.0	0	0.0
	NAUSEA	1	1.7	1	1.7	0	0.0
	VOMITING	1	1.7	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	1	1.7	0	0.0
	LYMPHOCYTOSIS	0	0.0	1	1.7	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	1.7	0	0.0
	SGOT INCREASED	0	0.0	1	1.7	0	0.0
Nervous System	TOTAL	0	0.0	2	3.4	0	0.0

(CONTINUED)

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=59), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	CONCENTRATION IMPAIRED	0	0.0	1	1.7	0	0.0
	HOSTILITY	0	0.0	1	1.7	0	0.0
Respiratory System	TOTAL	1	1.7	3	5.1	0	0.0
	COUGH INCREASED	0	0.0	1	1.7	0	0.0
	RESPIRATORY DISORDER	1	1.7	2	3.4	0	0.0
Skin and Appendages	TOTAL	0	0.0	1	1.7	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	1.7	0	0.0
Urogenital System	TOTAL	1	1.7	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.7	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=36), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=23), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=36)	Total (N=61)
Body System	Preferred Term			
TOTAL	TOTAL	4 (16.0%)	5 (13.9%)	9 (14.8%)
Nervous System	TOTAL	4 (16.0%)	3 (8.3%)	7 (11.5%)
	HOSTILITY	2 (8.0%)	0	2 (3.3%)
	NERVOUSNESS	2 (8.0%)	0	2 (3.3%)
	AGITATION	1 (4.0%)	1 (2.8%)	2 (3.3%)
	INSOMNIA	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	1 (4.0%)	2 (5.6%)	3 (4.9%)
	DYSPEPSIA	1 (4.0%)	1 (2.8%)	2 (3.3%)
	NAUSEA	0	1 (2.8%)	1 (1.6%)
	VOMITING	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	1 (4.0%)	1 (2.8%)	2 (3.3%)
	URINARY INCONTINENCE	1 (4.0%)	1 (2.8%)	2 (3.3%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=14)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=34)	Total (N=58)
Body System	Preferred Term			
TOTAL	TOTAL	4 (16.7%)	11 (32.4%)	15 (25.9%)
Nervous System	TOTAL	3 (12.5%)	10 (29.4%)	13 (22.4%)
	HYPERKINESIA	3 (12.5%)	1 (2.9%)	4 (6.9%)
	NERVOUSNESS	0	4 (11.8%)	4 (6.9%)
	HOSTILITY	0	3 (8.8%)	3 (5.2%)
	ANXIETY	0	1 (2.9%)	1 (1.7%)
	DYSKINESIA	0	1 (2.9%)	1 (1.7%)
	LACK OF EMOTION	0	1 (2.9%)	1 (1.7%)
	PSYCHOSIS	0	1 (2.9%)	1 (1.7%)
	TREMOR	0	1 (2.9%)	1 (1.7%)
Body as a Whole	TOTAL	1 (4.2%)	2 (5.9%)	3 (5.2%)
	HEADACHE	1 (4.2%)	1 (2.9%)	2 (3.4%)
	ABDOMINAL PAIN	0	1 (2.9%)	1 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.7%)
	WEIGHT GAIN	0	1 (2.9%)	1 (1.7%)

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Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=22)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=12)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=70)	Total (N=119)
Body System	Preferred Term			
TOTAL	TOTAL	8 (16.3%)	16 (22.9%)	24 (20.2%)
Nervous System	TOTAL	7 (14.3%)	13 (18.6%)	20 (16.8%)
	NERVOUSNESS	2 (4.1%)	4 (5.7%)	6 (5.0%)
	HOSTILITY	2 (4.1%)	3 (4.3%)	5 (4.2%)
	HYPERKINESIA	3 (6.1%)	1 (1.4%)	4 (3.4%)
	AGITATION	1 (2.0%)	1 (1.4%)	2 (1.7%)
	TREMOR	0	2 (2.9%)	2 (1.7%)
	ANXIETY	0	1 (1.4%)	1 (0.8%)
	DYSKINESIA	0	1 (1.4%)	1 (0.8%)
	INSOMNIA	0	1 (1.4%)	1 (0.8%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.8%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.8%)
Body as a Whole	TOTAL	1 (2.0%)	2 (2.9%)	3 (2.5%)
	HEADACHE	1 (2.0%)	1 (1.4%)	2 (1.7%)
	ABDOMINAL PAIN	0	1 (1.4%)	1 (0.8%)
Digestive System	TOTAL	1 (2.0%)	2 (2.9%)	3 (2.5%)
	DYSPEPSIA	1 (2.0%)	1 (1.4%)	2 (1.7%)
	NAUSEA	0	1 (1.4%)	1 (0.8%)
	VOMITING	0	1 (1.4%)	1 (0.8%)
Urogenital System	TOTAL	1 (2.0%)	1 (1.4%)	2 (1.7%)
	URINARY INCONTINENCE	1 (2.0%)	1 (1.4%)	2 (1.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.4%)	1 (0.8%)
	WEIGHT GAIN	0	1 (1.4%)	1 (0.8%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=44)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=26)	Total (N=53)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=30)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	3 (12.0%)	3 (10.0%)	6 (10.9%)
Nervous System	TOTAL	3 (12.0%)	3 (10.0%)	6 (10.9%)
	SOMNOLENCE	2 (8.0%)	0	2 (3.6%)
	NERVOUSNESS	1 (4.0%)	1 (3.3%)	2 (3.6%)
	AGITATION	0	1 (3.3%)	1 (1.8%)
	EMOTIONAL LABILITY	0	1 (3.3%)	1 (1.8%)
	INSOMNIA	0	1 (3.3%)	1 (1.8%)
Digestive System	TOTAL	1 (4.0%)	0	1 (1.8%)
	NAUSEA	1 (4.0%)	0	1 (1.8%)
	VOMITING	1 (4.0%)	0	1 (1.8%)
Body as a Whole	TOTAL	0	1 (3.3%)	1 (1.8%)
	ABDOMINAL PAIN	0	1 (3.3%)	1 (1.8%)
	HEADACHE	0	1 (3.3%)	1 (1.8%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=15)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=15)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=27)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	3 (15.0%)	2 (7.4%)	5 (10.6%)
Nervous System	TOTAL	3 (15.0%)	1 (3.7%)	4 (8.5%)
	HOSTILITY	1 (5.0%)	1 (3.7%)	2 (4.3%)
	HYPERKINESIA	1 (5.0%)	1 (3.7%)	2 (4.3%)
	ANXIETY	1 (5.0%)	0	1 (2.1%)
	INSOMNIA	1 (5.0%)	0	1 (2.1%)
	MANIC REACTION	1 (5.0%)	0	1 (2.1%)
	NERVOUSNESS	1 (5.0%)	0	1 (2.1%)
Body as a Whole	TOTAL	1 (5.0%)	0	1 (2.1%)
	ASTHENIA	1 (5.0%)	0	1 (2.1%)
Digestive System	TOTAL	0	1 (3.7%)	1 (2.1%)
	DECREASED APPETITE	0	1 (3.7%)	1 (2.1%)

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Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=18)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=9)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=57)	Total (N=102)
Body System	Preferred Term			
TOTAL	TOTAL	6 (13.3%)	5 (8.8%)	11 (10.8%)
Nervous System	TOTAL	6 (13.3%)	4 (7.0%)	10 (9.8%)
	NERVOUSNESS	2 (4.4%)	1 (1.8%)	3 (2.9%)
	SOMNOLENCE	2 (4.4%)	0	2 (2.0%)
	HOSTILITY	1 (2.2%)	1 (1.8%)	2 (2.0%)
	HYPERKINESIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	INSOMNIA	1 (2.2%)	1 (1.8%)	2 (2.0%)
	ANXIETY	1 (2.2%)	0	1 (1.0%)
	MANIC REACTION	1 (2.2%)	0	1 (1.0%)
	AGITATION	0	1 (1.8%)	1 (1.0%)
	EMOTIONAL LABILITY	0	1 (1.8%)	1 (1.0%)
Body as a Whole	TOTAL	1 (2.2%)	1 (1.8%)	2 (2.0%)
	ASTHENIA	1 (2.2%)	0	1 (1.0%)
	ABDOMINAL PAIN	0	1 (1.8%)	1 (1.0%)
	HEADACHE	0	1 (1.8%)	1 (1.0%)
Digestive System	TOTAL	1 (2.2%)	1 (1.8%)	2 (2.0%)
	NAUSEA	1 (2.2%)	0	1 (1.0%)
	VOMITING	1 (2.2%)	0	1 (1.0%)
	DECREASED APPETITE	0	1 (1.8%)	1 (1.0%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=33)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=24)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=50)	Placebo (N=66)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	7 (14.0%)	8 (12.1%)	15 (12.9%)
Nervous System	TOTAL	7 (14.0%)	6 (9.1%)	13 (11.2%)
	NERVOUSNESS	3 (6.0%)	1 (1.5%)	4 (3.4%)
	AGITATION	1 (2.0%)	2 (3.0%)	3 (2.6%)
	HOSTILITY	2 (4.0%)	0	2 (1.7%)
	SOMNOLENCE	2 (4.0%)	0	2 (1.7%)
	INSOMNIA	0	2 (3.0%)	2 (1.7%)
	EMOTIONAL LABILITY	0	1 (1.5%)	1 (0.9%)
	TREMOR	0	1 (1.5%)	1 (0.9%)
Digestive System	TOTAL	2 (4.0%)	2 (3.0%)	4 (3.4%)
	DYSPEPSIA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	NAUSEA	1 (2.0%)	1 (1.5%)	2 (1.7%)
	VOMITING	1 (2.0%)	1 (1.5%)	2 (1.7%)
Urogenital System	TOTAL	1 (2.0%)	1 (1.5%)	2 (1.7%)
	URINARY INCONTINENCE	1 (2.0%)	1 (1.5%)	2 (1.7%)
Body as a Whole	TOTAL	0	1 (1.5%)	1 (0.9%)
	ABDOMINAL PAIN	0	1 (1.5%)	1 (0.9%)
	HEADACHE	0	1 (1.5%)	1 (0.9%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=37)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=29)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=61)	Total (N=105)
Body System	Preferred Term			
TOTAL	TOTAL	7 (15.9%)	13 (21.3%)	20 (19.0%)
Nervous System	TOTAL	6 (13.6%)	11 (18.0%)	17 (16.2%)
	HYPERKINESIA	4 (9.1%)	2 (3.3%)	6 (5.7%)
	HOSTILITY	1 (2.3%)	4 (6.6%)	5 (4.8%)
	NERVOUSNESS	1 (2.3%)	4 (6.6%)	5 (4.8%)
	ANXIETY	1 (2.3%)	1 (1.6%)	2 (1.9%)
	INSOMNIA	1 (2.3%)	0	1 (1.0%)
	MANIC REACTION	1 (2.3%)	0	1 (1.0%)
	DYSKINESIA	0	1 (1.6%)	1 (1.0%)
	LACK OF EMOTION	0	1 (1.6%)	1 (1.0%)
	PSYCHOSIS	0	1 (1.6%)	1 (1.0%)
	TREMOR	0	1 (1.6%)	1 (1.0%)
Body as a Whole	TOTAL	2 (4.5%)	2 (3.3%)	4 (3.8%)
	HEADACHE	1 (2.3%)	1 (1.6%)	2 (1.9%)
	ASTHENIA	1 (2.3%)	0	1 (1.0%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (1.0%)
Digestive System	TOTAL	0	1 (1.6%)	1 (1.0%)
	DECREASED APPETITE	0	1 (1.6%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.6%)	1 (1.0%)
	WEIGHT GAIN	0	1 (1.6%)	1 (1.0%)

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Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=40)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=21)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=94)	Placebo (N=127)	Total (N=221)
Body System	Preferred Term			
TOTAL	TOTAL	14 (14.9%)	21 (16.5%)	35 (15.8%)
Nervous System	TOTAL	13 (13.8%)	17 (13.4%)	30 (13.6%)
	NERVOUSNESS	4 (4.3%)	5 (3.9%)	9 (4.1%)
	HOSTILITY	3 (3.2%)	4 (3.1%)	7 (3.2%)
	HYPERKINESIA	4 (4.3%)	2 (1.6%)	6 (2.7%)
	AGITATION	1 (1.1%)	2 (1.6%)	3 (1.4%)
	INSOMNIA	1 (1.1%)	2 (1.6%)	3 (1.4%)
	SOMNOLENCE	2 (2.1%)	0	2 (0.9%)
	ANXIETY	1 (1.1%)	1 (0.8%)	2 (0.9%)
	TREMOR	0	2 (1.6%)	2 (0.9%)
	MANIC REACTION	1 (1.1%)	0	1 (0.5%)
	DYSKINESIA	0	1 (0.8%)	1 (0.5%)
	EMOTIONAL LABILITY	0	1 (0.8%)	1 (0.5%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.5%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.5%)
Body as a Whole	TOTAL	2 (2.1%)	3 (2.4%)	5 (2.3%)
	HEADACHE	1 (1.1%)	2 (1.6%)	3 (1.4%)
	ABDOMINAL PAIN	0	2 (1.6%)	2 (0.9%)
	ASTHENIA	1 (1.1%)	0	1 (0.5%)
Digestive System	TOTAL	2 (2.1%)	3 (2.4%)	5 (2.3%)
	DYSPEPSIA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	NAUSEA	1 (1.1%)	1 (0.8%)	2 (0.9%)
	VOMITING	1 (1.1%)	1 (0.8%)	2 (0.9%)
	DECREASED APPETITE	0	1 (0.8%)	1 (0.5%)
Urogenital System	TOTAL	1 (1.1%)	1 (0.8%)	2 (0.9%)
	URINARY INCONTINENCE	1 (1.1%)	1 (0.8%)	2 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.8%)	1 (0.5%)
	WEIGHT GAIN	0	1 (0.8%)	1 (0.5%)

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=77)	Total (N=126)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716
Interim Output
Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=45)	Placebo (N=50)	Total (N=95)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Serious Adverse Event Narratives

716

Table 15.1.9

Interim Report Safety Narratives

SB Document Number: BRL-029060/RSD-101C1T/1

Serious Adverse Event Narratives

PID: **716.004.25405**
Protocol: 29060 716
AEGIS number: 2000036595-1
Study medication: PAROXETINE 20 MG
PAROXETINE 10 MG

Verbatim[preferred term]: LEFT RETROPHARYNGEAL ABSCESS [ABSCESS] (Coded as Abscess [L. Pharyngeal Abscess])

Case reference number 2000036595-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a seven-year-old female (patient identification number 716.004.25405).

The patient previously participated in the double-blind study 29060/704 (patient identification number 704.004.25405).

The patient's medical history and concomitant medications were not provided.

On 06-Jul-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg PO once daily. On 12-Jul-2000, study medication was uptitrated to 20 mg once daily. On 10-Dec-2000, 157 days after the start of study medication and 163 days after uptitration to 20 mg, the patient was hospitalized with a left retropharyngeal abscess. Treatment with study medication was not stopped due to this event. The event resolved on 17-Dec-2000.

The investigator reported the left retropharyngeal abscess as not related to treatment with study medication.

On 02-Jan-2001, the patient completed the study, and received the last dose of open-label treatment phase study medication.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

This white female patient was 8 years old at the time of entry in extension Study 716. The patient’s primary diagnosis was obsessive-compulsive disorder (OCD). The patient entered extension Protocol 716 after completing the double-blind

acute study Protocol 704 (patient identification number 704.004.25405). The patient had been randomised to the paroxetine treatment group in the previous acute double-blind study, Protocol 704.

The serious adverse experience, left retropharygeal abscess, was considered by the investigator to be severe in intensity.

The patient received the last dose study medication at a dose of 20mg/day during the open-label treatment phase of the study on 02 January 2001 (Day 181). The dose was decreased to 10 mg/day (taper phase) on 03 January 2001 and the final dose of 10 mg/day was taken on 09 January 2001 (Day 188).

The patient received numerous concomitant medications during the study including: Augmentin® (amoxicillin trihydrate, clavulanic acid) for prevention of infection; One-A-Day Complete Kid's® multivitamins and multiminerals as dietary supplement; Clarityn® (loratidine) for allergies; Cefzil® (cefprozil monohydrate) for ear ache; Triaminic Triaminicol Cold and Cough Medication®/Triaminic Cough and Cold®/Triaminic Sore Throat Formula®, Children's Sudafed Cough and Cold® (pseudoephedrine hCl, dextromethorphan hydrobromide), and Junior Strength Tylenol® (paracetamol)/Children's Tylenol® (paracetamol) medication for nasal congestion and/or cough, and/or sore throat, and/or headache and/or ear ache and/or pain from abscess; Tylenol® (paracetamol) for headache, leg aches; Tylenol with Codeine (paracetamol, codeine phosphate) for pain secondary to abscess. The following additional medications were prescribed for treatment of retropharyngeal abscess: IV Zinacef® (cefuroxime sodium), IV/Oral Cleocin® (clindamycin hCl), Decadron® (dexamethasone), Fentanyl® (fentanyl), Versed® (midazolam hCl), Morphine Sulfate® (morphine sulfate), metoclopramide and propofol.

Numerous other non-serious adverse experiences were reported during the study. Mild headaches were reported on 19 July 2000 (Day 14), 19 August 2000 (Day 45), 07 October 2000 (Day 94), and 14 November 2000 (Day 132). Moderately severe headaches were reported on 29 November 2000 (Day 147). Headaches resolved with treatment in 1, 1, 18 (5 episodes/18 days), 1, and 48 (9 episodes/48 days) days, respectively. The investigator considered the headache with onset on Day 132 to be unrelated to study medication, headaches on Days 94 and 147 to be probably unrelated, and headaches on Days 14 and 45 to be possibly related to treatment with study medication.

The patient reported mild nausea on 21 July 2000 (Day 16) and on 15 August 2000 (Day 41). Both events resolved without treatment in one day. Onset of

nausea on Day 16 was considered by the investigator to be possibly related to treatment with study medication; onset of nausea on Day 41 was considered to be probably unrelated.

Episodes of mild pain (leg ache) were reported on 02 August 2000 (Day 28), 29 October 2000 (Day 116), 02 November 2000 (Day 120). All were treated and resolved within one day. The investigator considered the event on Day 28 to be

possibly related to treatment with study medication, but the events on Days 116 and 120 to be unrelated to treatment with study medication. On 10 January 2001 (one day after the final taper dose of study medication) the patient again reported mild pain (leg pain) that resolved with treatment in one day. This was considered to be probably unrelated to treatment with study medication.

The patient reported mild dyspepsia (upset stomach) on 06 August 2000 (Day 32), that resolved without treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

Mildly increased cough (cough, cough/congestion), and mild rhinitis (nasal congestion, cough/congestion) each were reported on 06 September 2000 (Day 63) and on 04 December 2000 (Day 152). Each episode resolved with treatment in 3 days (episodes of increased cough, rhinitis on Day 63), and 7 days (episodes of increased cough, rhinitis on Day 152). The investigator considered the episodes of increased cough and rhinitis on Day 63 to be unrelated to treatment with study medication; and the second episodes of increased cough and rhinitis on Day 152 to be probably unrelated. On 08 January 2001 (one day before the final dose of study medication during the taper phase), the patient reported moderately severe sinusitis (sinus infection). This continued through the end of the study reporting period despite corrective therapy. This was considered to be probably unrelated to treatment with study medication by the investigator.

Mild pharygitis (sore throat) was reported on 10 October 2000 (Day 97). This resolved with treatment in one day, and was considered by the investigator to be unrelated to treatment with study medication. Severe pharyngitis (sore throats) was reported on 29 November 2000 (Day 147). This resolved with treatment within 20 days (5 episodes in 20 days), and was considered by the investigator to be unrelated to treatment with study medication.

Moderately severe pain (pain secondary to incision and drainage of abscess) was reported 13 December 2000 (Day 161). This resolved with treatment in three days. The investigator considered this to be probably unrelated to treatment with study medication. Two episodes of mild diarrhea, that lasted one day, were also

reported on Day 161. No treatment was given for this condition which was considered to be probably unrelated to treatment with study medication.

Moderately severe ear pain (bilateral ear aches) was reported on 09 December 2000 (Day 157). Six episodes were reported over a period continuing through the end of the study. On 28 December 2000 (Day 176), moderately severe otitis media (right ear infection) was reported. This also continued through the end of the study. Both events were treated and considered to be probably unrelated to treatment with study medication

No other non-serious adverse experiences were reported during the study.

PID: **716.014.25652**
Protocol: 29060 716
AEGIS number: 2000036931-1
Study medication: PAROXETINE 30 MG
PAROXETINE 10 MG

Verbatim [preferred term]: INCREASED DEPRESSION [DEPRESSION AGGRAVATED]

SUICIDAL IDEATION [SUICIDE ATTEMPT] (Coded as Depression, Emotional Lability [increased depression, suicidal ideation, held knife to chest])

Case reference number 2000036931-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a nine-year-old female (patient identification number 716.014.25652).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number were not provided).

The patient's medical history included obesity. No significant concomitant medication use was reported.

On 11-Sep-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg once daily. On 14-Nov-2000, the dose was uptitrated to 30 mg daily. On 27-Dec-2000, 107 days after starting therapy with study medication and 43 days after uptitration to 30 mg daily, the patient was admitted to the hospital for exacerbation of depressive symptomology and suicidal ideation, with the gesture of holding a knife up to her chest. On 28-Dec-2000, the event was reported as resolved. The patient was withdrawn from the study and received the last dose of study medication on 29-Dec-2000.

The investigator reported the increased depression and suicidal ideation as not related to treatment with study medication and associated with family discord.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 9 year old white female with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number

701.161.25652). The patient had been randomised to the paroxetine treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experiences, Depression, and emotional lability (increased depression, suicidal ideation, held knife to chest) were considered to be severe in intensity by the investigator.

Concomitant medications included Pepto Bismol® (bismuth subsalicylate) for dyspepsia, and Sudafed® (pseudoephedrine hCl) for sinus congestion.

The patient reported several non-serious adverse experiences during the study. On 04 October 2000 (Day 24), the patient experienced mild sinusitis (sinus congestion) that continued through the end of the study despite corrective therapy. The investigator considered this event to be unrelated to treatment with study medication.

The patient reported mild dyspepsia on 13 October 2000 (Day 33) which resolved with treatment in one day. The investigator considered dyspepsia to be unrelated to treatment with study medication.

On 12 November 2000 (Day 63), the patient experienced moderately severe herpes zoster (chicken pox). This resolved without treatment in 11 days and was considered by the investigator to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported.

PID: **716.019.25751**
Protocol: 29060 716
AEGIS number: 2000029901-1
Study medication: PAROXETINE 20 MG
PAROXETINE 10 MG

Verbatim[preferred term]: COMPOUND FRACTURE OF LEFT ARM [INJURY] (Coded as Trauma [fractured left ulna and radius (compound fracture of left arm))

Case reference number 2000029901-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 10-year-old male (patient identification number 716.019.25751).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number were not provided).

The patient's medical history included migraine headaches and seasonal allergies. No relevant concomitant medications were reported.

On 23-Aug-2000, the patient began treatment with flexible dosing study medication, paroxetine 10 mg once daily. On 09-Sep-2001 (2000), the study medication was uptitrated to dose level 20 mg once daily. On 06-Oct-2000, 44 days after the start of study medication and 27 days after uptitration to 20 mg, the patient fell off of a slide and suffered a compound fracture of the left arm. The patient was admitted via the emergency room, and had surgery to set the arm with placement of two pins. Treatment with study medication was not stopped due to this event.

The investigator reported the compound fracture of the left arm as not related to the treatment with study medication.

The patient received his last dose of study medication on 16-Feb-2001.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 10 year old white male with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number

701.178.25751). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, compound fracture of left arm, was considered to be severe in intensity by the investigator and corrective therapy was provided. The duration of the event was reported to be 43 days.

The patient received the last 20 mg/day dose of study medication in the active treatment phase of the study on 16 February 2001 (Day 178). The dose was decreased to 10 mg/day for the taper phase of the study beginning on 17 February 2001 (Day 179). The final dose of 10 mg/day was given on 26 February 2001 (Day 188).

Numerous concomitant medications were given for the compound fracture. These medications included intravenous Fentanyl® (fentanyl), Versed® (midazolam hCl), Zofran® (ondansetron hCl), Mepergan® (pethidine hCl), morphine, and Propofol® (properfol) for orthopedic pin placement in left arm; Tylenol® and Tylenol #3® (paracetamol, paracetamol/codeine phosphate), and IV meperidine for pain secondary to compound fracture; topical Bacitracin®

(bacitracin), topical Benzocaine® (benzocaine), oral Cefhalexin® (cephalexin), and intravenous Cefazolin® (cefazolin) for compound fracture. Additional concomitant medications included Nyquil® (dextromethorphan hydrobromide, doxylamine succinate, paracetamol, pseudoephedrine hCl) for cold symptoms, Advil® (ibuprofen) for headache, and one 20 mg dose of prescription Paxil® (paroxetine) for major depressive disorder (MDD) on 06 October 2000.

Numerous non-serious adverse experiences were reported during the study.

On 24 August 2000 (Day 2), the patient reported mildly decreased appetite (decreased appetite in a.m.) that resolved without treatment in 14 days. The investigator considered this event to be possibly related to treatment with study medication.

On 28 August 2000 (Day 6), the patient reported rhinitis (runny nose), pharyngitis (sore throat), and migraine (migraine headache, emesis secondary to migraine headache). Rhinitis and pharyngitis were reportedly mild in severity, and each of these resolved without treatment in 5 days. Migraine headache was reportedly severe in intensity; emesis was

reported as moderately severe in intensity. Both of these events resolved without treatment in one day. All four adverse experiences were considered to be unrelated to treatment with study medication by the investigator.

On 19 October 2000 (Day 58), the patient experienced a moderately severe infection (infection of orthopedic pins) that resolved with treatment in 15 days. The investigator considered this to be unrelated to treatment with study medication.

On 06 November 2000 (Day 76), the patient reported a moderately severe headache that resolved with treatment in one day. The investigator considered the headache to be probably unrelated to treatment with study medication.

On 11 January 2001 (Day 142), the patient reported a moderately severe respiratory disorder (cold symptoms) that resolved with treatment in 3 days. On 05 March 2001 (7 days after the last dose of study medication in the taper phase of the study), the patient again reported a moderately severe respiratory disorder (upper respiratory infection) that cleared with treatment in 4 days. The investigator considered both of these events to be unrelated to treatment with study medication.

On 19 January 2001 (Day 150), the patient experienced 4 episodes of mild dizziness within 28 days that resolved without treatment. The investigator considered dizziness to be possibly related to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: **716.019.25752**
Protocol: 29060 716
AEGIS number: 2000028184-1
Study medication: PAROXETINE 30 MG
PAROXETINE 10 MG

Verbatim[preferred term]: AUDITORY HALLUCINATIONS [HALLUCINATION] (Coded as Hallucinations [auditory hallucinations]), PARALYSIS OF RIGHT LEG [PARALYSIS] (Coded as Paralysis [temporary paralysis of right leg])

Case reference number 2000028184-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to an 11-year-old male (patient identification number 716.019.25752).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number not provided). The patient's medical history included depression, penicillin allergy, seasonal allergies, vocal cord nodules, and canker sores. Concomitant medications included ibuprofen (Advil).

On 19-Aug-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg once daily. On 09-Sep-2000, study medication was uptitrated to 20 mg once daily. On 18-Sep-2000, 28 days after the start of study medication and nine days after uptitration to 20 mg, the patient was hit in the back with a helmet during football practice. The patient could not feel or move his right leg. He was admitted to the hospital through the emergency room for observation. All routine laboratory tests and X-rays were within normal limits. Movement returned approximately five hours after sustaining the injury. The pediatric neurologist released the patient with a diagnosis of "psychological trauma" not due to any physiological source. The investigator reported the event as resolved the same day, 18-Sep-2000. Treatment with study medication was not interrupted due to this event.

The investigator reported the temporary paralysis of the leg as disabling and incapacitating and not related to treatment with study medication.

On 17-Oct-2000, the patient's dosage was uptitrated to 30 mg once daily. On 24-Oct-2000, the patient's mother learned that the patient had told a school counselor that a child in the neighborhood had a "hit list" and that the children in his

physical education class were trying to "trip and choke him."On 25-Oct-2000, 67 days after receiving the first treatment with study medication and eight days after uptitration to 30 mg, the patient was seen bythe investigator to assess these allegations. The patient became very irritated and agitated, and ran off. The patient was found and returned home with his parents. Later that day, the patient complained of auditory hallucinations. He reportedly heard voices telling him to "run away" and that "nobody loves you." The patient was hospitalized that evening in a private psychiatric inpatient hospital for evaluation. As of 18-Jun-2001, the event was reported as ongoing. Treatment with study medication was discontinued on 25-Oct-2000 due to this event, and the patient was withdrawn from the study.

The investigator reported the auditory hallucinations as unlikely to be related to treatment with study medication, and probably associated with possible bipolar disorder, incompletely treated depression, or intermittent explosive disorder.

December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.

Patient is a 11 year old white male with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number 701.178.25752). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, hallucinations (auditory hallucinations), was considered to be moderately severe in intensity by the investigator and no corrective therapy was recorded (confirmation regarding corrective therapy is pending). The serious adverse experience, paralysis (temporary paralysis of right leg) was considered to be severe in intensity by the investigator.

The patient received the last 20 mg/day dose of study medication in the active treatment phase of the study on 16 October 2000 (Day 59). The dose was up-titrated to 30 mg/day on 17 October 2000 (Day 60) and the final dose of study medication (30 mg/day) was given on 25 October 2000 (Week 12; Day 68). The taper phase of the study began on 26 October 2000, at which time the patient was down-titrated to 10 mg/day. The final dose of 10 mg/day was given on 27 October 2000 (Day 70).

Concomitant medications included Xanax® (alprazolam) as prophylaxis for MRI, Benedryl® (diphenhydramine hCl) for spider bite, Advil® (ibuprofen) for left

elbow pain due to secondary joint infusion; muscle soreness; and pain in left fingers, and Nasonex® nasal spray (mometasone furoate) for cold.

Several other non-serious adverse experiences were reported during the study. On 20 August 2000 (Day 2), the patient reported mild dyspepsia (upset stomach) that resolved without treatment in one day. The investigator considered this to be possibly related to treatment with study medication.

On 21 August 2000 (Day 3), the patient reported moderately severe pain (pain in left fingers) that resolved with treatment in 7 days. The investigator considered this event to be unrelated to treatment with study medication.

On 11 September 2000 (Day 24), the patient reported moderately severe myalgia (general muscle soreness) that resolved with treatment in 5 days. The investigator considered this to be unrelated to treatment with study medication.

On 18 September 2000 (Day 31), the patient reported moderately severe arthosis (pain in left elbow secondary to joint effusion), and moderately severe hypesthesia (right leg numbness). Arthrosis resolved with treatment in 6 days, and hypesthesia resolved without treatment in 3 days. On 19 September 2000 (Day 32) the patient reported mild back pain that cleared without treatment in 9 days. The investigator considered all three events to be unrelated to treatment with study medication.

On 23 September 2000 (Day 36), the patient reported mild respiratory disorder (cold symptoms) that continued through the end of the study reporting period. No corrective therapy was given for this event, that the investigator considered to be unrelated to treatment with study medication.

On 27 September 2000 (Day 40), the patient reported severe euphoria (disinhibition; Xanax® reaction) that resolved without treatment in one day. The investigator considered this to be probably unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID:	**716.020.25458**
Protocol:	29060 716
AEGIS number:	2000034535-1
Study medication:	PAROXETINE 50 MG
	PAROXETINE 10 MG

Verbatim[preferred term]: PSYCHOSIS NOS [PSYCHOSIS] (Coded as Psychosis [Psychosis Nos])

Case reference number 2000034535-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder. This report refers to an 11-year-old female (patient identification number 716.020.25458).

The patient previously participated in the double-blind study 29060/704(patient identification number 704.004.25405). INCORRECT PREVIOUS PID – see below. No relevant medical history or concomitant medication use was indicated.

On 19-Sep-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg PO once daily. On 10-Oct-2001 (2000), study medication was uptitrated to 50 mg once daily. On 24-Nov-2000, 66 days after receiving the first treatment with study medication and 45 days after uptitration to 50 mg, the patient presented to the site with superficial cuts and burns to her left hand. The patient did not present as suicidal or homicidal. The patient was voluntarily admitted to a hospital by her parents with complaints of auditory, visual, and tactile hallucinations, as well as self-injurious behavior. The patient tolerated the admission well, and was comfortable with the procedure. Treatment with study medication was stopped on 24-Nov-2000. The patient was treated with risperidone (Risperdal). The final diagnosis was psychosis {NOS}. As of 04-Dec-2000, an outcome of the event was not provided.

The investigator reported the psychosis {NOS} as probably unrelated to treatment with study medication.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 11 year old white female with a primary diagnosis of obsessive-compulsive disorder (OCD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 704 (patient identification

number 704.020.25458). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 704.

The serious adverse experience, psychosis (psychosis, nos), was considered to be moderately severe in intensity by the investigator.

The patient was up-titrated from 10 mg/day (started on 19 September) to 20 mg/day on 21 September 2000 (Day 3), then to 30 mg/day on 26 September 2000 (Day 8), then to 40 mg/day on 03 October 2000 (Day 15), then to the highest dose of 50 mg/day on 10 October 2000 (Day 28). The patient remained at 50 mg/day through the end of the study (final dose was given on 24 November 2000; Day 67).

Concomitant medications included risperidone for psychotic episode. Prescription Paxil® (paroxetine) was given post-study for OCD.

No non-serious adverse experiences were reported during the study.

PID:	**716.025.25802**
Protocol:	29060 716
AEGIS number:	2000027696-1
Study medication:	PAROXETINE 30 MG
	PAROXETINE 10 MG

Verbatim[preferred term]: HOMICIDAL MUTILATION TO SELF {OUTBURST OF ANGER}[AGGRESSIVE REACTION] (Coded as Hostility [Homicidal Ideation])

Case reference number 2000027696-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 12-year-old male (patient identification number 716.025.25802).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number were not provided).

Relevant medical history and concomitant medications were not provided at the time of this report.

On 07-Aug-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg once daily. On 22-Aug-2000, study medication was uptitrated to 30 mg once daily. On 17-Sep-2000, 41 days after the first dose of study medication and 26 days after the dose was uptitrated to 30 mg daily, the patient experienced an outburst of anger, where he put a BB gun to his mom's head and stated that he was going to hurt somebody. It was reported that the patient has had these intermittent outbursts in the past and felt remorseful afterwards. The patient started that he would like to get more help. He has also been self-mutilating by picking at skin on his hands until bleeding and sore. The final diagnosis was suicidal mutilation to self. Treatment with study medication was stopped on 17-Sep-2000 due to this event, and study medication was not re-introduced. The event was reported to be resolved on 22-Sep-2000.

The investigator reported the suicidal mutilation to self as not related to treatment with study medication, but associated with another condition (not specified).

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 12 year old white male with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number 701.181.25802). The patient had been randomized to the paroxetine treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, hostility (homicidal ideation), was considered to be severe in intensity by the investigator, and unrelated to treatment with study medication. The patient was given Celexa® (citalopram) for homicidal mutilation of self, beginning on 17 September 2000 (Day 42; last day of treatment with study medication).

The patient was up-titrated from 10 mg/day (started on 07 August 2000) to 20 mg/day on 11 August 2000 (Day 5), then to 30 mg/day on 22 August 2000 (Day 16). The patient remained at 30 mg/day through the end of the study (final dose was given on 17 September 2000; Day 42).

Concomitant medication (in addition to Celexa®, noted above) included Claritin® (loratidine) for seasonal allergies, and Vioxx® for achilles tendonitis.

Further information regarding non-serious adverse events of seasonal allergies and Achilles tendonitis is pending confirmation from the site.

PID:	**716.028.27683**
Protocol:	29060 716
AEGIS number:	2001007400-1
Study medication:	PAROXETINE 20 MG
	PAROXETINE 10 MG

Verbatim[preferred term]: ACUTE EXACERBATION OF MAJOR DEPRESSIVE DISORDER [DEPRESSION AGGRAVATED] (Coded as Depression [Acute Exacerbation of Major Depressive Disorder])

Case reference number 2001007400-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 12-year-old female (patient identification number 716.028.27683).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number were not provided).

The patient's medical history included recurrent headaches, environmental allergies, recurrent sore throat, and asthma. The patient had no significant concomitant medication use.

On 30-Dec-2001 (=2000), the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg PO once daily. On 09-Feb-2001, study medication was uptitrated to 30 mg daily. After the dose change at visit eight, the patient decompensated with increased irritability, was withdrawn, impulsive, and the patient pulled out her eyelashes and eyebrow hairs (not reported as serious adverse events). A decision was made for early withdrawal of the patient from the study. On 20-Feb-01, study medication was decreased to 20 mg daily and the patient received the last dose on 05-Mar-2001. On 16-Mar-2001, 11 days after the patient received the last dose of study medication, the patient was hospitalized due to an exacerbation of major depressive disorder. The event was reported to be resolved on 20-Mar-2001.

The investigator reported the exacerbation of major depressive disorder as not related to treatment with study medication, and associated the event with psychosocial factors and the patient's family/living situation.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 12 year old black female with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number 701.185.27683). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, depression (acute exacerbation of major depressive disorder), was considered to be moderately severe in intensity by the investigator. Corrective therapy was given for depression.

The patient received the last dose of study medication (20 mg/day) on 05 March 2001, in the active treatment phase of the study. The patient was down-titrated to 10 mg/day on 06 March 2001 (Day 77).

Concomitant medication included Zithromax® (azithromycin), Tylenol® (paracetamol), and Tylenol PM®, for sinus infection; Diflucan® (fluconazole) for yeast infection; Tylenol® (paracetamol) for flu, fever, recurrent headache; Tigan® (trimethobenzamide) for nausea and vomiting; Allegra® (fexofenadine hCl) for seasonal allergies; Albuterol® (salbutamol) for asthma, and Paxil® (paroxetine) for depression.

Several non-serious adverse experiences were reported during the study. The onset of a mild respiratory disorder (upper respiratory infection) was reported 5 days before the first dose of study medication was taken in Protocol 716, and the onset of mild myalgia (musculoskeletal pain) was reported one day before the first dose of study medication in this study. Both resolved in one day after the first dose of study medication was given, no corrective therapy was given for either, and the investigator considered both to be unrelated to treatment with study medication.

On 18 January 2001 (Day 20), the patient reported a mild infection (flu) that resolved with treatment in 2 days. The investigator considered flu to be unrelated to treatment with study medication.

On 03 February 2001 (Day 36), the patient experienced moderately severe nausea and mildly severe vomiting (4 episodes over 7 days) that resolved with treatment in 15 days, and 7 days, respectively. The dose of study medication was decreased in response to these conditions. The investigator considered nausea to be probably unrelated, and vomiting to be possibly related to treatment with study medication.

On 06 February 2001 (Day 39), the patient reported the onset of mild fever, and moderately severe sinusitis, each of which cleared with treatment in 2 days, and 5 days, respectively. Both were considered to be unrelated to treatment with study medication by the investigator.

On 27 February 2001 (Day 60), the patient reported the onset of a mild infection (yeast infection) that resolved with treatment in 7 days. The investigator considered the yeast infection to be unrelated to treatment with study medication.

On 28 February 2001 (Day 61), the patient experienced the onset of mild depression (plucking own eyelashes/brows) that resolved without treatment in one day. The investigator considered depression to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

The patient was withdrawn from the study for lack of efficacy.

PID: **716.028.27685**
Protocol: 29060 716
AEGIS number: 2001006352-1
Study medication: PAROXETINE 20 MG
PAROXETINE 10 MG

Verbatim[preferred term]: AGGRESSION [AGGRESSIVE REACTION] (Coded as Hostility [aggression])

Case reference number 2001006352-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to an 11-year-old female (patient identification number 716.028.27685).

The patient previously participated in the double-blind portion of the study 29060/701 (patient identification number 701.185.27685).

The patient's medical history included Major Depressive Disorder (MDD), headaches, and gastric upset. The patient had no concomitant medication use.

On 01-Feb-2001, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg PO once daily. On 08-Feb-2001, study medication was up-titrated to 20 mg once daily. On 08-Mar-2001, 35 days after the first dose of study medication and 28 days after up-titration, the patient's therapist reported that the patient was "out of control", acting out, and unsafe to herself and others. The patient was admitted to the hospital for evaluation of her aggression. On 13-Mar-2001, the event was reported as resolved. The study medication was discontinued due to the event, and the investigator site could not confirm if the patient was taking her study medication as instructed.

The investigator reported the aggression as not related to treatment with study medication, and associated with psychosocial factors.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 11 year old black female with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number 701.185.27685). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, hostility (aggression), was considered to be moderately severe in intensity by the investigator. Corrective therapy was given for this condition.

The patient received the 20 mg/day dose of study medication from 08 February 2001 (Day 8) to 07 March 2001 (Day 35), which is the last day of study medication.

Concomitant medication included children's vitamins (non-specified) for prophylaxis, Robitussin DM® (dextromethorphan hydrobromide, ethanol, guaifenesin) for cough and cold, and aspirin (acetasalicylic acid) for headache.

Mild respiratory disorder (recurrent upper respiratory infection) was reported on 30 November 2000 (Day –62) before the study of study medication in Protocol 716. The respiratory infection resolved with treatment in 68 days (by 06 February 2001), and was considered by the investigator to be unrelated to treatment with study medication.

On 15 March 2001 (Day 43; 8 days after the last dose of study medication), mild urinary incontinence (incontinence stool, urine), mild fecal incontinence (incontinence stool, urine), and moderately severe increased SGOT (elevated liver enzymes) were reported. Urinary incontinence was treated, fecal incontinence was not treated; both resolved in 12 days. Increase in SGOT continued through the end of the study reporting period. Urinary and fecal incontinence were considered to be unrelated to treatment with study medication by the investigator; elevated SGOT was considered to be possibly related to treatment with study medication. All, with one exception, (noted below) abnormal laboratory results are shown in the table below. All other laboratory test results were within normal range, except for a slightly decreased absolute lymphocyte count of 0.8 10^9/L (normal range, 0.85 – 4.1 10^9/L) noted at screening in the previous acute study 701.

Selected Laboratory Values – Protocol 716 (Patient 716.028.27685)				
Analyte	Screening (701) (Day –82)	Week 4 (Day 28)	Week 6 (Day 42)*	Post-Week 24 (Day 219)
Alkaline Phosphatase (IU/L) (normal range = 60-415 IU/L)	457.0	432.0	412.0	359.0
Aspartate Aminotransferase (IU/L) (normal range, 0 –42 IU/L)	47.0	51.0	82.0	48.0
Alanine Aminotransferase (IU/L) (normal range, 0-45 IU/L)	17.0	18.0	64.0	20.0

*non-serious AE = elevated liver enzymes reported with onset on Day 43

No other non-serious adverse experiences were reported during the study period.

PID:	**716.044.27656**
Protocol:	29060 716
AEGIS number:	2001001028-1
Study medication:	PAROXETINE 50 MG
	PAROXETINE 20 MG

Verbatim[preferred term]: SUICIDAL [SUICIDE ATTEMPT](Coded as Emotional Lability [Suicidal])

Case report number 2001001028-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 13-year-old male (patient identification number 716.044.27656).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number not reported).

The patient's medical history included borderline hypertension, hypertrophic cardiomyopathy, heart murmur, spinal meningitis, and allergies to clarithromycin (Biaxin) and cefaclor (Ceclor). Concomitant medications were not provided.

On 08-Nov-2000, the patient initiated treatment with flexible-dosing study medication, paroxetine 20 mg daily. On 08-Dec-2000, study medication was uptitrated to 50 mg daily. The patient was seen for his regular clinic visit and stated that on 16-Dec-2000, 38 days after the start of treatment with study medication and eight days after uptitration to 50 mg, he attempted suicide. Multiple scratches were noted over both forearms and chest wall, which the patient claimed, were made with a knife. The patient was admitted to the hospital at that time, and treated with olanzapine (Zyprexa) and clonidine (Catapress). On 22-Dec-2000, the event resolved, and the patient was discharged from the hospital. Treatment with study medication was stopped due to this event.

The investigator reported the suicidal event as not related to treatment with study medication, and to be associated with severe parent/child dysfunction.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 13-year-old black male with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number

701.149.27656). The patient had been randomized to the paroxetine treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, emotional lability (suicidal), was considered to severe in intensity by the investigator.

The patient received the 20 mg/day dose of study medication from 08 November 2000 (first dose) to 16 November 2000 (Day 7); the dose was increased to 30 mg/day on 17 November 2000 (Day 8); then increased to 40 mg/day on 01 December 2000 (Day 24); then increased to 50 mg/day on 08 December 2000 (Day 31). The last dose of study medication was taken on 20 December 2000 (Day 43).

Concomitant medication included prescription Paxil® (paroxetine), Catapres® (clonidine hCl), and Zyprexa® (olanzapine) for “suicidal”.

On 20 December 2000 (Day 43), the patient experienced a severe lack of emotion (flat effect, dysphoric) that continued through the end of the reporting period. No corrective therapy was given for this non-serious event, that the investigator considered to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported.

PID:	**716.049.28149**
Protocol:	29060 716
AEGIS number:	2001017308-1
Study medication:	PAROXETINE 50 MG
	PAROXETINE 10 MG

Verbatim[preferred term]: OVERDOSE {ACCIDENTAL} {ASYMPTOMATIC} [THERAPEUTIC RESPONSE INCREASED] (Coded as Abnormal Laboratory Value [Unintentional Overdose]).

Case reference number 2001017308-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 14-year-old male (patient identification number 716.049.28149).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number not reported).

The patient's medical history included a small lump behind left nipple. The patient had no concomitant medication use.

On 17-Apr-2001, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg daily. From 22-May-2001 until 12-Jul-2001, the patient received paroxetine 50 mg daily. On 12-Jul-2001, 86 days after starting therapy with study medication and 51 days after uptitration to dose level 50 mg, the patient inadvertently dosed twice with study medication. At 8:00 AM on 12-Jul-2001, one of the patient's parents woke the patient to remind him to take his study medication, and he took five pills (50 mg). At 12 noon, the other parent called the patient and reminded him to take his study medication. The patient forgot that he took it in the morning and he took a second dose of study medication (five pills = 50 mg). The patient was evaluated by a physician and it was noted he had no side effects from the overdose. The patient was diagnosed with unintentional, asymptomatic overdose. The event was reported as resolved the same day, 12-Jul-2001. Treatment with study medication was not stopped due to this event.

The investigator reported the unintentional, asymptomatic overdose as unrelated to treatment with study medication, and probably due to the subject's inadvertent error in carrying out the dosing procedure.

December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.

Patient is a 14 year old white male with a primary diagnosis of obsessive compulsive disorder (OCD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 704 (patient identification number 701.049.28149). The patient had been randomized to the paroxetine treatment group in the previous acute double-blind study, Protocol 704.

The serious adverse experience, abnormal laboratory screening (unintentional overdose), was considered to be mild in intensity by the investigator.

The patient received the 10 mg/day dose of study medication from 17 April 2001 (first dose) to 23 April 2001 (Day 7). The dose was up-titrated to the highest dose of 50 mg/day on 22 May 2001 (Day 36) and remained at that dose until 10 August 2001 (final dose of study medication).

Concomitant medication included Benedryl® (diphenhydramine hCl) for seasonal allergy, Sudafed® (pseudoephedrine hCl) for URI, and Exlax® (yellow phenolphthalein) taken by the patient “as a joke”.

Two non-serious adverse experiences were reported during the study. On 22 April 2001 (Day 5), the patient reported the onset of moderately severe respiratory disorder (URI) that resolved without treatment in 9 days. The investigator considered the URI to be unrelated to treatment with study medication.

On 27 May 2001 (Day 41), the patient experienced the onset of a moderately severe allergic reaction (seasonal allergies/sinus) that resolved with treatment in one day. This event was considered to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: **716.151.25607**
Protocol: 29060 716
AEGIS number: 2000029447-1
Study medication: PAROXETINE 30 MG
PAROXETINE 10 MG

Verbatim[preferred term]: SUICIDE ATTEMPT [SUICIDE ATTEMPT] (Coded as Emotional Lability [Hospitalized for Suicide Attempt])

Case reference number 2000029447-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 16-year-old female (patient identification number 716.151.25607).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number not provided).

The patient had no significant medical history. Concomitant medications included fexofenadine (Allegra) and loratadine (Claritin).

On 30-Jun-2000, the patient initiated treatment with flexible dosing study medication, paroxetine 10 mg once daily. On 21-Sep-2000, the study medication was uptitrated to 30 mg daily. On 02-Oct-2000, 94 days after starting therapy with study medication and 11 days after uptitration to 30 mg, the patient ingested thirty ibuprofen. The patient became frightened and informed her mother, who then administered (ipecacuanha) Ipecac. On 02-Oct-2000, the patient was evaluated by the investigator, and was admitted to the hospital for psychiatric care. The last dose of study medication was on 02-Oct-2000. During hospitalization, the patient was given prescription paroxetine (Paxil) at a dose of 40 mg. On 04-Oct-2000, the event was reported as resolved and the patient was discharged from the hospital.

The investigator reported the suicide attempt as not related to treatment with study medication, and associated with "major depression".

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 16 year old white female with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number

701.151.25607). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, emotional lability (hospitalised for suicide attempt), was considered to be severe in intensity by the investigator.

The patient received the 10 mg/day dose of study medication from 30 June 2000 (first dose) to 14 July 2000 (Day 15). The dose was up-titrated to the highest dose of 30 mg/day on 21 September 2000 (Day 84) and remained at that dose until 02 October 2000 (final dose of study medication).

Concomitant medication included Tylenol® (paracetamol) for facial pain, and prescription Paxil® (paroxetine) for depression.

Two non-serious adverse experiences were reported during the study. On 14 July 2000 (Day 15), the patient reported the onset of mild asthenia (tiredness) that was not treated, and continued through the end of the study reporting period. On 01 August 2000 (Day 33), the patient experienced mild pain (facial pain) that resolved with treatment in 4 days. The investigator considered the asthenia to be possibly related to treatment with study medication and the pain to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID:	**716.176.27678**
Protocol:	29060 716
AEGIS number:	2001011534-1
Study medication:	PAROXETINE 40 MG
	PAROXETINE 50 MG

Verbatim[preferred term]: WORSENING OF ASTHMA [ASTHMA] (Coded as Asthma [worsening of asthma])

Case report number 2001011534-1 is a clinical trial report from open-label extension study 29060/716 to Assess the Long Term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a nine-year-old male (patient identification number 716.176.27678).

The patient previously participated in the double-blind portion of the study (protocol and patient identification number not reported).

The patient's medical history included asthma and seasonal allergic rhinitis. Concomitant medications included guaifenesin (Robitussin) and naphazoline HCL/antazline phosphate (Vasocon-A).

On 24-Jan-2001, the patient initiated treatment with flexible dosing study medication, paroxetine 40 mg once daily. On 08-May-2001, 105 days after the start of study medication, a chest x-ray was performed and the patient was hospitalized with a diagnosis of worsening asthma. The patient was treated with prednisone. On 10-May-2001, the event was reported as resolved. No action was taken with respect to study medication.

The investigator reported the worsening asthma as not related to treatment with study medication.

On 13-Jun-2001, the patient was uptitrated to dose level 50 mg. On 10-Jul-2001, the patient completed the study, and received the last dose of study medication.

<u>December 18, 2001: Additional clarifying information, available at time of interim reporting, is provided below.</u>

Patient is a 9 year old white male with a primary diagnosis of major depressive disorder (MDD). The patient entered extension Protocol 716 after completing the double-blind acute study Protocol 701 (patient identification number

701.176.27678). The patient had been randomized to the placebo treatment group in the previous acute double-blind study, Protocol 701.

The serious adverse experience, asthma (worsening of asthma), was considered to be severe in intensity by the investigator.

The patient received a 40 mg/day dose of study medication from 24 January 2001 (first dose) to 12 June 2001 (Day 140). The dose was up-titrated to the highest dose of 50 mg/day on 13 June 2001 (Day 141) and remained at that dose until 10 July 2001 (final dose of study medication in the active treatment phase). The dose of study medication was gradually down-titrated to 10 mg/day during the taper phase of the study; the final dose of study medication was taken on 06 August 2001 (Day 195)

Concomitant medication included Children's Tylenol® (paracetamol) and Robitussin® (guaifenesin) for upper respiratory infection; hydroxyzine and Pediapred® (prednisolone sodium phosphate) for poison ivy rash; Vasocon-A® (antazoline phosphate, naphazoline hCl) eyedrops for allergic ocular irritation; Flonase® inhaler (fluticasone propionate) and Claritin Reditabs® (loratidine) for seasonal allergic rhinitis; Albuterol® (salbutamol) inhalation and Serevent® (salmeterol hydroxynaphthoate) inhalation for asthma, and IV Rocephin® (ceftriaxone sodium), IV Solu-Medrol® (methylprednisolone sodium succinate), and prednisone for worsening asthma; and Benedryl® (diphenhydramine hCl) for allergy testing discomfort.

Several other non-serious adverse experiences were reported during the study. Mild allergic reaction (seasonal allergic rhinitis), and mild asthma, in addition to tooth caries were all reportedly continuing through the study reporting period of Protocol 716 from 01 January 1993. Corrective treatment was given for all; all were considered to be unrelated to treatment with study medication.

Mild respiratory disorder (upper respiratory infection) was reported on 30 January 2001 (Day 7), and moderately severe respiratory disorder (upper respiratory infection) was reported on 16 February 2001 (Day 24). Both were treated and resolved in 5 days, and 6 days, respectively. Moderately severe respiratory disorder (cold) was reported on 29 April 2001 (Day 96). This was treated and resolved in 10 days. The investigator considered all three reports of respiratory disorder to be unrelated to treatment with study medication.

On 27 May 2001 (Day 124), the patient reported the onset of moderately severe contact dermatitis (poison ivy rash) that resolved with treatment in 14 days. The

investigator considered this event to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported.

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Narratives for Patients with Non-Serious Adverse Events Leading to Withdrawal

716

Table 15.1.10

Interim Report Safety Narratives

SB Document Number: BRL-029060/RSD-101C1R/1

Narratives for Patients with Non-Serious Adverse Events Leading to Withdrawal

PID: 716.004.25403

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hyperkinesia (Hyperactivity), Manic Reaction (Hypomanic Symptoms)

This 10-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.004.25403), and received treatment with placebo in that study.

Concomitant medications included Advil® (ibuprofen) for otitis externa, Nasocort® (budesonide) nasal spray for allergies, Ritalin® (methylphenidate hCl) for attention deficit hyperactivity disorder (ADHD), Risperdal® (risperidone) for hypomanic symptoms(and Claritin® (loratidine) for allergies.

The patient received the first dose of study medication on 21 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 28 June 2000. The dose was decreased to 10 mg/day on 08 July 2000. The patient discontinued study medication on 11 July 2000 (Week 3, Day 21).

On 06 July 2000 (Day 16), the patient experienced moderately severe hyperkinesia (hyperactivity) and manic reaction (hypomanic symptoms) both of which were considered to be possibly related to treatment with study medication. These events resulted in withdrawal from the study. Treatment included Ritalin® (methylphenidate hCl) for ADHD and Risperdal® (risperidone) for hypomanic symptoms. The conditions were continuing at the time of withdrawal from the study.

On 24 June 2000 (Day 4), the patient reported mild trauma (burned right hand) that resolved without treatment within 14 days.

On 07 July 2000 (Day 17) the patient reported mild nausea that resolved without treatment in one day. Both of these non-serious events were considered to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.006.25418

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Agitation (Increased Agitation), Emotional Lability (Mood Swing), Hostility (Aggression, Temper Outburst), Nervousness (Irritability)

This 13-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.006.25418), and received treatment with placebo in that study.

Concomitant medications included Benedryl® (diphenhydramine hCl) for agitation.

The patient received the first dose of study medication on 28 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments to the highest dose of 30 mg/day on 12 October 2000. The dose was decreased to 20 mg/day on 30 October 2000, and further decreased to 10 mg/day on 01 November 2000. The patient discontinued study medication on 03 November 2000 (Week 6, Day 37).

On 27 October 2000 (Day 30), the patient experienced moderately severe agitation (increased agitation) that was considered to be possibly related to treatment with study medication. Also reported on Day 30 were emotional lability (mood swing), hostility (aggression, temper outburst), and nervousness (irritability), all of which were considered to be probably unrelated to treatment with study medication. These events resulted in withdrawal from the study. Corrective treatment was given for agitation; no treatment was given for emotional lability, hostility or nervousness. All events were continuing at the time of withdrawal from the study.

On 09 October 2000 (Day 12), the patient reported mild headache that resolved without treatment in one day. This event was considered to be unrelated to treatment with study medication.

On 12 October 2000 (Day 15), the patient experienced mild fever and headache that resolved without treatment in two days. These two events were considered to

be probably unrelated to treatment with study medication. Also reported on Day 15 was mild nausea. This resolved without treatment in two days and was considered to be possibly related to treatment with study medication.

On 14 October 2000 (Day 17), the patient experienced moderately severe asthenia, considered to be possibly related to treatment with study medication, and for which no treatment was given. Asthenia continued throughout the study.

On 7 November 2000 (Day 41; 4 days after the last dose of study medication), the patient reported mild diarrhea and vomiting, and moderately severe nausea. Diarrhea and nausea resolved within 2 days without treatment; vomiting resolved in one day without treatment. All three events were considered to be probably unrelated to treatment with study medication.

On 09 November 2000 (Day 43; 6 days after the last dose of study medication), the patient was reported to have abnormal liver function test results (elevated liver enzymes). On Day 43, lab results showed an elevated aspartate aminotransferase (ASAT) of 104 IU/L (normal range 0 - 42 IU/L), and an elevated alanine aminotransferase (ALAT) of 169 IU/L (normal range 0 – 48 IU/L). All other laboratory values on Day 43 and throughout the study were within normal range, except for a slightly decreased red blood cell count (RBC's) of 4.0 10^{12}/L on Day 28 (Week 4). No follow-up laboratory test results were provided.

No other non-serious adverse events were reported during the study.

PID: 716.008.25644

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Somnolence (Sedation).

This 16-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.158.25644), and received treatment with paroxetine in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication at a dose of 10 mg/day on 11 July 2000. The last dose of study medication was taken on 28 July 2000 (Day 18).

On 31 May 2000 (before initiation of study medication in Study 716), the patient experienced the onset of moderately severe somnolence (sedation) that resolved without treatment in 62 days. This event was considered to be possibly related to treatment with study medication, and resulted in withdrawal from the study.

On 17 July 2000 (Day 7), the patient reported moderately severe nausea that was considered to be possibly related to treatment with study medication. No corrective treatment was given and the nausea continued unresolved at the end of the study.

No other non-serious adverse events were reported during the study.

PID: 716.010.25371

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Abnormal ejaculation (Delayed ejaculation)

This 16-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Protocol 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.010.25371), and received treatment with placebo in that study.

No concomitant medications were reported during this study.

On 30 June 2000 (Day 2), the patient experienced mild rash that resolved without treatment in 14 days. This event was considered to be probably unrelated to treatment with study medication. On June 12, 2000 (16 days prior to the start of 716 open-label medication) the patient experienced moderate abnormal ejaculation (delayed ejaculation) which lasted 32 days (July 13, 2000). This event was considered to be related to treatment with study medication and resulted in withdrawal from the study. The patient discontinued study medication on 12 July 2000 (Day 14).

No other non-serious adverse events were reported during the study.

PID: 716.010.25606

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Aggression)

This 13-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.162.25606), and received treatment with paroxetine in that study.

Concomitant medications included inhaled Albuterol® (salbutamol) for exercise-induced asthma (began ~3 months before the first dose of study medication in Protocol 716), and Robaxin® (methocarbamol) and Naproxen® (naproxen) for lower back pain.

The patient received the first dose of study medication on 05 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 40 mg/day on 24 October 2000. The patient was tapered, in 10 mg/week increments, to 30 mg/day on 07 November 2000 (Day 126), then to 20 mg/day on 14 November 2000 (Day 133), and to 10 mg/day on 23 November 2000 (Day 142). The final dose of study medication was taken on 03 December 2000 (Day 152).

On 01 December 2000 (Day 150), the patient experienced moderately severe hostility (aggression) that resolved without treatment in three days. This event was considered to be possibly related to treatment with study medication, and resulted in withdrawal from the study.

On 21 July 2000 (Day 17), the patient reported mild insomnia that resolved without treatment in 23 days. This event was considered to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.014.25651

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Aggression, Anger)

This 17-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 704.161.25651), and received treatment with placebo in that study.

Concomitant medications included generic non-specific daytime/nighttime cold medication and Tylenol® (paracetamol) for cold, nitrous oxide as anesthesia for dental extraction, Darvocet-N 100® (dextropropoxyphene) PRN for pain due to dental extraction, and Minocycline® (minocycline) for acne.

The patient received the first dose of study medication on 26 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 50 mg/day on 23 October 2000 (Day 26). The patient received the last dose of study medication on 03 November 2000 (Week 6, cumulative dose Day 37).

On 01 November 2000 (relative dose Day 37), the patient experienced moderately severe hostility (Aggression, Anger) that resolved without treatment in one day. The event was considered to be possibly related to treatment with study medication, and resulted in withdrawal from the study.

On 28 September 2000 (Day 3), the patient experienced a mild respiratory disorder (cold, upper respiratory infection) that resolved with treatment in four days.

On 10 October (Day 15), the patient reported moderately severe acne (worsening acne) that was treated but continued throughout the study. The patient also reported moderately severe emotional lability (mood swings) on Day 15 that was untreated and continued through the end of the study. The investigator considered both of these conditions to be possibly related to treatment with study medication.

On 13 October 2000 (Day 18), the patient reported mildly severe emotional lability (patient cut on self [wrist]) that resolved in one day with no treatment. This event was considered by the investigator to be probably unrelated to treatment with study medication.

On 23 October 2000 (Day 28), the patient reported severe dental caries (dental decay) that were treated and resolved in one day. The investigator considered this condition to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: 716.015.25464

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Manic Reaction (Manic Activation)

This 7-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.015.25464), and received treatment with placebo in that study.

Concomitant medications included Dramamine® (diphenhydramine hCl) for car sickness, Benedryl® (diphenhydramine hCl) for itching rash, and topical hydrocortisone for rash.

The patient received the first dose of study medication on 02 August 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 30 mg/day on 28 August 2000.

On 14 July 2000 (before study medication was initiated), the patient experienced moderately severe manic reaction (manic activation) that was considered to be related to treatment with study medication. No treatment was given for this non-serious event, but the condition continued and the patient was withdrawn from the study. The patient discontinued study medication on 05 September 2000 (Week 4, Day 35).

On 05 August 2000 (Day 4), the patient reported 2 episodes of mild vertigo (car sickness) that resolved with treatment within nine days. On 01 September 2000 (Day 31) the patient reported mild rash that was treated, but remained unresolved at the end of the study. Both of these non-serious events were considered to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.015.25466

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Nervousness, Irritability

This 13-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.015.25466), and received treatment with placebo in that study.

Concomitant medications included Tylenol PM® (diphenhydramine hCl, paracetamol) for insomnia, Tylenol Sinus® (pseudoephedrine hCL, paracetamol) for hives and allergies (allergies continuing from previous protocol), and topical chloroxylenol for left otitis media (continuing from the previous acute protocol).

The patient received the first dose of study medication on 18 August 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 50 mg/day on 30 September 2000 (cumulative dose Day 43). The patient received his last dose of study medication on 12 October 2000 (Day 55).

On 30 September 2000 (relative dose Day 44), the patient experienced moderately severe nervousness (irritability) that was untreated and continued through the end of the study. The investigator considered this condition to be related to treatment with study medication and the patient was withdrawn from the study.

On 19 August 2000 (Day 2), the patient experienced mild dry mouth that cleared without treatment in 4 days. On 21 August 2000 (Day 4) the patient reported a mildly decreased appetite, which was not treated and continued through the end of the study. On 23 August 2000 (Day 6), the patient reported mild insomnia, which was treated, but continued through the end of the study. All of these events were considered to be possibly related to treatment with study medication.

On 30 August 2000 (Day 13), the patient reported mild flatulence (flatus) that resolved without treatment in 15 days. The investigator considered this event to be possibly related to treatment with study medication.

On 03 September 2000 (Day 17), the patient reported the onset of mild urticaria (hives) that resolved with treatment in one day. The investigator considered urticaria to be unrelated to treatment with study medication.

On 18 September 2000 (Day 32), the patient experienced mild ulcerative stomatitis (oral lesions) and acne (acneform lesions) which were considered by the investigator to be unrelated to treatment with study medication. The ulcerative stomatitis cleared without treatment in nine days; the acne continued through the end of the study.

No other non-serious adverse experiences were reported during the study.

PID: 716.015.25469

Treatment Group: Paroxetine (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Impaired Concentration, Hostility, Hyperkinesia (Exacerbation of ADHD)

This 8-year-old Hispanic male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.015.25469), and received treatment with paroxetine in that study.

No concomitant medications were reported during Study 716. The patient underwent speech evaluation for auditory processing on Day 20 (25 October 2000).

The patient received the first dose of study medication on 06 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 40 mg/day on 23 November 2000 (Day 49). The patient received the last dose of study medication on 07 December 2000 (Day 63)

On 08 November 2000 (Day 34), at a dose of 30 mg/day, the patient experienced mildly severe impaired concentration, hostility and hyperkinesias (exacerbation of attention deficit hyperactivity disorder [ADHD]) which were considered to be related to treatment with study medication. No treatment was given for these non-serious events, but the patient was withdrawn from the study. The events were continuing at the time of withdrawal. The patient discontinued study medication on 07 December 2000 (Week 8, Day 63).

On 19 October 2000 (Day 14), at a dose of 20 mg/day, the patient was reported to have experienced mild myoclonus (vocal tic) that resolved without treatment in 4 days. This event was considered to be possibly related to treatment with study medication. No other non-serious adverse events were reported during the study.

PID: 716.015.27043

Treatment Group: Paroxetine (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Emotional Lability (Suicidal Ideation)

This 16-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.015.27043), and received treatment with paroxetine in that study.

Concomitant medications included Amoxicillin® (amoxicillin) for pleurisy, diphenhydramine for viral syndrome, Atuss DM® (chlorphenamine maleate), doxylamine/dextromethorphan/acetaminophen/pseudoephedrine (dextromethorphan, paracetamol) and Benedryl® (diphenhydramine hCL) for cough.

The patient received the first dose of study medication on 06 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 30 mg/day on 03 January 2000 (Day 30). The dose was reduced to 20 mg/day on 23 January 2000 (Day 50), and further reduced to 10 mg/day on 30 January 2001 (Day 57). The last dose of study medication was taken on 08 February 2001 (Day 66).

On 15 January 2001, the patient experienced moderately severe emotional lability (suicidal ideation) that resolved without treatment in two days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

The patient entered into the extension study with the ongoing adverse experiences of: pelvic pain (onset 25 November 2000); chest wall pain (onset 27 November 2000); cough (onset 25 November 2000); and upper respiratory infection (onset 25 November 2000). Pelvic pain, cough and upper respiratory infection were considered by the investigator to be unrelated to treatment with study medication; chest wall pain was considered to be probably unrelated to treatment with study medication. Pelvic pain, chest wall pain, cough, and upper respiratory infection, resolved in 20, 24, 19 and 47 days, respectively.

The patient was reportedly treated with Amoxicillin® for pleurisy, but no information on “pleurisy” was provided in the case report form. Confirmation of this adverse experience is pending.

On 20 January 2001 (Day 46), the patient experienced mild blepharitis (stye in right eye) that cleared without treatment in four days. The investigator considered this condition to be unrelated to treatment with study medication.

On 04 February 2001 (Day 61), the patient experienced a mild viral infection that was treated, but which continued through the end of the study. The investigator considered this event to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.016.25447

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Aggression)

This 7-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.016.25447), and received treatment with placebo in that study.

Concomitant medications included Ibuprofen® (ibuprofen) for headache; Rhinocort® Inhaler (budesonide), Rynatan® suspension (chlorphenamine tannate, mepyramine tannate, phenylephrine tannate), and Claritin® syrup (loratidine) for allergies (allergies continued from previous protocol).

The patient received the first dose of study medication on 13 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day on 30 June 2000 (Day 24). The dose was decreased to 20 mg/day on 07 July 2000 (Day 25), and further decreased to 10 mg/day on 01 August 2000 (Day 50). The patient received the last dose of study medication on 06 August 2000 (Day 55).

On 02 July 2000 (Day 20), the patient reported moderately severe hostility (aggression) that resolved without treatment in seven days. The investigator decreased the dose of study medication in response to this event, which was considered to be possibly related to treatment with study medication. On 29 July 2000 (Day 47), the patient experienced severe hostility (aggression) that resolved without treatment in eight days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

On 21 June 2000 (Day 9), the patient reported a moderately severe headache that persisted continuously for 44 days. The patient was given corrective therapy for this event, and the investigator decreased the dose of study medication. The investigator considered the headache to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.016.25450

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Nervousness (Irritability)

This 11-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.016.25450), and received treatment with placebo in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 10 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 30 mg/day on 29 July 2000 (Day 21). The dose was decreased to 20 mg/day on 12 August 2000 (Day 34), and further decreased to 10 mg/day on 26 August 2000 (Day 48). The patient received the last dose of study medication on 30 August 2000 (Day 52).

On 23 August 2000 (Day 45), the patient experienced moderately severe nervousness (irritability) that resolved without treatment in six days. The investigator considered this event to be possibly related to treatment with study medication, and the patient was withdrawn from the study.

On 07 August 2000 (Day 29), the patient experienced moderately severe hyperkinesia (hyperactivity) that resolved without treatment in 22 days. This investigator considered this event to be possibly related to treatment with study medication, and the dose of study medication was decreased. No other non-serious adverse experiences were reported during the study.

PID: 716.016.27017

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Oppositional Behavior)

This 12-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of protein in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.016.27017), and received treatment with placebo in that study.

Concomitant medications included Tylenol® (paracetamol) for headache.

The patient received the first dose of study medication on 16 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 04 January 2001 (Day 20), and further to 30 mg/day on 09 January 2001 (Day 25). The dose was decreased to 20 mg/day on 30 January 2001 (Day 46). The patient received the last dose of study medication on 12 February 2001 (Day 59).

On 05 February 2001 (Day 52), the patient experienced severe hostility (oppositional behavior) that resolved without treatment in ten days. The investigator considered this event to be related to treatment with study medication, and the patient was withdrawn from the study.

On 04 December 2000, during treatment in the acute study, and before active medication was administered in Study 716, the patient experienced mild leukopenia (slight decrease in white blood cells) that continued into the extension study. The investigator considered this condition to be possibly related to treatment with study medication. No corrective treatment was given for this condition.

On 17 December 2000 (Day 2), the patient reported mild headache that resolved with treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

On 23 January 2001 (Day 32), the patient experienced moderately severe hostility (defiant) and hyperkinesia (hyperactivity) that resolved without treatment in five

days. The dose of study medication was reportedly decreased in response to these events. Both of these events were considered to be related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.016.27019

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hyperkinesia (Hyperactivity)

This 11-year-old white male, with a primary diagnosis of obsessive compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.016.27019), and received treatment with placebo in that study.

Concomitant medications included Tylenol® (paracetamol) for headache, and Claritin® (loratidine) for rhinitis.

The patient received the first dose of study medication on 24 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day on 14 February 2001 (Day 16). The dose was decreased to 20 mg/day on 20 March 2001 (Day 56), and further reduced to 10 mg/day on 23 April 2001 (Day 90). The final dose of study medication was taken on 26 April 2001 (Day 93).

On 23 April 2001 (Day 90), the patient experienced moderately severe hyperkinesia (hyperactivity) which resolved without treatment in five days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

On 09 February 2001 (Day 17), the patient experienced mild vasodilation (hot flashes) that resolved in 82 days; no corrective treatment was given. The investigator considered this event to be related to treatment with study medication.

On 12 March 2001 (Day 48), the patient experienced a moderately severe lack of emotion (apathy) that resolved in 55 days; no corrective treatment was given. The investigator considered this condition to be related to treatment with study medication, and the dose of study medication was decreased.

On 17 March 2001 (Day 53), the patient reported mild rhinitis that continued throughout the study; corrective treatment was given for this event. Also, on Day

53, the patient reported the onset of mild headache that resolved with treatment in one day. The investigator considered rhinitis to be probably unrelated to treatment with study medication, and headache to be possibly related to treatment with study medication.

On 23 April 2001 (Day 90), the patient experienced mild urinary incontinence (enuresis). This event resolved without treatment in 11 days. The investigator considered this event to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.016.27021

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hyperkinesia (Hyperactivity)

This 8-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.016.27021), and received treatment with placebo in that study.

Concomitant medications included oral Diprosone® (betamethasone dipropionate), and topical triamcinolone cream (triamcinolone, triamcinolone acetonide) for eczema.

The patient received the first dose of study medication on 05 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 16 January 2001 (Day 12). The dose was decreased to 10 mg/day on 01 February 2001 (Day 28). The patient received the last dose of study medication on 03 February 2001 (Day 30).

On 31 January 2001 (Day 27), the patient experienced severe hyperkinesia (hyperactivity) that resolved without treatment in eight days. The investigator considered the event to be related to treatment with study medication, and the patient was withdrawn from the study.

On 01 August 2000, during the previous acute study and before study medication was given in Protocol 716, the patient reported the onset of moderately severe eczema. The condition persisted throughout this extension study. Corrective treatment was given. The investigator considered the condition to be unrelated to treatment with study medication.

On 17 January 2001 (Day 13), the patient reported mild myoclonus (increase in tics) that resolved without treatment in 14 days. The investigator considered this condition to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.025.25822

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Agitation (Increased Agitation)

This 7-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.181.25822), and received treatment with placebo in that study.

Concomitant medications included Paxil® (paroxetine) for major depression. Prescription Paxil® began on 25 September 2000 (Day 20).

The patient received the first dose of study medication on 06 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments to the highest dose of 30 mg/day on 19 September 2000 (Day 14). The last dose was taken on 26 September 2000 (Day 21). (Start date of paroxetine was recently amended through site confirmation).

On 25 September 2000 (Day 20), the patient experienced moderately severe agitation (increased agitation) that resolved with treatment in 18 days. The investigator considered this condition to be possibly related to treatment with study medication, and the patient was withdrawn from the study.

No other non-serious adverse events were reported during the study.

PID: 716.025.27059

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Anxiety (Anxiety Increased)

This 14-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.025.27059), and received treatment with placebo in that study.

Concomitant medications included prednisone for poison ivy.

The patient received the first dose of study medication on 10 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to the highest dose of 20 mg/day on 19 October 2000 (Day 10). The patient remained at the dose of 20 mg/day throughout the study and received the last dose of study medication on 01 March 2001 (Day 143).

On 05 February 2001 (Day 129), the patient experienced moderately severe anxiety (anxiety increased) that continued through the end of the study, and resulted in withdrawal from the study. No corrective treatment was given for this condition that the investigator considered to be unrelated to treatment with study medication

No other non-serious adverse events were reported during the study.

PID: 716.025.27060

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Oppositional Defiant)

This 9-year-old black male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 8 years old at entry into acute Protocol 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.025.27060), and received treatment with placebo in that study.

Concomitant medications included DDAVP® (desmopressin) for bedwetting, and Risperdal® (risperidone) for oppositional defiant behavior. Treatment for bedwetting was started in the previous acute protocol and was continued into extension Protocol 716.

The patient received the first dose of study medication on 12 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 05 December 2000 (Day 55). The dose remained at 20 mg/day throughout the study. The final dose of study medication was taken on 01 March 2001 (Day 141).

On 15 February 2001 (Day 127), the patient experienced moderately severe hostility (oppositional defiant) that continued throughout the study. Corrective treatment was given, and the patient was withdrawn from the study. The investigator considered the event to be unrelated to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: 716.043.27696

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Hostility (Defiant Behavior)

This 9-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 8 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.150.27696), and received treatment with placebo in that study.

Concomitant medications included Tylenol Cough and Cold Medication® (chlorpheniramine maleate, dextromethorphan hydrobromide, paracetamol, pseudoephedrine hCl) and Claritin® (loratidine) for allergic rhinitis, Clonidine® (clonidine) for defiant behavior, and Children's Tylenol® (paracetamol) for sinus allergy (taken since January 1995).

The patient received the first dose of study medication on 17 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 31 January 2001 (Day 15). The dose was decreased to 10 mg/day on 07 February 2001 (Day 22). The last dose of study medication was taken on 23 February 2001 (Day 38).

On 12 February 2001 (Day 27), the patient experienced severe hostility (defiant behavior) that resolved with treatment in 24 days. The investigator considered this condition to be unrelated to treatment with study medication, but withdrew the patient from the study.

On 16 January 2001 (Day -1), one day before treatment in extension Protocol 716 began, the patient reported moderately severe rhinitis (allergic rhinitis) that resolved with treatment in five days. This event was considered to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.044.27655

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Anxiety (Post-Traumatic Syndrome)

This 13-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 12 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.149.27655), and received treatment with placebo in that study.

Concomitant medications included Risperdal® (risperidone) for post-traumatic syndrome.

The patient received the first dose of study medication on 08 November 2000. The patient began treatment at a dose of 30 mg/day, which was decreased to 20 mg/day on 29 November 2000 (Day 22). The final dose of study medication was taken on 06 December 2000 (Day 29).

On 01 December 2000 (Day 24), the patient experienced severe anxiety (post-traumatic syndrome) that continued through the end of the study. Corrective therapy was given. The investigator considered this to be unrelated to treatment with study medication, but withdrew the patient from the study.

No other non-serious adverse events were reported during the study.

PID: 716.047.27156

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Adverse Experience: Asthenia (Fatigue)

This 12-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.047.27156), and received treatment with placebo in that study.

Concomitant medications included non-specified multivitamins for nutritional supplement.

The patient received the first dose of study medication on 27 March 2001. The patient began treatment at a dose of 10 mg/day and was given her last dose of study medication on 03 April 2001 (Day 8).

On 27 March 2001 (Day 1), the patient experienced moderately severe asthenia (fatigue) that resolved without treatment in 10 days. The investigator considered this event to be possibly related to treatment with study medication and withdrew the patient from the study. Also, on 27 March 2001 (Day 1), the patient reported moderately severe dizziness that resolved without treatment in three days. This was also considered to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.164.25721

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Anxiety (Post-Traumatic Syndrome)

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.164.25721), and received treatment with paroxetine in that study.

Concomitant medications included ibuprofen and Tylenol® (paracetamol) for headache, Compazine® (prochlorperazine) for nausea, and Zyrtec® (cetirizine HCl) for macular pruritis.

The patient received the first dose of study medication on 07 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 19 July 2000 (Day 13). This dose was maintained throughout the study. The final dose of study medication was taken on 13 October 2000 (Day 99).

On 29 September 2000 (Day 85), the patient experienced moderately severe nausea that resolved with treatment in 21 days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

On 20 May 2000, and 05 July 2000 (during the previous acute study and before the first dose of study medication in Protocol 716) the patient reported the onset of mild left heel pain, and mild left jaw pain, respectively. Both events continued into and through the extension study. No corrective therapy was given, and the investigator considered these to be unrelated to treatment with study medication.

On 11 July 2000 (Day 5), the patient reported mild headache that resolved with treatment in one day. The investigator considered the headache to be possibly related to treatment with study medication. On 19 July 2000 (Day 13), the patient reported moderately severe headache that resolved with treatment in one day. This headache was considered to be probably unrelated to treatment with study medication. On 26 July 2000 (Day 20), mild headache was again reported; this

resolved without treatment in one day and was considered to be probably unrelated to treatment with study medication.

On 02 October 2000 (Day 88) and again on 03 October 2000 Day (89), the patient reported moderately severe headaches that each cleared with treatment in one day. These events were considered to be possibly related to treatment with study medication.

On 29 July 2000 (Day 23), the patient reported moderately severe trauma (left wrist contusion) that continued throughout the study. No corrective treatment was given. The investigator considered this event to be unrelated to treatment with study medication.

On 01 October 2000 (Day 87), the patient reported moderately severe vomiting that resolved without treatment in one day. This was considered to be possibly related to treatment with study medication.

On 16 November 2000 (post-study), the patient experienced moderately severe gastritis that was continuing at the end of this study reporting period. Corrective therapy was given for this condition, which was considered to be possibly related to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: 716.165.25664

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Electrocardiogram Abnormal (Abnormal ECG)

This 10-year-old Hispanic male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 9 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.165.25664), and received treatment with placebo in that study.

Concomitant medications included Children's Motrin® (ibuprofen) for back pain, and Benedryl® (diphenhydramine hCl) for agitation.

The patient received the first dose of study medication on 10 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 17 October 2000 (Day 8). The dose was decreased to 10 mg/day on 20 October 2000 (Day 11), and then increased again to 20 mg/day on 25 October 2000 (Day 16). The dose was gradually increased, in 10 mg/week increments, to the highest dose of 50 mg/day 06 December 2000 (Day 58). The dose was gradually decreased, in 10 mg/week increments, to 10 mg/day by 24 February 2001 (Day 138). The final dose was given on 26 February 2001 (Day 140).

On 13 February 2001 (Day 127), while at a dose of 50 mg/day, the patient was found to have an abnormal electrocardiogram. This was considered to be mildly abnormal and this resolved without treatment in 15 days. Vital signs recorded on 13 February 2001 (Day 127) were within normal limits. The investigator considered this to be unrelated to treatment with study medication, but the patient was withdrawn from the study. Also, on Day 127, the patient reported a mildly increased weight gain that continued through the end of the study. The investigator considered this to be probably unrelated to treatment with study medication. The patient's body weight at baseline in the previous acute study (Protocol 701) was 32.7 kg; baseline body weight in Protocol 716 was 34.0 kg; body weight on 13 February 2001 (Day 127) was 38.2 kg. No additional body weight was provided.

On 08 October 2000 (one day before treatment began in Protocol 716), the patient reported mild back pain (neck ache) that resolved without treatment in three days. Mild back pain (back pain) was also reported on 19 November 2000 (Day 41). Back pain resolved with treatment in one day. Both of these events were considered to be unrelated to treatment with study medication.

On 17 October 2000 (Day 8), the patient experienced mild dyspepsia, and moderately severe vomiting, both of which resolved without treatment in 15 days. The investigator considered both of these conditions to be probably unrelated to treatment with study medication.

On 16 November 2000 (Day 38), the patient experienced severe agitation which resolved with treatment in one day. On 26 January 2001 (Day 109), moderately severe agitation (increased agitation) was again reported. This continued through the end of the study despite corrective treatment. The investigator considered both events to be urelated to treatment with study medication. Study medication was decreased as a result of the episode on Day 109.

On 02 January 2001 (Day 85), the patient was reported to have mildly abnormal liver function test results (increased liver enzymes), that resolved without treatment in 84 days. The investigator considered these abnormal test results to be unrelated to treatment with study medication. At screening of Protocol 716, the patient's aspartate aminotransferase (ASAT) value was within normal limits at 42 IU/L (normal range 0 – 42 IU/L); alanine aminotransferase (ALAT) was slightly elevated at 46 IU/L (normal range 0 – 45 IU/L). The values for these analytes throughout the study are provided in the table below. No additional follow-up values were provided.

Analyte	Screening (Day –69)	Week 4 (Day 29)	Week 12 (Day 85)	Week 20 Day 127)	Follow-Up (Day 141)
ASAT	42 IU/L	28 IU/L	54 IU/L	59 IU/L	104 IU/L
ALAT	46 IU/L	16 IU/L	84 IU/L	79 IU/L	179 IU/L

On 28 February 2001 (Day 142; two days after the final dose of study medication), the patient experienced moderately severe impaired concentration (attention deficit disorder), which was continuing at the time the study ended. Corrective therapy was given for this condition, which was considered to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.176.25794

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Syncope (Syncope)

This 11-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.176.25794), and received treatment with placebo in that study.

Concomitant medications included intravenous saline solution for syncope and dehydration, and non-specified multivitamins for dietary supplementation.

The patient received the first dose of study medication on 22 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 30 mg/day on 19 January 2001 (Day 29). The patient received the last dose of 30 mg/day on 15 February 2001 (Day 56). The dose was tapered down to 20 mg/day, then 10 mg/day and the final dose of study medication was given on 06 March 2001 (Day 75).

On 12 February 2001 (Day 53), 16 February 2001 (Day 57), 19 February 2001 (Day 60), and on 21 February 2001 (Day 62), the patient experienced moderately severe episodes of syncope, all of which cleared in one day. Corrective therapy was provided only for the episode on Day 53. The investigator considered all four episodes to be possibly related to treatment with study medication and the patient was withdrawn from the study following the fourth report of syncope on Day 62.

On 12 February 2001 (Day 53), the patient also experienced moderately severe dehydration that resolved with treatment in one day. The investigator considered this to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.180.25776

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Convulsion (Possible Seizure)

This 7-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.180.25776), and received treatment with paroxetine in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 26 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 04 October 2000 (Day 9). The dose remained at 20 mg/day through the final dose on 16 October 2000 (Day 21).

On 01 October 2000 (Day 6), the patient experienced moderately severe convulsion (possible seizure activity) which reportedly persisted (unknown number of episodes) over a 26 day period. No corrective treatment was given for this event, which the investigator considered to be possibly related to treatment with study medication. The patient was withdrawn from the study due to this event. Also, on Day 6, the patient reported mildly dry mouth, and mild hallucinations, both of which continued through the end of the study. No treatment was given for either event. The investigator considered the dry mouth to be possibly related to treatment with study medication and the hallucinations to be unrelated to treatment with study medication.

On 17 October 2000 (Day 22; one day after the last dose of study medication), the patient reported mild myalgia (intermittent spasms in leg) that continued, without treatment, through the end of the study. The investigator considered this condition to be possibly related to treatment with study medication.

On 19 October 2000 (Day 24; 3 days after the last dose of study medication), the patient reported mild abdominal pain (stomach aches) and mild headache (headaches), both of which resolved without treatment in eight days. The

investigator considered both of these events to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.183.25901

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Libido Decreased (Decreased Libido)

This 17-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.183.25901), and received treatment with placebo in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 26 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg/day on 07 December 2000 (Day 43). The dose remained at 30 mg/day through the final dose of study medication on 31 January 2001 (Day 98).

On 20 December 2000 (Day 56), the patient reported mildly decreased libido (decreased libido, inorgasmia) persisting for 42 days (to Day 98) with no action taken; the same event was reported again on 31 January 2001 (Day 98) and was reported to have continued for 15 days and resulting in withdrawal from the study. Both events were reported as mild, continuous episodes. Corrective therapy was not given for either reported event. The investigator considered this condition (both reports) to be related to treatment with study medication.

No other non-serious adverse experiences were reported during the study.

PID: 716.192.25870

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Adverse Experience: Hallucinations (Auditory, Visual Hallucinations)

This 18-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 17 years old at entry into Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.192.25870), and received treatment with placebo in that study.

Concomitant medications included Seroquel® (quetiapine) for hallucinations.

The patient received the first dose of study medication on 28 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to the highest dose of 40 mg/day on 06 December 2000 (Day 40). The dose was decreased to 30 mg/day on 15 March 2001 (Day 139). The final dose of study medication was given on 16 March 2001 (Day 140).

On 03 March 2001 (Day 127), the patient experienced severe auditory and visual hallucinations that continued through the end of the study. Corrective therapy was given, and the investigator considered the adverse experience(s) to be unrelated to treatment with study medication.

On 30 January 2001 (Day 98), the patient reported mild weight gain that continued through the end of the study. No corrective therapy was given. The investigator considered this to be possibly related to treatment with study medication. The patient's body weight at screening in the previous acute study was 67.2 kg, and at baseline in Protocol 716 was 66.0 kg. At Week 12 of Protocol 716 (30 January 2001), body weight was 71.0 kg, and follow-up body weight (14 March 2001) was 75 kg. No further values were provided.

No other non-serious adverse events were reported during the study.

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	104.2	102.0	10.29	90	126	70	103.9	102.0	11.25	74	137	119	104.0	102.0	10.82	74	137
Change from Acute Study Baseline to 716:																		
Week 1	39	-1.8	-2.0	11.86	-28	21	59	2.9	2.0	13.27	-26	38	98	1.1	0.5	12.88	-28	38
Week 2	38	0.2	0.0	11.50	-30	23	61	1.6	0.0	12.02	-22	26	99	1.1	0.0	11.78	-30	26
Week 3	38	-0.8	-1.5	10.33	-28	22	61	0.8	0.0	16.02	-36	61	99	0.2	0.0	14.07	-36	61
Week 4	44	0.3	1.5	9.91	-27	22	59	5.3	4.0	14.78	-22	49	103	3.2	2.0	13.10	-27	49
Week 6	38	2.3	4.0	10.37	-19	26	52	1.5	0.0	13.03	-30	36	90	1.8	3.5	11.93	-30	36
Week 8	41	2.2	1.0	11.04	-25	30	49	0.2	0.0	13.05	-27	27	90	1.1	0.0	12.15	-27	30
Week 12	26	0.5	0.0	10.51	-20	21	37	0.7	0.0	14.35	-26	36	63	0.6	0.0	12.81	-26	36
Week 16	23	2.4	2.0	11.30	-20	27	28	1.1	0.0	11.68	-21	22	51	1.7	2.0	11.41	-21	27
Week 20	21	1.1	4.0	9.98	-18	18	24	-1.4	0.5	11.73	-25	20	45	-0.2	2.0	10.90	-25	20
Week 24	19	0.6	0.0	10.97	-30	14	16	-0.1	3.0	11.81	-22	16	35	0.3	2.0	11.20	-30	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	109.4	110.0	11.09	88	132	57	111.7	110.0	10.48	90	142	102	110.7	110.0	10.76	88	142
Change from Acute Study Baseline to 716:																		
Week 1	39	2.0	2.0	10.93	-24	22	48	4.4	4.0	13.62	-31	42	87	3.3	2.0	12.47	-31	42
Week 2	38	1.4	3.0	9.64	-25	20	49	4.0	6.0	10.36	-22	33	87	2.9	4.0	10.08	-25	33
Week 3	38	3.4	2.0	10.34	-25	30	43	2.8	2.0	13.10	-22	40	81	3.1	2.0	11.82	-25	40
Week 4	41	1.7	2.0	9.48	-24	23	49	3.1	2.0	14.69	-26	50	90	2.4	2.0	12.54	-26	50
Week 6	38	3.3	1.5	8.65	-14	20	42	3.7	2.0	11.36	-24	30	80	3.5	2.0	10.10	-24	30
Week 8	38	3.8	6.0	11.09	-31	25	38	4.6	3.5	10.72	-20	30	76	4.2	4.0	10.84	-31	30
Week 12	32	4.4	4.0	10.44	-16	24	31	6.0	6.0	11.58	-26	32	63	5.2	4.0	10.96	-26	32
Week 16	29	3.1	6.0	11.58	-25	20	29	5.9	0.0	12.42	-10	36	58	4.5	4.0	11.99	-25	36
Week 20	17	3.7	2.0	11.04	-12	26	19	8.8	6.0	10.65	-6	38	36	6.4	6.0	10.99	-12	38
Week 24	14	9.7	11.0	10.62	-8	22	14	10.9	7.0	12.85	-13	34	28	10.3	9.5	11.59	-13	34

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	106.7	106.0	10.94	88	132	127	107.4	108.0	11.54	74	142	221	107.1	107.0	11.27	74	142
Change from Acute Study Baseline to 716:																		
Week 1	78	0.1	0.0	11.49	-28	22	107	3.6	2.0	13.38	-31	42	185	2.1	2.0	12.70	-31	42
Week 2	76	0.8	0.0	10.56	-30	23	110	2.7	2.5	11.33	-22	33	186	1.9	2.0	11.03	-30	33
Week 3	76	1.3	0.0	10.49	-28	30	104	1.6	1.0	14.85	-36	61	180	1.5	0.0	13.15	-36	61
Week 4	85	1.0	2.0	9.67	-27	23	108	4.3	2.0	14.71	-26	50	193	2.8	2.0	12.82	-27	50
Week 6	76	2.8	3.0	9.50	-19	26	94	2.5	1.5	12.30	-30	36	170	2.6	2.0	11.11	-30	36
Week 8	79	3.0	2.0	11.02	-31	30	87	2.1	2.0	12.22	-27	30	166	2.5	2.0	11.64	-31	30
Week 12	58	2.7	2.0	10.56	-20	24	68	3.1	2.0	13.33	-26	36	126	2.9	2.0	12.09	-26	36
Week 16	52	2.8	3.0	11.35	-25	27	57	3.6	0.0	12.20	-21	36	109	3.2	2.0	11.75	-25	36
Week 20	38	2.3	2.5	10.41	-18	26	43	3.1	4.0	12.26	-25	38	81	2.7	4.0	11.37	-25	38
Week 24	33	4.5	7.0	11.60	-30	22	30	5.0	5.0	13.33	-22	34	63	4.7	6.0	12.35	-30	34

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	65.8	64.0	8.84	44	85	70	66.4	66.0	9.10	40	86	119	66.2	66.0	8.96	40	86
Change from Acute Study Baseline to 716:																		
Week 1	39	-0.6	0.0	10.08	-24	18	59	1.1	2.0	10.88	-29	26	98	0.4	0.0	10.55	-29	26
Week 2	38	-0.3	0.0	9.60	-31	18	61	-0.6	0.0	10.99	-30	31	99	-0.5	0.0	10.43	-31	31
Week 3	38	0.8	0.0	10.82	-21	30	61	-1.7	-2.0	9.85	-24	23	99	-0.7	0.0	10.25	-24	30
Week 4	44	1.3	3.0	10.43	-31	17	59	1.0	2.0	10.25	-22	24	103	1.1	2.0	10.28	-31	24
Week 6	38	0.3	0.0	9.99	-24	18	52	1.2	2.5	10.56	-22	24	90	0.8	1.0	10.28	-24	24
Week 8	41	1.1	4.0	11.89	-31	20	49	0.0	0.0	11.05	-22	33	90	0.5	2.0	11.39	-31	33
Week 12	26	-0.2	0.0	9.27	-19	22	37	-0.3	0.0	11.11	-21	28	63	-0.2	0.0	10.31	-21	28
Week 16	23	0.6	0.0	10.83	-19	22	28	1.1	2.0	10.18	-22	26	51	0.9	0.0	10.37	-22	26
Week 20	21	2.3	2.0	10.78	-18	20	24	0.2	-2.0	12.79	-30	28	45	1.2	0.0	11.81	-30	28
Week 24	19	0.5	0.0	11.15	-18	22	16	-1.9	0.0	11.08	-30	13	35	-0.6	0.0	11.02	-30	22

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	68.1	70.0	9.40	40	85	57	69.1	70.0	9.40	44	86	102	68.6	70.0	9.37	40	86
Change from Acute Study Baseline to 716:																		
Week 1	39	1.2	1.0	10.07	-23	20	48	1.9	3.0	11.05	-20	26	87	1.6	2.0	10.57	-23	26
Week 2	38	1.5	0.0	9.02	-24	20	49	-0.1	0.0	11.36	-30	28	87	0.6	0.0	10.37	-30	28
Week 3	38	2.2	2.5	6.22	-14	12	43	2.2	2.0	10.03	-22	24	81	2.2	2.0	8.41	-22	24
Week 4	41	2.0	2.0	8.71	-18	30	49	2.6	2.0	9.81	-26	27	90	2.3	2.0	9.28	-26	30
Week 6	38	0.9	4.0	8.74	-24	12	42	2.8	3.0	11.48	-26	37	80	1.9	4.0	10.25	-26	37
Week 8	38	1.7	2.0	7.77	-16	18	38	1.3	2.0	8.94	-19	14	76	1.5	2.0	8.32	-19	18
Week 12	32	3.0	2.0	8.05	-18	20	31	3.4	2.0	9.12	-12	25	63	3.2	2.0	8.52	-18	25
Week 16	29	1.7	3.0	9.87	-24	18	29	1.2	0.0	8.02	-12	23	58	1.4	1.0	8.91	-24	23
Week 20	17	1.2	4.0	10.26	-20	14	19	2.4	2.0	8.49	-18	20	36	1.9	2.0	9.25	-20	20
Week 24	14	3.0	4.0	8.24	-12	13	14	1.0	2.5	8.83	-18	12	28	2.0	3.5	8.44	-18	13

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	66.9	68.0	9.14	40	85	127	67.6	69.0	9.29	40	86	221	67.3	68.0	9.21	40	86
Change from Acute Study Baseline to 716:																		
Week 1	78	0.3	0.0	10.05	-24	20	107	1.5	2.0	10.91	-29	26	185	1.0	1.0	10.54	-29	26
Week 2	76	0.6	0.0	9.30	-31	20	110	-0.4	0.0	11.10	-30	31	186	0.0	0.0	10.39	-31	31
Week 3	76	1.5	2.0	8.79	-21	30	104	-0.1	0.0	10.06	-24	24	180	0.6	1.5	9.55	-24	30
Week 4	85	1.6	2.0	9.59	-31	30	108	1.7	2.0	10.04	-26	27	193	1.7	2.0	9.82	-31	30
Week 6	76	0.6	2.0	9.33	-24	18	94	1.9	2.5	10.95	-26	37	170	1.3	2.0	10.25	-26	37
Week 8	79	1.4	3.0	10.06	-31	20	87	0.6	2.0	10.15	-22	33	166	1.0	2.0	10.08	-31	33
Week 12	58	1.6	2.0	8.69	-19	22	68	1.4	1.0	10.34	-21	28	126	1.5	2.0	9.57	-21	28
Week 16	52	1.2	1.0	10.21	-24	22	57	1.1	0.0	9.06	-22	26	109	1.2	0.0	9.58	-24	26
Week 20	38	1.8	3.5	10.42	-20	20	43	1.2	0.0	11.04	-30	28	81	1.5	2.0	10.69	-30	28
Week 24	33	1.6	4.0	9.95	-18	22	30	-0.6	2.0	10.04	-30	13	63	0.6	2.0	9.97	-30	22

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	84.5	84.0	10.88	60	102	70	81.6	81.0	11.67	52	110	119	82.8	82.0	11.39	52	110
Change from Acute Study Baseline to 716:																		
Week 1	39	0.6	-1.0	11.86	-16	24	59	-1.9	-2.0	11.71	-32	28	98	-0.9	-2.0	11.78	-32	28
Week 2	38	-0.6	-1.5	12.77	-20	32	61	-2.0	-2.0	11.56	-33	25	99	-1.5	-2.0	11.99	-33	32
Week 3	38	-2.2	-3.5	11.33	-26	28	61	0.8	0.0	11.88	-28	24	99	-0.4	0.0	11.71	-28	28
Week 4	44	1.5	1.0	12.18	-20	32	59	3.7	2.0	11.73	-30	32	103	2.8	2.0	11.92	-30	32
Week 6	39	2.9	1.0	11.00	-24	27	52	2.9	2.0	10.81	-20	28	91	2.9	2.0	10.83	-24	28
Week 8	41	-1.2	0.0	12.57	-29	28	49	3.4	4.0	13.25	-39	29	90	1.3	1.5	13.08	-39	29
Week 12	27	-2.0	-2.0	13.74	-37	16	37	2.3	1.0	12.73	-20	32	64	0.5	0.5	13.23	-37	32
Week 16	23	0.5	-4.0	14.86	-17	48	28	6.2	7.0	13.32	-20	34	51	3.6	0.0	14.18	-20	48
Week 20	21	2.3	3.0	10.27	-17	30	23	2.7	2.0	10.99	-16	22	44	2.5	2.5	10.53	-17	30
Week 24	19	-1.9	-4.0	13.10	-24	28	16	1.4	1.5	12.71	-28	25	35	-0.4	0.0	12.84	-28	28

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	78.4	80.0	9.81	60	104	57	74.7	76.0	8.93	52	96	102	76.3	76.0	9.46	52	104
Change from Acute Study Baseline to 716:																		
Week 1	39	0.0	-2.0	12.26	-36	28	48	1.8	0.0	12.35	-23	28	87	1.0	0.0	12.27	-36	28
Week 2	38	2.2	0.0	13.19	-20	38	49	1.3	2.0	12.14	-32	32	87	1.7	0.0	12.54	-32	38
Week 3	38	1.0	0.0	14.12	-36	36	43	3.7	2.0	11.89	-20	35	81	2.4	1.0	12.97	-36	36
Week 4	41	3.0	2.0	11.98	-32	28	49	3.8	4.0	10.73	-21	27	90	3.4	3.0	11.26	-32	28
Week 6	38	2.9	1.0	14.52	-32	42	42	4.7	2.5	12.17	-15	40	80	3.8	2.0	13.28	-32	42
Week 8	38	3.7	2.5	10.87	-24	24	38	5.0	4.0	10.56	-28	32	76	4.3	4.0	10.67	-28	32
Week 12	32	4.8	5.0	14.42	-24	36	31	6.2	8.0	10.50	-21	30	63	5.5	6.0	12.56	-24	36
Week 16	29	0.5	2.0	14.98	-36	34	29	3.9	4.0	8.65	-16	20	58	2.2	3.0	12.24	-36	34
Week 20	17	1.5	0.0	13.99	-36	28	19	2.0	4.0	13.72	-26	24	36	1.8	1.0	13.65	-36	28
Week 24	14	-3.9	-3.0	12.49	-36	14	14	-4.6	1.0	16.96	-40	16	28	-4.3	-1.0	14.62	-40	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	81.5	80.0	10.77	60	104	127	78.5	79.0	11.04	52	110	221	79.8	80.0	11.00	52	110
Change from Acute Study Baseline to 716:																		
Week 1	78	0.3	-2.0	11.99	-36	28	107	-0.3	0.0	12.09	-32	28	185	-0.0	-1.0	12.02	-36	28
Week 2	76	0.8	0.0	12.98	-20	38	110	-0.5	0.0	11.88	-33	32	186	0.0	0.0	12.32	-33	38
Week 3	76	-0.6	-0.5	12.81	-36	36	104	2.0	1.0	11.92	-28	35	180	0.9	0.0	12.34	-36	36
Week 4	85	2.2	2.0	12.04	-32	32	108	3.8	3.0	11.24	-30	32	193	3.1	2.0	11.59	-32	32
Week 6	77	2.9	1.0	12.77	-32	42	94	3.7	2.0	11.41	-20	40	171	3.4	2.0	12.01	-32	42
Week 8	79	1.1	2.0	11.96	-29	28	87	4.1	4.0	12.11	-39	32	166	2.7	3.5	12.10	-39	32
Week 12	59	1.7	2.0	14.40	-37	36	68	4.1	4.0	11.84	-21	32	127	3.0	3.0	13.09	-37	36
Week 16	52	0.5	-2.0	14.78	-36	48	57	5.0	6.0	11.15	-20	34	109	2.9	2.0	13.14	-36	48
Week 20	38	1.9	2.0	11.91	-36	30	42	2.4	3.0	12.15	-26	24	80	2.2	2.0	11.96	-36	30
Week 24	33	-2.8	-3.0	12.69	-36	28	30	-1.4	1.0	14.89	-40	25	63	-2.1	0.0	13.68	-40	28

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	139.83	137.80	12.886	114.5	165.0	70	138.80	139.85	10.329	115.6	161.0	119	139.23	139.70	11.410	114.5	165.0
Change from Acute Study Baseline to 716:																		
Week 12	24	0.82	1.45	5.519	-23.1	6.4	35	3.04	2.00	5.049	-0.1	24.9	59	2.13	1.50	5.313	-23.1	24.9
Week 24	18	4.80	3.85	10.416	-19.0	39.5	14	4.13	4.00	2.839	0.0	8.9	32	4.51	3.95	7.936	-19.0	39.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	166.15	166.00	10.101	139.5	188.0	56	165.79	167.60	8.351	149.9	180.3	101	165.95	166.40	9.126	139.5	188.0
Change from Acute Study Baseline to 716:																		
Week 12	28	0.08	0.00	1.903	-5.1	4.4	26	0.68	0.45	1.518	-3.0	3.9	54	0.37	0.00	1.739	-5.1	4.4
Week 24	13	0.59	0.00	1.733	-1.3	4.5	14	1.34	0.30	2.793	-3.0	7.9	27	0.98	0.00	2.330	-3.0	7.9

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	152.43	154.95	17.570	114.5	188.0	126	150.80	151.20	16.458	115.6	180.3	220	151.50	152.40	16.922	114.5	188.0
Change from Acute Study Baseline to 716:																		
Week 12	52	0.42	0.90	3.974	-23.1	6.4	61	2.03	1.00	4.097	-3.0	24.9	113	1.29	1.00	4.103	-23.1	24.9
Week 24	31	3.04	2.00	8.193	-19.0	39.5	28	2.73	2.05	3.108	-3.0	8.9	59	2.89	2.00	6.264	-19.0	39.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	41.73	38.10	16.419	20.4	79.5	70	38.82	34.50	14.615	20.5	104.0	119	40.02	35.20	15.383	20.4	104.0
Change from Acute Study Baseline to 716:																		
Week 12	24	3.05	2.10	2.787	0.0	10.5	36	1.85	1.95	1.996	-2.9	5.0	60	2.33	2.05	2.396	-2.9	10.5
Week 24	18	5.11	4.85	3.150	0.0	14.8	14	4.26	4.10	2.824	-0.5	11.0	32	4.74	4.50	2.994	-0.5	14.8

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	69.78	65.00	20.023	32.5	132.6	56	67.45	62.45	19.822	38.2	131.4	101	68.49	62.70	19.846	32.5	132.6
Change from Acute Study Baseline to 716:																		
Week 12	28	2.78	2.05	3.333	-4.1	9.6	27	3.29	3.20	3.531	-1.8	14.1	55	3.03	2.90	3.409	-4.1	14.1
Week 24	13	6.75	7.00	3.845	-0.5	13.0	14	5.65	3.65	5.695	-0.8	16.8	27	6.18	6.50	4.833	-0.8	16.8

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	55.16	55.25	22.963	20.4	132.6	126	51.54	46.80	22.244	20.5	131.4	220	53.09	51.85	22.574	20.4	132.6
Change from Acute Study Baseline to 716:																		
Week 12	52	2.90	2.10	3.067	-4.1	10.5	63	2.47	2.70	2.827	-2.9	14.1	115	2.66	2.30	2.933	-4.1	14.1
Week 24	31	5.80	5.40	3.495	-0.5	14.8	28	4.96	4.10	4.467	-0.8	16.8	59	5.40	4.60	3.973	-0.8	16.8

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	20.72	18.50	5.675	13.9	32.8	70	19.73	18.15	5.279	13.6	40.1	119	20.14	18.20	5.444	13.6	40.1
Change from Acute Study Baseline to 716:																		
Week 12	24	1.25	0.95	1.602	-1.7	6.1	35	0.12	0.60	1.568	-5.3	2.2	59	0.58	0.70	1.664	-5.3	6.1
Week 24	18	1.34	1.70	2.680	-5.8	6.4	14	0.94	0.70	1.688	-1.4	5.5	32	1.17	1.00	2.275	-5.8	6.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	25.16	23.10	6.632	16.5	45.9	56	24.39	22.80	6.373	16.4	45.4	101	24.73	22.80	6.468	16.4	45.9
Change from Acute Study Baseline to 716:																		
Week 12	28	1.02	0.85	1.338	-1.9	3.3	26	1.00	0.95	1.129	-0.8	3.1	54	1.01	0.90	1.230	-1.9	3.3
Week 24	13	2.27	2.80	1.370	-0.3	4.1	14	1.58	0.85	1.652	-0.3	5.4	27	1.91	1.50	1.534	-0.3	5.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	22.84	21.50	6.512	13.9	45.9	126	21.80	20.05	6.218	13.6	45.4	220	22.25	20.75	6.351	13.6	45.9
Change from Acute Study Baseline to 716:																		
Week 12	52	1.12	0.90	1.456	-1.9	6.1	61	0.50	0.70	1.455	-5.3	3.1	113	0.78	0.80	1.482	-5.3	6.1
Week 24	31	1.73	2.20	2.244	-5.8	6.4	28	1.26	0.75	1.671	-1.4	5.5	59	1.51	1.20	1.990	-5.8	6.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	104.2	102.0	10.29	90	126	70	103.9	102.0	11.25	74	137	119	104.0	102.0	10.82	74	137
Change from Acute Study Baseline to 716:																		
Week 1	1	14.0	14.0	.	14	14	0	.	.	.	.	.	1	14.0	14.0	.	14	14
Week 2	0	.	.	.	.	.	1	-14.0	-14.0	.	-14	-14	1	-14.0	-14.0	.	-14	-14
Week 3	1	18.0	18.0	.	18	18	1	2.0	2.0	.	2	2	2	10.0	10.0	11.31	2	18
Week 4	1	16.0	16.0	.	16	16	3	-8.3	-3.0	11.93	-22	0	4	-2.3	-1.5	15.59	-22	16
Week 6	0	.	.	.	.	.	4	12.5	13.0	9.15	2	22	4	12.5	13.0	9.15	2	22
Week 8	3	7.3	10.0	4.62	2	10	4	6.5	4.0	9.98	-2	20	7	6.9	8.0	7.56	-2	20
Week 12	3	0.0	4.0	11.53	-13	9	7	5.6	8.0	8.82	-6	18	10	4.2	6.0	9.33	-13	18
Week 16	2	-7.0	-7.0	12.73	-16	2	2	3.3	10.0	13.32	-12	12	4	-0.8	2.0	12.70	-16	12
Week 20	0	.	.	.	.	.	3	-7.5	-6.0	9.71	-20	2	3	-7.5	-6.0	9.71	-20	2
Week 24	11	-1.9	-4.5	12.87	-24	14	9	-1.2	0.0	14.97	-23	20	20	-1.6	-1.5	13.53	-24	20
Post Week 24	5	-2.5	-1.0	6.38	-10	6	4	4.0	2.0	4.69	0	12	9	0.5	1.0	6.38	-10	12

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	109.4	110.0	11.09	88	132	57	111.7	110.0	10.48	90	142	102	110.7	110.0	10.76	88	142
Change from Acute Study Baseline to 716:																		
Week 1	0	.	.	.	.	.	1	-20.0	-20.0	.	-20	-20	1	-20.0	-20.0	.	-20	-20
Week 2	0	.	.	.	.	.	0	.	.	.	.	.	0	.	.	.	.	.
Week 3	1	0.0	0.0	.	0	0	1	4.0	4.0	.	4	4	2	2.0	2.0	2.83	0	4
Week 4	0	.	.	.	.	.	2	-3.0	-3.0	4.24	-6	0	2	-3.0	-3.0	4.24	-6	0
Week 6	1	-4.0	-4.0	.	-4	-4	3	8.0	8.0	2.00	6	10	4	5.0	7.0	6.22	-4	10
Week 8	1	22.0	22.0	.	22	22	3	1.8	1.0	6.24	-5	10	4	5.8	2.0	10.55	-5	22
Week 12	1	4.0	4.0	.	4	4	1	5.0	5.0	.	5	5	2	4.5	4.5	0.71	4	5
Week 16	4	6.3	11.0	10.21	-9	12	2	6.0	6.0	19.80	-8	20	6	6.2	11.0	11.87	-9	20
Week 20	1	6.0	6.0	.	6	6	2	0.5	0.5	10.61	-7	8	3	2.3	6.0	8.14	-7	8
Week 24	14	-1.3	-6.0	11.84	-14	30	12	5.0	3.0	13.44	-14	36	26	1.8	0.0	12.81	-14	36
Post Week 24	6	-2.7	-7.5	11.83	-12	20	1	-6.0	-6.0	.	-6	-6	7	-3.1	-6.0	10.87	-12	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	106.7	106.0	10.94	88	132	127	107.4	108.0	11.54	74	142	221	107.1	107.0	11.27	74	142
Change from Acute Study Baseline to 716:																		
Week 1	1	14.0	14.0	.	14	14	1	-20.0	-20.0	.	-20	-20	2	-3.0	-3.0	24.04	-20	14
Week 2	0	.	.	.	.	.	1	-14.0	-14.0	.	-14	-14	1	-14.0	-14.0	.	-14	-14
Week 3	2	9.0	9.0	12.73	0	18	2	3.0	3.0	1.41	2	4	4	6.0	3.0	8.16	0	18
Week 4	1	16.0	16.0	.	16	16	5	-6.2	-3.0	9.18	-22	0	6	-2.5	-1.5	12.23	-22	16
Week 6	1	-4.0	-4.0	.	-4	-4	7	10.6	8.0	7.00	2	22	8	8.8	8.0	8.28	-4	22
Week 8	4	11.0	10.0	8.25	2	22	7	4.1	1.0	8.11	-5	20	11	6.4	5.0	8.48	-5	22
Week 12	4	1.0	4.0	9.63	-13	9	8	5.5	6.5	8.32	-6	18	12	4.2	4.5	8.59	-13	18
Week 16	6	1.8	6.0	11.91	-16	12	4	4.4	10.0	13.74	-12	20	10	3.0	10.0	12.17	-16	20
Week 20	1	6.0	6.0	.	6	6	5	-4.8	-4.5	9.81	-20	8	6	-3.3	-2.0	9.84	-20	8
Week 24	25	-1.6	-5.0	12.07	-24	30	21	2.4	2.0	14.13	-23	36	46	0.3	0.0	13.10	-24	36
Post Week 24	11	-2.6	-4.0	9.06	-12	20	5	2.3	2.0	5.85	-6	12	16	-0.9	0.0	8.30	-12	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	65.8	64.0	8.84	44	85	70	66.4	66.0	9.10	40	86	119	66.2	66.0	8.96	40	86
Change from Acute Study Baseline to 716:																		
Week 1	1	14.0	14.0	.	14	14	0	.	.	.	.	.	1	14.0	14.0	.	14	14
Week 2	0	.	.	.	.	.	1	-15.0	-15.0	.	-15	-15	1	-15.0	-15.0	.	-15	-15
Week 3	1	-2.0	-2.0	.	-2	-2	1	4.0	4.0	.	4	4	2	1.0	1.0	4.24	-2	4
Week 4	1	6.0	6.0	.	6	6	3	6.7	1.0	11.59	-1	20	4	6.5	3.5	9.47	-1	20
Week 6	0	.	.	.	.	.	4	11.5	10.0	13.99	-4	30	4	11.5	10.0	13.99	-4	30
Week 8	3	3.7	2.0	7.64	-3	12	4	5.5	7.0	8.39	-6	14	7	4.7	6.0	7.45	-6	14
Week 12	3	5.0	10.0	9.54	-6	11	7	5.1	10.0	11.02	-13	16	10	5.1	10.0	10.24	-13	16
Week 16	2	-9.0	-9.0	26.87	-28	10	2	5.7	6.0	4.51	1	10	4	-0.2	6.0	15.97	-28	10
Week 20	0	.	.	.	.	.	3	-5.5	-7.0	5.74	-10	2	3	-5.5	-7.0	5.74	-10	2
Week 24	11	3.6	0.0	13.17	-14	28	9	-1.2	-2.0	6.46	-11	8	20	1.4	-1.0	10.71	-14	28
Post Week 24	5	-1.2	-1.0	9.22	-14	14	4	4.8	6.0	3.63	0	8	9	1.5	1.0	7.58	-14	14

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	68.1	70.0	9.40	40	85	57	69.1	70.0	9.40	44	86	102	68.6	70.0	9.37	40	86
Change from Acute Study Baseline to 716:																		
Week 1	0	.	.	.	.	.	1	0.0	0.0	.	0	0	1	0.0	0.0	.	0	0
Week 2	0	.	.	.	.	.	0	.	.	.	.	.	0	.	.	.	.	.
Week 3	1	-2.0	-2.0	.	-2	-2	1	2.0	2.0	.	2	2	2	0.0	0.0	2.83	-2	2
Week 4	0	.	.	.	.	.	2	-3.0	-3.0	7.07	-8	2	2	-3.0	-3.0	7.07	-8	2
Week 6	1	-7.0	-7.0	.	-7	-7	3	-2.0	-10.0	13.86	-10	14	4	-3.3	-8.5	11.59	-10	14
Week 8	1	5.0	5.0	.	5	5	3	4.5	2.0	5.00	2	12	4	4.6	2.0	4.34	2	12
Week 12	1	0.0	0.0	.	0	0	1	2.0	2.0	.	2	2	2	1.0	1.0	1.41	0	2
Week 16	4	8.0	6.0	5.42	4	16	2	7.5	7.5	16.26	-4	19	6	7.8	6.0	8.40	-4	19
Week 20	1	2.0	2.0	.	2	2	2	0.5	0.5	6.36	-4	5	3	1.0	2.0	4.58	-4	5
Week 24	14	1.8	2.0	7.52	-8	20	12	2.8	4.5	8.13	-10	18	26	2.3	2.0	7.69	-10	20
Post Week 24	6	1.7	0.0	9.24	-10	18	1	4.0	4.0	.	4	4	7	2.0	0.0	8.49	-10	18

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	66.9	68.0	9.14	40	85	127	67.6	69.0	9.29	40	86	221	67.3	68.0	9.21	40	86
Change from Acute Study Baseline to 716:																		
Week 1	1	14.0	14.0	.	14	14	1	0.0	0.0	.	0	0	2	7.0	7.0	9.90	0	14
Week 2	0	.	.	.	.	.	1	-15.0	-15.0	.	-15	-15	1	-15.0	-15.0	.	-15	-15
Week 3	2	-2.0	-2.0	0.00	-2	-2	2	3.0	3.0	1.41	2	4	4	0.5	0.0	3.00	-2	4
Week 4	1	6.0	6.0	.	6	6	5	2.8	1.0	10.38	-8	20	6	3.3	1.5	9.37	-8	20
Week 6	1	-7.0	-7.0	.	-7	-7	7	5.7	10.0	14.63	-10	30	8	4.1	3.0	14.27	-10	30
Week 8	4	4.0	3.5	6.27	-3	12	7	5.0	4.0	6.41	-6	14	11	4.7	3.5	6.10	-6	14
Week 12	4	3.8	5.0	8.18	-6	11	8	4.8	9.0	10.43	-13	16	12	4.5	9.0	9.54	-13	16
Week 16	6	2.3	6.0	15.46	-28	16	4	6.4	6.0	8.79	-4	19	10	4.2	6.0	12.45	-28	19
Week 20	1	2.0	2.0	.	2	2	5	-3.5	-4.0	6.12	-10	5	6	-2.7	-4.0	5.96	-10	5
Week 24	25	2.6	0.0	10.23	-14	28	21	1.1	0.0	7.59	-11	18	46	1.9	0.0	9.03	-14	28
Post Week 24	11	0.3	0.0	8.93	-14	18	5	4.7	5.0	3.27	0	8	16	1.7	0.5	7.70	-14	18

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	84.5	84.0	10.88	60	102	70	81.6	81.0	11.67	52	110	119	82.8	82.0	11.39	52	110
Change from Acute Study Baseline to 716:																		
Week 1	1	-6.0	-6.0	.	-6	-6	0	.	.	.	.	.	1	-6.0	-6.0	.	-6	-6
Week 2	0	.	.	.	.	.	1	23.0	23.0	.	23	23	1	23.0	23.0	.	23	23
Week 3	1	-20.0	-20.0	.	-20	-20	1	0.0	0.0	.	0	0	2	-10.0	-10.0	14.14	-20	0
Week 4	1	8.0	8.0	.	8	8	3	-8.0	-5.0	8.89	-18	-1	4	-4.0	-3.0	10.80	-18	8
Week 6	0	.	.	.	.	.	4	-7.0	-12.0	14.65	-18	14	4	-7.0	-12.0	14.65	-18	14
Week 8	3	5.3	0.0	11.02	-2	18	4	8.3	7.5	13.38	-6	24	7	7.0	1.0	11.50	-6	24
Week 12	3	-1.0	-4.0	14.73	-14	15	7	1.6	2.0	10.14	-16	16	10	0.9	1.0	10.75	-16	16
Week 16	2	7.0	7.0	12.73	-2	16	2	-3.0	0.0	8.89	-13	4	4	1.0	0.0	10.49	-13	16
Week 20	0	.	.	.	.	.	3	3.3	4.0	14.68	-15	20	3	3.3	4.0	14.68	-15	20
Week 24	11	0.3	2.0	9.86	-20	14	9	-2.9	-6.5	11.43	-16	23	20	-1.1	0.0	10.47	-20	23
Post Week 24	5	6.5	8.0	8.67	-8	16	4	4.0	2.0	6.78	-4	12	9	5.4	6.0	7.59	-8	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	78.4	80.0	9.81	60	104	57	74.7	76.0	8.93	52	96	102	76.3	76.0	9.46	52	104
Change from Acute Study Baseline to 716:																		
Week 1	0	.	.	.	.	.	1	16.0	16.0	.	16	16	1	16.0	16.0	.	16	16
Week 2	0	.	.	.	.	.	0	.	.	.	.	.	0	.	.	.	.	.
Week 3	1	8.0	8.0	.	8	8	1	-12.0	-12.0	.	-12	-12	2	-2.0	-2.0	14.14	-12	8
Week 4	0	.	.	.	.	.	2	-6.0	-6.0	8.49	-12	0	2	-6.0	-6.0	8.49	-12	0
Week 6	1	6.0	6.0	.	6	6	3	0.7	0.0	13.01	-12	14	4	2.0	3.0	10.95	-12	14
Week 8	1	-38.0	-38.0	.	-38	-38	3	5.0	4.0	6.00	0	12	4	-3.6	0.0	19.92	-38	12
Week 12	1	20.0	20.0	.	20	20	1	4.0	4.0	.	4	4	2	12.0	12.0	11.31	4	20
Week 16	4	18.0	20.0	7.66	8	24	2	18.5	18.5	13.44	9	28	6	18.2	20.0	8.45	8	28
Week 20	1	-4.0	-4.0	.	-4	-4	2	7.0	7.0	9.90	0	14	3	3.3	0.0	9.45	-4	14
Week 24	14	2.5	4.0	7.86	-16	20	12	0.6	3.0	13.83	-30	20	26	1.6	4.0	10.98	-30	20
Post Week 24	6	-2.3	-2.0	5.13	-8	4	1	-5.0	-5.0	.	-5	-5	7	-2.7	-4.0	4.79	-8	4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	81.5	80.0	10.77	60	104	127	78.5	79.0	11.04	52	110	221	79.8	80.0	11.00	52	110
Change from Acute Study Baseline to 716:																		
Week 1	1	-6.0	-6.0	.	-6	-6	1	16.0	16.0	.	16	16	2	5.0	5.0	15.56	-6	16
Week 2	0	.	.	.	.	.	1	23.0	23.0	.	23	23	1	23.0	23.0	.	23	23
Week 3	2	-6.0	-6.0	19.80	-20	8	2	-6.0	-6.0	8.49	-12	0	4	-6.0	-6.0	12.44	-20	8
Week 4	1	8.0	8.0	.	8	8	5	-7.2	-5.0	7.66	-18	0	6	-4.7	-3.0	9.24	-18	8
Week 6	1	6.0	6.0	.	6	6	7	-3.7	-8.0	13.44	-18	14	8	-2.5	-4.0	12.91	-18	14
Week 8	4	-5.5	-1.0	23.46	-38	18	7	6.6	4.5	9.75	-6	24	11	2.6	0.5	15.69	-38	24
Week 12	4	4.3	5.5	15.97	-14	20	8	1.8	3.0	9.59	-16	16	12	2.5	3.0	11.13	-16	20
Week 16	6	14.3	16.0	9.99	-2	24	4	5.6	4.0	14.94	-13	28	10	10.4	9.0	12.65	-13	28
Week 20	1	-4.0	-4.0	.	-4	-4	5	4.5	4.0	12.36	-15	20	6	3.3	0.0	11.73	-15	20
Week 24	25	1.5	4.0	8.69	-20	20	21	-0.9	0.0	12.74	-30	23	46	0.4	2.0	10.74	-30	23
Post Week 24	11	2.1	2.0	8.21	-8	16	5	2.5	1.0	7.09	-5	12	16	2.2	2.0	7.64	-8	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	139.83	137.80	12.886	114.5	165.0	70	138.80	139.85	10.329	115.6	161.0	119	139.23	139.70	11.410	114.5	165.0
Change from Acute Study Baseline to 716:																		
Week 12	3	-5.13	1.30	12.644	-19.7	3.0	2	2.50	2.50	0.707	2.0	3.0	5	-2.08	2.00	9.876	-19.7	3.0
Week 24	3	3.17	3.50	2.021	1.0	5.0	2	15.05	15.05	16.051	3.7	26.4	5	7.92	3.70	10.432	1.0	26.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	166.15	166.00	10.101	139.5	188.0	56	165.79	167.60	8.351	149.9	180.3	101	165.95	166.40	9.126	139.5	188.0
Change from Acute Study Baseline to 716:																		
Week 12	1	0.00	0.00	.	0.0	0.0	0	.	.	.	.	.	1	0.00	0.00	.	0.0	0.0
Week 24	7	-1.56	0.00	9.772	-20.9	8.0	3	1.77	1.00	1.779	0.5	3.8	10	-0.56	0.25	8.182	-20.9	8.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	152.43	154.95	17.570	114.5	188.0	126	150.80	151.20	16.458	115.6	180.3	220	151.50	152.40	16.922	114.5	188.0
Change from Acute Study Baseline to 716:																		
Week 12	4	-3.85	0.65	10.638	-19.7	3.0	2	2.50	2.50	0.707	2.0	3.0	6	-1.73	1.65	8.874	-19.7	3.0
Week 24	10	-0.14	0.50	8.353	-20.9	8.0	5	7.08	3.70	10.905	0.5	26.4	15	2.27	1.00	9.552	-20.9	26.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	41.73	38.10	16.419	20.4	79.5	70	38.82	34.50	14.615	20.5	104.0	119	40.02	35.20	15.383	20.4	104.0
Change from Acute Study Baseline to 716:																		
Week 12	3	3.95	4.14	2.157	1.7	6.0	2	1.10	1.10	2.687	-0.8	3.0	5	2.81	3.00	2.562	-0.8	6.0
Week 24	3	5.30	2.50	6.286	0.9	12.5	2	7.80	7.80	2.546	6.0	9.6	5	6.30	6.00	4.822	0.9	12.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	69.78	65.00	20.023	32.5	132.6	56	67.45	62.45	19.822	38.2	131.4	101	68.49	62.70	19.846	32.5	132.6
Change from Acute Study Baseline to 716:																		
Week 12	1	-4.10	-4.10	.	-4.1	-4.1	0	.	.	.	.	.	1	-4.10	-4.10	.	-4.1	-4.1
Week 24	7	4.39	5.30	5.298	-3.7	11.0	3	2.17	0.50	3.329	0.0	6.0	10	3.72	5.10	4.725	-3.7	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	55.16	55.25	22.963	20.4	132.6	126	51.54	46.80	22.244	20.5	131.4	220	53.09	51.85	22.574	20.4	132.6
Change from Acute Study Baseline to 716:																		
Week 12	4	1.93	2.92	4.392	-4.1	6.0	2	1.10	1.10	2.687	-0.8	3.0	6	1.66	2.35	3.634	-4.1	6.0
Week 24	10	4.66	5.10	5.262	-3.7	12.5	5	4.42	6.00	4.084	0.0	9.6	15	4.58	5.30	4.752	-3.7	12.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	49	20.72	18.50	5.675	13.9	32.8	70	19.73	18.15	5.279	13.6	40.1	119	20.14	18.20	5.444	13.6	40.1
Change from Acute Study Baseline to 716:																		
Week 12	3	4.60	2.20	4.776	1.5	10.1	2	-0.20	-0.20	0.990	-0.9	0.5	5	2.68	1.50	4.308	-0.9	10.1
Week 24	3	1.57	0.80	1.779	0.3	3.6	2	-0.55	-0.55	5.586	-4.5	3.4	5	0.72	0.80	3.275	-4.5	3.6

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	45	25.16	23.10	6.632	16.5	45.9	56	24.39	22.80	6.373	16.4	45.4	101	24.73	22.80	6.468	16.4	45.9
Change from Acute Study Baseline to 716:																		
Week 12	1	-2.00	-2.00	.	-2.0	-2.0	0	.	.	.	.	.	1	-2.00	-2.00	.	-2.0	-2.0
Week 24	7	2.53	0.60	4.021	-0.6	11.0	3	0.30	0.00	0.794	-0.3	1.2	10	1.86	0.45	3.476	-0.6	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	94	22.84	21.50	6.512	13.9	45.9	126	21.80	20.05	6.218	13.6	45.4	220	22.25	20.75	6.351	13.6	45.9
Change from Acute Study Baseline to 716:																		
Week 12	4	2.95	1.85	5.108	-2.0	10.1	2	-0.20	-0.20	0.990	-0.9	0.5	6	1.90	1.00	4.301	-2.0	10.1
Week 24	10	2.24	0.70	3.421	-0.6	11.0	5	-0.04	0.00	2.887	-4.5	3.4	15	1.48	0.60	3.338	-4.5	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	47	N/A	68	N/A	115	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	47	100.0	68	100.0	115	100.0
Low	22	46.8	27	39.7	49	42.6
Significant Decrease	2	4.3	3	4.4	5	4.3
Low & Significant Decrease	2	4.3	3	4.4	5	4.3
Low & Significant Increase	0	0.0	1	1.5	1	0.9
High	1	2.1	0	0.0	1	0.9
Significant Increase	0	0.0	2	2.9	2	1.7
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	55	N/A	99	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	55	100.0	99	100.0
Low	11	25.0	5	9.1	16	16.2
Significant Decrease	1	2.3	1	1.8	2	2.0
Low & Significant Decrease	1	2.3	0	0.0	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	2	4.5	2	3.6	4	4.0
Significant Increase	0	0.0	2	3.6	2	2.0
High & Significant Increase	0	0.0	2	3.6	2	2.0
High & Significant Decrease	1	2.3	0	0.0	1	1.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	91	N/A	123	N/A	214	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	91	100.0	123	100.0	214	100.0
Low	33	36.3	32	26.0	65	30.4
Significant Decrease	3	3.3	4	3.3	7	3.3
Low & Significant Decrease	3	3.3	3	2.4	6	2.8
Low & Significant Increase	0	0.0	1	0.8	1	0.5
High	3	3.3	2	1.6	5	2.3
Significant Increase	0	0.0	4	3.3	4	1.9
High & Significant Increase	0	0.0	2	1.6	2	0.9
High & Significant Decrease	1	1.1	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	47	N/A	68	N/A	115	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	47	100.0	68	100.0	115	100.0
Low	5	10.6	9	13.2	14	12.2
Significant Decrease	5	10.6	6	8.8	11	9.6
Low & Significant Decrease	1	2.1	2	2.9	3	2.6
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	5	10.6	4	5.9	9	7.8
Significant Increase	1	2.1	2	2.9	3	2.6
High & Significant Increase	1	2.1	1	1.5	2	1.7
High & Significant Decrease	1	2.1	0	0.0	1	0.9

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	55	N/A	99	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	55	100.0	99	100.0
Low	0	0.0	5	9.1	5	5.1
Significant Decrease	2	4.5	4	7.3	6	6.1
Low & Significant Decrease	0	0.0	1	1.8	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	3	6.8	5	9.1	8	8.1
Significant Increase	1	2.3	1	1.8	2	2.0
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	91	N/A	123	N/A	214	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	91	100.0	123	100.0	214	100.0
Low	5	5.5	14	11.4	19	8.9
Significant Decrease	7	7.7	10	8.1	17	7.9
Low & Significant Decrease	1	1.1	3	2.4	4	1.9
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	8	8.8	9	7.3	17	7.9
Significant Increase	2	2.2	3	2.4	5	2.3
High & Significant Increase	1	1.1	1	0.8	2	0.9
High & Significant Decrease	1	1.1	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	47	N/A	68	N/A	115	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	47	100.0	68	100.0	115	100.0
Low	6	12.8	16	23.5	22	19.1
Significant Decrease	2	4.3	2	2.9	4	3.5
Low & Significant Decrease	1	2.1	2	2.9	3	2.6
Low & Significant Increase	0	0.0	1	1.5	1	0.9
High	2	4.3	0	0.0	2	1.7
Significant Increase	2	4.3	4	5.9	6	5.2
High & Significant Increase	2	4.3	0	0.0	2	1.7
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	55	N/A	99	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	55	100.0	99	100.0
Low	0	0.0	6	10.9	6	6.1
Significant Decrease	2	4.5	3	5.5	5	5.1
Low & Significant Decrease	0	0.0	1	1.8	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	0	0.0	2	3.6	2	2.0
Significant Increase	3	6.8	6	10.9	9	9.1
High & Significant Increase	0	0.0	1	1.8	1	1.0
High & Significant Decrease	0	0.0	1	1.8	1	1.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	91	N/A	123	N/A	214	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	91	100.0	123	100.0	214	100.0
Low	6	6.6	22	17.9	28	13.1
Significant Decrease	4	4.4	5	4.1	9	4.2
Low & Significant Decrease	1	1.1	3	2.4	4	1.9
Low & Significant Increase	0	0.0	1	0.8	1	0.5
High	2	2.2	2	1.6	4	1.9
Significant Increase	5	5.5	10	8.1	15	7.0
High & Significant Increase	2	2.2	1	0.8	3	1.4
High & Significant Decrease	0	0.0	1	0.8	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	30	N/A	48	N/A	78	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	30	100.0	48	100.0	78	100.0
Low	0	0.0	0	0.0	0	0.0
Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	13	43.3	13	27.1	26	33.3
Significant Increase	20	66.7	28	58.3	48	61.5
High & Significant Increase	6	20.0	6	12.5	12	15.4
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	32	N/A	37	N/A	69	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	32	100.0	36	100.0	68	100.0
Low	1	3.1	0	0.0	1	1.5
Significant Decrease	1	3.1	1	2.8	2	2.9
Low & Significant Decrease	1	3.1	0	0.0	1	1.5
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	11	34.4	11	30.6	22	32.4
Significant Increase	14	43.8	11	30.6	25	36.8
High & Significant Increase	6	18.8	3	8.3	9	13.2
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	62	N/A	85	N/A	147	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	62	100.0	84	100.0	146	100.0
Low	1	1.6	0	0.0	1	0.7
Significant Decrease	1	1.6	1	1.2	2	1.4
Low & Significant Decrease	1	1.6	0	0.0	1	0.7
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	24	38.7	24	28.6	48	32.9
Significant Increase	34	54.8	39	46.4	73	50.0
High & Significant Increase	12	19.4	9	10.7	21	14.4
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	48	N/A	70	N/A	118	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	48	100.0	70	100.0	118	100.0
Low	24	50.0	27	38.6	51	43.2
Significant Decrease	2	4.2	3	4.3	5	4.2
Low & Significant Decrease	2	4.2	3	4.3	5	4.2
Low & Significant Increase	0	0.0	1	1.4	1	0.8
High	1	2.1	0	0.0	1	0.8
Significant Increase	0	0.0	2	2.9	2	1.7
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	56	N/A	100	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	56	100.0	100	100.0
Low	11	25.0	6	10.7	17	17.0
Significant Decrease	1	2.3	1	1.8	2	2.0
Low & Significant Decrease	1	2.3	0	0.0	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	2	4.5	2	3.6	4	4.0
Significant Increase	0	0.0	2	3.6	2	2.0
High & Significant Increase	0	0.0	2	3.6	2	2.0
High & Significant Decrease	1	2.3	0	0.0	1	1.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	92	N/A	126	N/A	218	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	92	100.0	126	100.0	218	100.0
Low	35	38.0	33	26.2	68	31.2
Significant Decrease	3	3.3	4	3.2	7	3.2
Low & Significant Decrease	3	3.3	3	2.4	6	2.8
Low & Significant Increase	0	0.0	1	0.8	1	0.5
High	3	3.3	2	1.6	5	2.3
Significant Increase	0	0.0	4	3.2	4	1.8
High & Significant Increase	0	0.0	2	1.6	2	0.9
High & Significant Decrease	1	1.1	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	48	N/A	70	N/A	118	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	48	100.0	70	100.0	118	100.0
Low	6	12.5	9	12.9	15	12.7
Significant Decrease	6	12.5	6	8.6	12	10.2
Low & Significant Decrease	2	4.2	2	2.9	4	3.4
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	5	10.4	4	5.7	9	7.6
Significant Increase	1	2.1	3	4.3	4	3.4
High & Significant Increase	1	2.1	1	1.4	2	1.7
High & Significant Decrease	1	2.1	0	0.0	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	56	N/A	100	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	56	100.0	100	100.0
Low	0	0.0	5	8.9	5	5.0
Significant Decrease	2	4.5	4	7.1	6	6.0
Low & Significant Decrease	0	0.0	1	1.8	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	3	6.8	6	10.7	9	9.0
Significant Increase	1	2.3	1	1.8	2	2.0
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	92	N/A	126	N/A	218	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	92	100.0	126	100.0	218	100.0
Low	6	6.5	14	11.1	20	9.2
Significant Decrease	8	8.7	10	7.9	18	8.3
Low & Significant Decrease	2	2.2	3	2.4	5	2.3
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	8	8.7	10	7.9	18	8.3
Significant Increase	2	2.2	4	3.2	6	2.8
High & Significant Increase	1	1.1	1	0.8	2	0.9
High & Significant Decrease	1	1.1	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	48	N/A	70	N/A	118	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	48	100.0	70	100.0	118	100.0
Low	7	14.6	16	22.9	23	19.5
Significant Decrease	2	4.2	2	2.9	4	3.4
Low & Significant Decrease	1	2.1	2	2.9	3	2.5
Low & Significant Increase	1	2.1	1	1.4	2	1.7
High	3	6.3	0	0.0	3	2.5
Significant Increase	2	4.2	4	5.7	6	5.1
High & Significant Increase	2	4.2	0	0.0	2	1.7
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	44	N/A	56	N/A	100	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	44	100.0	56	100.0	100	100.0
Low	0	0.0	6	10.7	6	6.0
Significant Decrease	2	4.5	3	5.4	5	5.0
Low & Significant Decrease	0	0.0	1	1.8	1	1.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	0	0.0	2	3.6	2	2.0
Significant Increase	3	6.8	6	10.7	9	9.0
High & Significant Increase	0	0.0	1	1.8	1	1.0
High & Significant Decrease	0	0.0	1	1.8	1	1.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	92	N/A	126	N/A	218	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	92	100.0	126	100.0	218	100.0
Low	7	7.6	22	17.5	29	13.3
Significant Decrease	4	4.3	5	4.0	9	4.1
Low & Significant Decrease	1	1.1	3	2.4	4	1.8
Low & Significant Increase	1	1.1	1	0.8	2	0.9
High	3	3.3	2	1.6	5	2.3
Significant Increase	5	5.4	10	7.9	15	6.9
High & Significant Increase	2	2.2	1	0.8	3	1.4
High & Significant Decrease	0	0.0	1	0.8	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	36	N/A	54	N/A	90	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	36	100.0	54	100.0	90	100.0
Low	0	0.0	0	0.0	0	0.0
Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	16	44.4	14	25.9	30	33.3
Significant Increase	22	61.1	30	55.6	52	57.8
High & Significant Increase	7	19.4	6	11.1	13	14.4
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	37	N/A	44	N/A	81	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	37	100.0	43	100.0	80	100.0
Low	1	2.7	0	0.0	1	1.3
Significant Decrease	1	2.7	1	2.3	2	2.5
Low & Significant Decrease	1	2.7	0	0.0	1	1.3
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	11	29.7	14	32.6	25	31.3
Significant Increase	15	40.5	15	34.9	30	37.5
High & Significant Increase	6	16.2	5	11.6	11	13.8
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716
Interim Output
Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	73	N/A	98	N/A	171	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	73	100.0	97	100.0	170	100.0
Low	1	1.4	0	0.0	1	0.6
Significant Decrease	1	1.4	1	1.0	2	1.2
Low & Significant Decrease	1	1.4	0	0.0	1	0.6
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	27	37.0	28	28.9	55	32.4
Significant Increase	37	50.7	45	46.4	82	48.2
High & Significant Increase	13	17.8	11	11.3	24	14.1
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Narratives for Patients with Vital Signs Associated with an Adverse Event And Meeting the Criteria for Clinical Concern

716

Table 15.2.3

Interim Report Safety Narratives

SB Document Number: BRL-029060/RSD-101C1W/1

Narratives for Patients with Vital Signs Associated with an Adverse Event And Meeting the Criteria for Clinical Concern

PID 716.028.25962

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Weight Loss

Adverse Experience Associated with Vital Sign of Concern: Decreased Body Weight

This 15-year-old black female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.185.25962), and received treatment with paroxetine in that study.

No concomitant medications were recorded during the study.

The patient received the first dose of study medication on 16 November 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 40 mg/day on 12 January 2001 (Day 58) until 06 February 2001 (Day 83). The dose of study medication was tapered to 30 mg/day on 07 February 2001 (Day 84), then to 20 mg/day on 13 February 2001 (Day 90), and then to 10 mg/day on 20 February 2001 (Day 97). The final dose of study medication was taken on 25 February 2001 (Day 102). The patient was withdrawn from the study on Day 89 for lack of efficacy.

At screening of the acute study 701, the patient weighed 40.9 kg. At baseline of Protocol 716, the body weight remained at 40.9 kg. On 06 February 2001 (Day 83), the patient's body weight had decreased to 36.8 kg. On 13 February 2001 (Week 12; Day 90), the patient's body weight maintained at 36.8 kg. No follow-up body weight was provided. Normal range for 15-year-old females is 38.6 to 79.9 kg. This decrease in body weight at Week 12 met the level of potential clinical concern. The level of potential clinical concern is defined as a body

weight above or below normal limits, with an increase or decrease in weight equal to or greater than 7% from baseline.

On 13 March 2001, the patient had an increase in sitting pulse rate of 116 beats/minute, which met the level of potential clinical concern. The pulse rate at baseline in the previous acute study 701 was 68 beats/min; the pulse rate at baseline of Protocol 716 was 76 beats/minute. The range for pulse rate during the study was 78 to 116 beats/minute.

On 29 November 2000 (Day 14), the patient experienced the onset of moderately severe weight loss that resolved without treatment in 105 days. The investigator considered the weight loss to be unrelated to treatment with study medication.

On 12 December 2000 (Day 27), the patient reported the onset of mild chest pain (chest pain, heartburn) and mild dyspepsia (chest pain, heartburn), both of which resolved without treatment in 9 days. The investigator considered both events to be unrelated to treatment with study medication.

On 14 December 2000 (Day 29), the patient experienced the onset of mild albuminuria (trace protein urine dipstick) that resolved without treatment in one day. Albuminuria was considered to be unrelated to treatment with study medication.

On 21 December 2000 (Day 36), the patient experienced the onset of mild respiratory disorder (upper respiratory infection) that resolved without treatment in 10 days. The investigator considered this event to be unrelated to treatment with study medication.

On 04 February 2001 (Day 81), the patient reported the onset of mild somnolence (sedation) that resolved without treatment in 10 days. The dose of study medication was reduced in response to this event. The investigator considered sedation to be possibly related to treatment with study medication.

On 06 February 2001 (Day 83), the patient reported the onset of mild nausea and mild vomiting, both of which cleared without treatment in one day. These events were considered to be possibly related to treatment with study medication and the investigator reduced the dose of study medication in response to these events.

No other adverse experiences were reported during the study.

PID 716.159.25628

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Weight Gain

Adverse Experience Associated with Vital Sign of Concern: Increased Body Weight

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.159.25628), and received treatment with placebo in that study.

Concomitant medications included aspirin (acetasalicylic acid) for headache; Theraflu® (chlorphenamine maleate, paracetamol, pseudoephedrine hCl) for upper respiratory infection; and inhaled Flovent® (fluticasone proprionate) and inhaled Serevent® (salmeterol hydroxynaphthoate for asthma.

The patient received the first dose of study medication on 20 June 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 20 mg/day on 27 June 2000 (Day 8) until 17 July 2000 (Day 28). The dose of study medication was temporarily reduced to 10 mg/day on 18 July 2000 (Day 29) until 24 July 2000 (Day 25), then increased again to 20 mg/day on 25 July 2000 (Day 26). The dose remained at 20 mg/day until the end of the active phase of the study, 13 December 2000 (Day 177), and then tapered to 10 mg/day on 14 December 2000 (Day 178). The final dose of study medication was taken on 27 December 2000 (Day 191). The patient completed the study as planned.

At acute screening in Protocol 701, the patient weighed 95 kg. At baseline in Protocol 716, the patient's body weight was 102.3 kg. By week 12, the patient's weight had increased to 109.1 kg, and by Week 24, body weight increased to 111.8 kg. Normal range for 14-year-old males is 35.9 to 74.5 kg. These increases in body weight during Protocol 716 met the level of potential clinical concern. The level of potential clinical concern is defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No follow-up body weight was provided. Systolic blood pressure on

24 July 2000 (Week 5) was also increased to 150 mmHg, which was at the level of potential clinical concern. The range of values for systolic blood pressure during the extension study was 122 mmHg to 150 mmHg. At baseline of the previous acute study, the systolic blood pressure was 100 mmHg.

Moderately severe abdominal pain (epigastric pain), mildly increased SGPT (elevated liver enzymes), mild weight gain, moderately severe depression (exacerbation of major depressive disorder), and somnolence (insomnia) began during the acute Protocol 701 and continued into extension protocol 716. Weight gain, somnolence, and abdominal pain were considered to be possibly related to treatment with study medication by the investigator; increased SGPT and depression were considered to be unrelated. Abdominal pain resolved with treatment in 113 days; increased SGPT resolved without treatment in 36 days; depression resolved with treatment in 5 days; somnolence and weight gain continued throughout Protocol 716.

On 17 August 2000 (Day 59), the patient reported the onset of mild respiratory disorder that resolved with treatment in 2 days. On 10 September 2000 (Day 83), the patient reported the onset of moderately severe respiratory disorder that resolved with treatment in 11 days. The investigator considered both to be unrelated to treatment with study medication.

Mild, intermittent headaches were reported on 18 July 2000 (Day 29) and 17 August 2000 (Day 59). Both resolved with treatment in 11 days, and 4 days, respectively. The investigator considered both events to be unrelated to treatment with study medication.

On 03 November 2000 (Day 137), the patient reported the onset of mild asthma that continued through the end of the study reporting period despite corrective therapy. The investigator considered asthma to be probably unrelated to treatment with study medication.

No other adverse experiences were reported during the study.

PID 716.167.25903

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Weight Gain

Adverse Experience Associated with Vital Sign of Concern: Increased Body Weight

This 12-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.167.25903), and received treatment with placebo in that study.

Concomitant medications included Zithromax® (azithromycin) for fever; Erythomycin® (erythromycin) for bronchitis; ibuprofen for headache, fever, and rhinitis; pseudoephedrine for rhinitis; Claritin® (loratidine) and Albuterol® inhaler (salbutamol) for seasonal allergies/wheezing; and Pepto-Bismol® (bismuth subsalicylate) and Tums (calcium carbonate) for intermittent stomach aches.

The patient received the first dose of study medication on 28 September 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg/day on 19 December 2000 (Day 83). The dose remained at 30 mg/day until the end of the study, 12 March 2001 (Day 166). The patient completed the study as planned.

At screening in the previous acute study 701, the patient weighed 60.4 kg., and at baseline of extension Protocol 716, the patient's body weight was unchanged at 60.4 kg. By week 12, the patient's weight had increased to 63.6 kg., and by Week 24 the body weight was 66.4 kg. Normal range for 12-year-old females is 28.1 to 63.1 kg. This increase in body weight at Week 24 met the level of potential clinical concern. The level of potential clinical concern is defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No follow-up body weight was provided.

On 16 January 2001 (Day 111), the patient reported the onset of mild weight gain that continued without treatment through the end of the study period. The

investigator considered weight gain to be possibly related to treatment with study medication.

On 14 October 2000 (Day 17), the patient reported the onset of mild increased cough (cough), mild rhinitis, and mild asthma (wheezing), all of which were considered to be unrelated to treatment with study medication by the investigator. Cough resolved without treatment in 26 days; asthma resolved with treatment in 19 days; and rhinitis continued throughout the study period despite treatment.

On 18 October 2000 (Day 21), the patient reported the onset of mild nausea that resolved without treatment in 3 days. On 19 October 2000 (Day 22), the patient reported the onset of moderately severe fever that resolved with treatment in 7 days. The investigator considered fever and nausea to be unrelated to treatment with study medication.

Mild headaches were reported on 17 December 2000 (Day 81), 15 January 2001 (Day 110), and 11 March 2001 (Day 165). Headaches on Day 81 and Day 165 resolved with treatment in one day; headache on Day 110 resolved without treatment in one day. The investigator considered headaches to be unrelated to treatment with study medication.

On 23 January 2001, the patient reported the onset of bronchitis that cleared with treatment in 4 days. The investigator considered bronchitis to be unrelated to treatment with study medication.

No other adverse experiences were reported.

PID 716.176.25668

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Weight Gain

Adverse Experience Associated with Vital Sign of Concern: Increased Body Weight

This 11-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.176.25668), and received treatment with paroxetine in that study.

Concomitant medications included Zithromax® (azithromycin) for tonsillitis; topical Cleocin® (clindamycin hCl) for acne; and Dayquil® (paracetamol, pseudoephedrine hCl, guaifenesin, dextromethorphan hydrobromide) and promethazine/codeine syrup for upper respiratory tract infection.

The patient received the first dose of study medication on 06 July 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 50 mg/day on 04 October 2000 (Day 91). The dose remained at 30 mg/day until 28 December 2000 (Day 176), which was the end of the active phase of the study. The dose was tapered to 10 mg/day and the last dose of study medication was given on 26 January 2001 (Day 205). The patient completed the study as planned.

At screening in the previous acute study 701, the patient weighed 67 kg. At baseline of Protocol 716, the patient weighed 73.0 kg. By week 12, the patient's weight had increased to 77.5 kg., and by Week 24 the patient's weight had increased further to 81.8 kg. Normal range for 11-year-old females is 25.0 to 56.3 kg. The increases in body weight at baseline of Protocol 716, and at Weeks 12 and 24 met the level of potential clinical concern. The level of potential clinical concern is defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No follow-up body weight was provided.

Also, at Week 24, there was a single decreased systolic blood pressure reading of 92 mmHg. At baseline in the previous acute study the systolic blood pressure was 122 mmHg; at baseline in Protocol 716, the systolic blood pressure was 108 mmHg. The range of values during the study was 92 - 126 mmHg. No other vital signs value met the level of potential clinical concern.

On 06 July 2000 (Day 1), the patient reported the onset of moderately severe weight gain that continued throughout the study. No corrective treatment was given for this condition, that the investigator considered to be possibly related to treatment with study medication.

On 17 August 2000 (Day 43), the patient reported the onset of mild acne that continued, with treatment, for the duration of the study. The investigator considered acne to be unrelated to treatment with study medication

On On 29 August 2000 (Day 55), the patient reported the onset of moderately severe pharyngitis (tonsillitis) that resolved with treatment in 5 days. The investigator considered pharyngitis to be unrelated to treatment with study medication.

On 24 November 2000 (Day 142), the patient experienced the onset of a moderately severe respiratory disorder (respiratory tract infection) that resolved with treatment in 8 days. The investigator considered this to be unrelated to treatment with study medication.

Several other non-serious adverse experiences were reported after study medication was discontinued.

On 28 January 2001 (Day 207; 31 days after the last dose of study medication), the patient reported moderately severe anxiety that resolved without treatment in 9 days, and mild respiratory disorder (upper respiratory tract infection) that resolved with treatment in 4 days. The investigator considered the respiratory infection to be unrelated to treatment with study medication and the anxiety to be possibly related.

On 29 January 2001 (Day 208; 32 days after study medication was discontinued), the patient reported the onset of moderately severe headache that resolved with treatment in 3 days. The investigator considered headache to be possibly related to treatment with study medication.

On 30 January 2001 (Day 209; 33 days after study medication was discontinued), the patient reported the onset of moderately severe abdominal pain that resolved

without treatment in two days, moderately severe increased appetite that resolved without treatment in 7 days, mild insomnia that resolved without treatment in 7 days, moderately severe nervousness (irritability) that resolved without treatment in 7 days, and moderately severe nausea that resolved without treatment in two days. The investigator considered abdominal pain and nausea to be unrelated to treatment with study medication and increased appetite, insomnia and nervousness to be possibly related.

No other adverse experiences were reported during the study.

PID 716.176.25795

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Abnormal Weight Gain

Adverse Experience Associated with Vital Sign of Concern: Increased Body Weight

This 11-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.176.25795), and received treatment with paroxetine in that study.

Concomitant medications included Benedryl® (diphenhydramine hCl) for upper respiratory infection; hydrocortisone cream, and hydroxyzine hydrochloride for poison ivy rash; Claritin® (loratidine) for seasonal allergic rhinitis; and Detrol® (tolterodine tartrate, Ditropan® (oxybutnin) and nitrofurantoin for urinary reflux.

The patient received the first dose of study medication on 11 January 2001. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 20 mg/day on 18 January 2001 (Day 11). The dose remained at 20 mg/day until 27 June 2001 (Day 168), which was the end of the active phase of the study. The dose was reduced to 10 mg/day on 28 June 2001 (Day 169) and the last dose of 10 mg/day was given on 05 July 2001 (Day 176). The patient completed the study as planned.

At screening in the previous acute study, 701, the patient weighed 60 kg., and at baseline in extension Protocol 716, the patient's body weight was 63.2 kg. By week 12, the patient's weight had increased to 69 kg, and by Week 24, the patient's weight had increased to 72.5 kg. Normal range for 11-year-old females is 25.0 to 56.3 kg. These increases in body weight at Weeks 12 and 24 met the level of potential clinical concern. The level of potential clinical concern is defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No follow-up body weight was provided. There were no other vital signs values of potential clinical concern reported.

On 05 April 2001 (Day 85), the patient reported the onset of moderately severe abnormal weight gain that continued without treatment throughout the study. Weight gain was considered to be possibly related to treatment with study medication by the investigator.

Moderately severe impaired concentration, and moderately severe abnormal kidney function were reported during the previous acute study 701 and continued, with treatment, through Protocol 716. The investigator considered both of these conditions to be unrelated to treatment with study medication.

On 16 February 2001 (Day 37), the patient reported a moderately severe respiratory disorder (upper respiratory infection) that resolved with treatment in 6 days. The investigator consider this to be unrelated to treatment with study medication.

On 31 March 2001 (Day 80), the patient reported a moderately severe contact dermatitis (poison ivy rash) that cleared with treatment in 42 days. The investigator considered this to be unrelated to treatment with study medication.

On 01 July 2001 (Day 207; 4 days after the last dose of study medication), the patient experienced mild depression that continued, without treatment, though the end of the study reporting period. The investigator considered depression to be unrelated to treatment with study medication

No other adverse experiences were reported.

PID 716.192.25872

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Weight Gain

Adverse Experience Associated with Vital Sign of Concern: Increased Body Weight

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.192.25872), and received treatment with paroxetine in that study.

Concomitant medications included topical aloe for frost bite, both ears; and ampicillin for upper respiratory infection.

The patient received the first dose of study medication on 07 November 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 50 mg/day on 28 February 2001 (Day 114). The dose remained at 50 mg/day until 23 April 2001 (Day 168), which was the end of the active phase of the study. The dose was tapered from 50 mg/day down to 10 mg/day beginning on 24 April 2001 (Day 169), and the last dose of 10 mg/day was given on 21 May 2001 (Day 196). The patient completed the study as planned.

At screening in the previous acute study, 701, the patient weighed 68 kg., and at baseline in Protocol 716, the patient weighed 69 kg. By week 12, the patient's weight had increased to 72 kg., and by Week 24, the patient's weight had increased to 79 kg. Normal range for 14-year-old males is 35.9 to 74.5 kg (79 to 164 lbs). The increase in body weight at Week 24 met the level of potential clinical concern. The level of potential clinical concern is defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No follow-up body weight was provided. No other vital signs values met the level of potential clinical concern.

On 24 April 2001 (Day 169; one day after the last dose of study medication), the patient reported the onset of mild weight gain that continued, without treatment,

theough the end of the study reporting period. The investigator considered this to be possibly related to treatment with study medication.

Moderately severe respiratory disorder (upper respiratory infection) began in the previous acute study and continued into Protocol 716. This cleared without treatment in 21 days. The investigator considered this condition to be unrelated to treatment with study medication.

On 22 February 2001 (Day 108), the patient reported moderately severe trauma (frost bite, both ears) that resolved with treatment in 8 days. The investigator considered this to be unrelated to treatment with study medication.

On 22 March 2001 (Day 136), the patient reported the onset of mild dyspepsia (heartburn), mild nausea, and mild dizziness (lightheadedness), all of which resolved without treatment in one day. The investigator considered all three events to be unrelated to treatment with study medication.

No other adverse experiences were reported.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Hemoglobin, Unit:G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	1	(1.4%)	1	(0.8%)
Number of Patients with Assessment	48	(100.0%)	70	(100.0%)	118	(100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	3 (6.3%)	6 (8.6%)	9 (7.6%)
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	4 (8.3%)	2 (2.9%)	6 (5.1%)
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (4.2%)	1 (1.4%)	3 (2.5%)
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	48 (100.0%)	70 (100.0%)	118 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Neutrophils Absolute, Unit:10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
High (Extended)	0	.	1	(1.4%)	1	(0.8%)
Low (Extended)	0	.	2	(2.9%)	2	(1.7%)
Number of Patients with Assessment	48	(100.0%)	70	(100.0%)	118	(100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.4%)	1 (0.8%)
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Creatinine, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Alanine Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.4%)	1 (0.8%)
Number of Patients with Assessment	49 (100.0%)	70 (100.0%)	119 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Hemoglobin, Unit:G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	2 (4.3%)	4 (7.0%)	6 (5.8%)
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.8%)	1 (1.0%)
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.8%)	1 (1.0%)
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Neutrophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	2 (4.3%)	1 (1.8%)	3 (2.9%)
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Creatinine, Unit:UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Alanine Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.1%)	0 .	1 (1.0%)
Number of Patients with Assessment	47 (100.0%)	57 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Hemoglobin, Unit:G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (0.8%)	1 (0.5%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	5 (5.3%)	10 (7.9%)	15 (6.8%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	4 (4.2%)	3 (2.4%)	7 (3.2%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (2.1%)	1 (0.8%)	3 (1.4%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.8%)	1 (0.5%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Neutrophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.8%)	1 (0.5%)
Low (Extended)	2 (2.1%)	3 (2.4%)	5 (2.3%)
Number of Patients with Assessment	95 (100.0%)	127 (100.0%)	222 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.8%)	1 (0.4%)
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Creatinine, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Alanine Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (1.0%)	1 (0.8%)	2 (0.9%)
Number of Patients with Assessment	96 (100.0%)	127 (100.0%)	223 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	8 (17.8%)	11 (19.0%)	19 (18.4%)
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.2%)	1 (1.7%)	2 (1.9%)
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	5 (11.1%)	0 .	5 (4.9%)
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (4.4%)	1 (1.7%)	3 (2.9%)
Low (Extended)	1 (2.2%)	2 (3.4%)	3 (2.9%)
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	45	(100.0%)	58	(100.0%)	103	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	45 (100.0%)	58 (100.0%)	103 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	42	(100.0%)	48	(100.0%)	90	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	7	(16.7%)	9	(18.8%)	16	(17.8%)
Number of Patients with Assessment	42	(100.0%)	48	(100.0%)	90	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	42	(100.0%)	48	(100.0%)	90	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.4%)	2 (4.2%)	3 (3.3%)
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
High (Extended)	0	.	1	(2.1%)	1	(1.1%)
Number of Patients with Assessment	42	(100.0%)	48	(100.0%)	90	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (2.1%)	1 (1.1%)
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.4%)	0 .	1 (1.1%)
Low (Extended)	2 (4.8%)	1 (2.1%)	3 (3.3%)
Number of Patients with Assessment	42 (100.0%)	48 (100.0%)	90 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	42 (100.0%)	49 (100.0%)	91 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	15 (17.2%)	20 (18.9%)	35 (18.1%)
Number of Patients with Assessment	87 (100.0%)	106 (100.0%)	193 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	2 (2.3%)	3 (2.8%)	5 (2.6%)
Number of Patients with Assessment	87 (100.0%)	106 (100.0%)	193 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	5 (5.7%)	1 (0.9%)	6 (3.1%)
Number of Patients with Assessment	87 (100.0%)	106 (100.0%)	193 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
High (Extended)	0	.	1	(0.9%)	1	(0.5%)
Number of Patients with Assessment	87	(100.0%)	106	(100.0%)	193	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	3 (3.4%)	1 (0.9%)	4 (2.1%)
Low (Extended)	3 (3.4%)	3 (2.8%)	6 (3.1%)
Number of Patients with Assessment	87 (100.0%)	106 (100.0%)	193 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	87 (100.0%)	107 (100.0%)	194 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	87	(100.0%)	107	(100.0%)	194	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	1	(12.5%)	1	(6.3%)
Number of Patients with Assessment	8	(100.0%)	8	(100.0%)	16	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	1 (12.5%)	1 (12.5%)	2 (12.5%)
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	8 (100.0%)	8 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	7	(100.0%)	13	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	1	(14.3%)	1	(7.7%)
Number of Patients with Assessment	6	(100.0%)	7	(100.0%)	13	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	7	(100.0%)	13	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	7 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	2	(28.6%)	2	(15.4%)
Number of Patients with Assessment	6	(100.0%)	7	(100.0%)	13	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	5 (100.0%)	8 (100.0%)	13 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	8	(100.0%)	14	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	8 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	8	(100.0%)	14	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	8	(100.0%)	14	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	6	(100.0%)	8	(100.0%)	14	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	8 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	2	(13.3%)	2	(6.9%)
Number of Patients with Assessment	14	(100.0%)	15	(100.0%)	29	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	1 (7.1%)	3 (20.0%)	4 (13.8%)
Number of Patients with Assessment	14 (100.0%)	15 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	16 (100.0%)	29 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)	30 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)	30 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	14	(100.0%)	16	(100.0%)	30	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)	30 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)	30 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)	30 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	47	(100.0%)	61	(100.0%)	108	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	8 (17.0%)	12 (19.7%)	20 (18.5%)
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	47	(100.0%)	61	(100.0%)	108	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.1%)	1 (1.6%)	2 (1.9%)
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	5 (10.6%)	0 .	5 (4.6%)
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (4.3%)	1 (1.6%)	3 (2.8%)
Low (Extended)	2 (4.3%)	2 (3.3%)	4 (3.7%)
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	47	(100.0%)	61	(100.0%)	108	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	47 (100.0%)	61 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	7 (16.3%)	10 (19.6%)	17 (18.1%)
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (2.3%)	2 (3.9%)	3 (3.2%)
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (2.0%)	1 (1.1%)
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (2.0%)	1 (1.1%)
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (2.3%)	0 .	1 (1.1%)
Low (Extended)	2 (4.7%)	3 (5.9%)	5 (5.3%)
Number of Patients with Assessment	43 (100.0%)	51 (100.0%)	94 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	43 (100.0%)	52 (100.0%)	95 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	90	(100.0%)	112	(100.0%)	202	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	15 (16.7%)	22 (19.6%)	37 (18.3%)
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	90	(100.0%)	112	(100.0%)	202	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	90	(100.0%)	112	(100.0%)	202	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (2.2%)	3 (2.7%)	5 (2.5%)
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	5 (5.6%)	1 (0.9%)	6 (3.0%)
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.9%)	1 (0.5%)
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	3 (3.3%)	1 (0.9%)	4 (2.0%)
Low (Extended)	4 (4.4%)	5 (4.5%)	9 (4.5%)
Number of Patients with Assessment	90 (100.0%)	112 (100.0%)	202 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	90	(100.0%)	113	(100.0%)	203	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	90 (100.0%)	113 (100.0%)	203 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716
Interim Output
Table 15.3.2

Criteria for Clinical Concern Flagging of Laboratory Parameters

Parameter	Gender	Age(Years)	Clinical Concern Low Value	Clinical Concern High Value	Unit
Hemoglobin	Female		95.00		G/L
	Male		115.00		G/L
Hematocrit	Both	12-17	36.00		%
		6-11	35.00		%
	Female	18-64	35.00		%
	Male	18-64	41.00		%
Red Blood Cell Count	Female			10.00	10^12/L
	Male			8.00	10^12/L
White Blood Cell Count	Both		2.80	16.00	10^9/L
Platelets	Both		75.00	700.00	10^9/L
Basophils Absolute	Both			0.40	10^9/L
Eosinophils Absolute	Both			0.79	10^9/L
Lymphocytes Absolute	Both		0.53	4.43	10^9/L
Monocytes Absolute	Both			1.38	10^9/L
Neutrophils Absolute	Both		1.58	8.64	10^9/L
Sodium	Both		126.00	156.00	MMOL/L
Potassium	Both		3.00	6.00	MMOL/L
Blood Urea Nitrogen	Both			10.71	MMOL/L
Creatinine	Both			176.80	UMOL/L
Aspartate Aminotransferase	Both			150.00	IU/L
Alanine Aminotransferase	Both			165.00	IU/L
Total Bilirubin	Both			34.20	UMOL/L
Thyroid Stimulating Hormone	Both			10.00	MU/L

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Narratives for Patients with Laboratory Parameters Associated with an Adverse Event and Meeting the Clinical Concern Criteria

716

Table 15.3.3

Interim Report Safety Narratives

SB Document Number: BRL-029060/RSD-101C1V/1

Narratives for Patients with Laboratory Parameters Associated with an Adverse Event and Meeting the Clinical Concern Criteria

PID 716.167.25696

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Decreased Absolute Neutrophils

Adverse Experience Reported: Leukopenia (Low Eosinophils, Low Neutrophils, Low White Cell Count), Leukocytosis (high lymphocytes)

This 8-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.167.25696), and received treatment with placebo in that study.

Concomitant medications included Rhinocort® nasal spray (budesonide) for nasal congestion, Benedryl® (diphenhydramine hCl) for skin rash, Motrin® (ibuprofen) for headache, and intramuscular penicillin for strep throat.

The patient received the first dose of study medication on 07 October 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg/day on 21 October 2000 (Day 15). The dose of study medication was reduced temporarily to 20 mg/day from 24 January 2001 to 26 January 2001 (Days 110 – 112), at which time the 30 mg/day dose was resumed. The final dose of study medication was taken on 23 March 2001 (Day 168).

Laboratory values assessed at screening of the previous acute protocol (Day -86) were within normal limits, with the exception of a decreased blood urea nitrogen (BUN) level of 1.4280 MMol/L g/L (normal: 2.856 – 7.497 MMol/L). Laboratory values assessed at Weeks 4 (Day 26) and 12 (Day 88) of Protocol 716 were all within normal limits.

On week 24 (Day 168), the patient had a decreased white blood count of 3.0 10^9/L (normal range, 4.5 – 3.5 10^9/L), decreased absolute eosinophils of 0.0 10^9/L

(normal range, 0.05 – 0.55 10^9/L), and decreased absolute neutrophils of 1.44 10^9/L (normal range, 1.8 – 8.0 10^9/L). The decrease in absolute neutrophil count was at the level of potential clinical concern.

Two weeks after the final dose of study medication was taken (Day 182) follow-up laboratory assessments were performed. The patient had a decrease in white blood count of 2.0 10^9/L, a decrease in absolute eosinophil count of 0.02 10^9/L, a decrease in absolute monocyte count of 0.18 10^9/L (normal range, 0.2 – 1.1 10^9/L), and a decrease in absolute neutrophil count of 0.9 10^9/L. The decrease in absolute neutrophil count was at the level of potential clinical concern. Laboratory results also showed atypical lymphocytes of 13% (normal range, 0.0 – 5.0 %). No further laboratory results were recorded.

On 23 March 2001 (Day 168), the patient was reported to have moderately severe leukopenia (low eosinophils, low neutrophils, and low white blood cell count). No corrective therapy was given and the investigator reported that this resolved in 20 days. The investigator considered leukopenia to be possibly related to treatment with study medication. On 06 April 2001 (Day 182), the patient experienced the onset of moderately severe leukocytosis (high lymphocytes) that cleared without treatment in 6 days. The investigator considered this condition to be possibly related to treatment with study medication.

Several other non-serious adverse experiences were reported during the study. On 13 October 2000 (Day 7) and on 20 October 2000 (Day 5), the patient experienced the onsets of mild headaches that each resolved with treatment in one day. The investigator considered headache to be unrelated to treatment with study medication.

On 11 October 2000 (Day 5), the onset of mild pharyngitis (sore throat) was reported; this resolved with treatment in one day. The investigator considered pharyngitis to be unrelated to treatment with study medication.

Mild albuminuria (urine dipstick positive for protein) was reported to have begun on 01 November 2000 (Day 26). This resolved without treatment in 3 days and was considered to be unrelated to treatment with study medication by the investigator.

On 13 November 2000 (Day 38), the patient reported the onset of mild rhinitis (nasal congestion) that resolved with treatment in 6 days. Rhinitis was considered to be unrelated to treatment with study medication by the investigator.

On 03 December (Day 85), the onsets of mild maculopapular rash (macular skin rash, left cheek and forearms) and pruritis were reported. Corrective therapy was given for rash only, and each resolved in 35 days. The investigator considered both to be unrelated to treatment with study medication.

On 09 January 2001 (Day 95), mild urinary incontinence (enuresis) was reported; this resolved without treatment in 75 days. The investigator considered enuresis to be possibly related to treatment with study medication.

On 15 January 2001 (Day 101), the patient reported the onset of mild abdominal pain (stomach ache) that resolved with treatment in 3 days.

On 20 February 2001 (Day 137), the patient reported the onset of moderately severe respiratory disorder (cold symptoms) that resolved without treatment in 11 days. The investigator considered cold to be unrelated to treatment with study medication.

Following cessation of study medication, on 03 April 2001 (Day 179), the patient reportedly experienced the onset of mild diarrhea and mild nausea, both of which resolved in 2 days without treatment. Both of these events were considered to be unrelated to treatment with study medication by the investigator.

No other adverse experiences were reported.

The patient completed the study as planned.

PID 716.169.25781

Treatment Group: Placebo (Protocol 701), Paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Decreased Hematocrit

Adverse Experience Reported: Anemia (Abnormal Laboratory Results), Leukopenia (Abnormal Laboratory Results)

This 10-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.169.25781), and received treatment with placebo in that study.

Concomitant medications included Vicks Vapor Rub® (camphor, eucalyptus oil, menthol, turpentine oil) for chest congestion; Clonidine® (clonidine), Remeron® (mirtazapine), and diphenhydramine for sleepless nights; children's aspirin (acetasalicylic acid), and Motrin® (ibuprofen) for flu symptoms; and Paxil® (paroxetine) for depression.

The patient received the first dose of study medication on 10 November 2000. The patient started study medication at a dose of 10 mg/day and remained at that dose throughout the study. The final dose of study medication was taken on 09 April 2001 (Day 151).

Laboratory values assessed at screening of the previous acute protocol (Day -64) were within normal limits, with the exception of a decreased hemoglobin of 111 G/L (normal range, 115 – 155 G/L), decreased hematocrit of 33.1% (normal range, 35.0 – 45.0 %), and decreased red blood cell count (RBC) of 3.7 10^9/L (normal range, 4.0 – 5.2 10^9/L). Hematocrit results were at the level of potential clinical concern. These values and subsequent laboratory test values are tabulated below. All other laboratory results were within normal limits.

Analyte	Acute Screening (Day –64)	Week 4 (Days 26,28)	Week 12 Days 81,83)	Week 24+ (Day 211)
Hemoglobin	111 G/L	116 G/L	108 G/L	114G/L
Hematocrit	33.1 % *	34.6%*	32.7 %*	34.8 %*
Red Blood Cells	3.7 10^9/L	3.9$10^9$/L	3.7 10^9/L	3.8 10^9/L
White Blood Cells	6.3 10^9/L	8.1 10^9/L	4.1 10^9/L	7.5 10^9/L
Abs. Monocytes**	0.27 10^9/L	0.29 10^9/L	0.06 10^9/L	0.38 10^9/L

*met level of clinical concern ** normal range = 0.2 – 1.1 10^9/L

On 02 February 2001 (Day 85), the patient experienced mild anemia (abnormal laboratory results) and mild leukopenia (abnormal laboratory results). These conditions resolved without treatment in 127 days. The investigator considered these to be unrelated to treatment with study medication.

Several other non-serious adverse experiences were reported during the study.

On 14 November 2000 (Day 5), the patient reported the onset of mild insomnia (sleeplessness) which continued despite treatment. On 13 March 2001 (Day 124), the onset of moderately severe insomnia was reported. This resolved with treatment in 47 days. The insomnia reported on Day 5 was considered to be probably unrelated to treatment with study medication; the episode on reported on Day 134 was considered to be unrelated to treatment with study medication.

On 27 November 2000 (Day 18), the patient experienced the onset of a moderately severe infection (gastrointestinal upset, flu symptoms) that resolved with treatment in 6 days. The investigator considered this to be unrelated to treatment with study medication.

On 19 December 2000 (Day 40), the patient reported the onset of a mild respiratory disorder (chest congestion) that resolved with treatment in 4 days. The investigator considered this to be unrelated to treatment with study medication.

No other adverse experiences were reported.

The patient completed the study as planned.

PID 716.176.27164

Treatment Group: Paroxetine (Protocol 704), Paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Decreased Hematocrit

Adverse Experience Reported: Anemia (Low Hemoglobin, Low Hematocrit)

This 11-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.048.27164), and received treatment with paroxetine in that study.

The patient received the first dose of study medication on 04 April 2001. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg/day on 18 April 2001 (Day 15). The dose of study medication remained at 30 mg/day throughout the rest of the study. The last dose of study medication recorded at the time of this report was on 23 July 2001 (Day 111). The patient continues in the study.

Concomitant medications included Rhinocort® inhaler (budesonide), Allegra® (fexofenadine hCl), and Ventolin® inhaler (salbutamol) for perennial allergic rhinitis; multivitamins with iron and Tums® (calcium carbonate) for dietary supplementation; simethicone (demeticone activated) for flatulence; and topical Silvadene® cream (sulfadiazine) silver for sunburn.

Laboratory values assessed at acute screening of Protocol 704 and at the first assessment in Protocol 716 (Week 4; Day 28) were within normal limits with the exception of decreased hematocrit of 33.7% and 33.9%, respectively (normal range, 35 – 45%). At Week 12 (Day 84), hemoglobin was slightly decreased at 112 G/L (normal range, 115 – 155 G/L) and hematocrit was decreased to 33.2%. At Week 24 (Day 168), decreases in hemoglobin (109 G/L), hematocrit (31.8%), and red blood cell count (3.9 [normal range, 4.0 – 5.2 10^9/L) were noted. At Week 24+ (Day 184), all laboratory values were within normal range with the exception of decreased hematocrit of 34.5%. Decreased hematocrit values throughout the study were at the level of potential clinical concern.

On 26 June 2001 (Day 84), the patient experienced the onset of mild anemia (low hematocrit, low hemoglobin) that was treated and continues at the time of this interim reporting. The investigator considers anemia to be unrelated to treatment with study medication.

Moderately severe flatulence and mild rhinitis continued into the Protocol 716 extension study from the double-blind acute study and continues to date. Corrective therapy was given for both. The investigator considers flatulence to be probably unrelated to treatment with study medication and rhinitis to be unrelated to treatment with study medication.

On 12 April 2001 (Day 9), the patient reported the onset of moderately severe somnolence (drowsiness) that resolved without treatment in 8 days. The investigator considered drowsiness to be related to treatment with study medication.

On 23 June 2001 (Day 81), the patient reported the onset of moderately severe trauma (sunburn) that resolved with treatment in 10 days. The investigator considered sunburn to be unrelated to treatment with study medication.

No other adverse experiences were reported during the study.

PID 716.176.27172

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Increased Absolute Eosinophils, Increased Absolute Monocytes

Adverse Experience Reported: Eosinophilia (Elevated Eosinophils), Monocytosis (Elevated Monocytes)

This 16-year-old American Indian male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Study 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.048.27172), and received treatment with placebo in that study.

The patient received the first dose of study medication on 15 June 2001. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 40 mg/day on 27 July 2001 (Day 43). The last dose of study medication recorded at the time of this report was on 09 August 2001 (Day 56). The patient continues in the study.

Concomitant medications included Robitussin® (guafenesin) for upper respiratory infection, Tylenol® (paracetamol), and Motrin® (ibuprofen) for headaches/intermittent sinus headaches.

Laboratory values assessed at acute screening in Protocol 704 (Day -105) were all within normal limits, as were all laboratory values assessed at baseline of Protocol 716. At Week 2 (Day 12), all laboratory values were within normal limits,with the exception of increased absolute eosinophils of 1.12 10^9/L (normal range, 0.05 – 0.55 10^9/L), and increased absolute monocytes of 1.61 10^9/L (normal range, 0.2 – 1.1 10^9/L). Both of these increased values met the level of potential clinical concern. All laboratory values were within normal limits at Week 4 (Day 28). At last assessment, Week 12 (Day 84), all laboratory values were within normal limits with the exception of a slightly decreased absolute eosinophil count of 0.02 10^9/L.

On 26 June 2001 (Day 12), the patient experienced the onset of moderately severe eosinophilia (elevated eosinophils), and moderately severe monocytosis (elevated monocytes). These conditions resolved without treatment in 17 days and the investigator considered these to be unrelated to treatment with study medication.

On 19 June 2001 (Day 5) the patient reported the onset of mild respiratory disorder (upper respiratory infection) that resolved with treatment in 12 days. The URI was considered to be related to treatment with study medication by the investigator.

On 25 June 2001 (Day 11), the patient reported the onset of mild epistaxis (epistaxis) that resolved without treatment in one day. The investigator considered epistaxis to be probably unrelated to treatment with study medication.

On 04 August 2001 (Day 51, the patient reported the onset of moderately severe abdominal pain (abdominal pains), moderately severe headaches, moderately severe diarrhea, and moderately severe nausea. Corrective therapy was given for headaches, but for none of the other events. Abdominal pain and nausea resolved within 4 days. Headaches and diarrhea reportedly continue.

On 26 June 2001 (Day 12), the patient reported the onset of mild allergic reaction that continues at the time of this interim reporting. No corrective therapy was given for this event that was considered to be unrelated to treatment with study medication.

No other adverse experiences were reported.

PID 716.192.25868

Treatment Group: Paroxetine (Protocol 701), Paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Decreased Absolute Neutrophils,

Adverse Experience Reported: Leukopenia (low absolute neutrophils, low white blood cell count)

This 16-year-old white male, with a primary diagnosis of major-depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.192.25868), and received treatment with paroxetine in that study.

The patient received the first dose of study medication on 25 October 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg/day on 18 November 2000 (Day 25). The 30 mg/day dose was reduced to 20 mg/day on 24 November 2000 (Day 31), and the patient remained at this dose until the end of the active study phase, 29 January 2001 (Week 12; Day 97). The dose of study medication was tapered to 10 mg/day on Day 98 and the last dose of study medication was taken on 07 February 2001 (Day 105). The patient was withdrawn from the study at Week 12 (Day 97) because of protocol violations.

No concomitant medications were reported during the study.

Laboratory values assessed at acute screening in Protocol 701 (Day -90) were all within normal limits, with the exception of a slightly increased hemoglobin of 164 G/L (normal range, 120 to 160 G/L) and hematocrit of 52.5% (normal range, 36.0 to 49.0%). At baseline of extension Protocol 716, only white blood count differential and urine dipstick was assessed. These were within normal limits. At Week 8 (Day 70), all laboratory values were within normal limits,with the exception of decreased white blood cell count of 3.0 10^9/L (normal range, 4.5 – 13.0 10^9/L), and decreased absolute neutrophils of 1.02 10^9/L (normal range, 1.8 – 8.0 10^9/L). The decreased absolute neutrophil value at Week 8 met the level of potential clinical concern. All laboratory values were within normal limits at Week 12 (Day 83) with the exception of a decreased white blood cell count of 3.0

10^9/L, and decreased absolute neutrophil count of 1.15 10^9/L. The decreased absolute neutrophil value at Week 12 again met the level of potential clinical concern.

At the last assessment, Week 16 (Day 99, 111), all laboratory values were within normal limits with the exception of a slightly increased alanine aminotransferase. The white blood cell count at Week 16 (Day 111) was 4.8 10^9/L , and the absolute neutrophil count was 2.06 10^9/L .

On 02 January 2001 (Day 70), the patient experienced the onset of mild leukopenia (low absolute neutrophils, low white blood cell count) the continued through the end of the study period. No corrective therapy was given and the investigator considered leukopenia to be possibly related to treatment with study medication.

Mild headaches were reported on 31 October 2000 (Day 7) and 01 November 2000 (Day 8), both of which cleared without treatment in one day. The investigator considered both headaches to be unrelated to treatment with study medication.

On 19 January 2001 (Day 87), the patient reported the onset of severe infection (intestinal infection) that cleared without treatment in 15 days. The investigator considered this event to be unrelated to treatment with study medication.

On 16 February 2001 (Day 115), the patient experienced the onset of moderately severe asthma that continued, despite treatment, through the end of the study period. The investigator considered asthma to be unrelated to treatment with study medication.

No other adverse experiences were reported

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hemoglobin Unit : Grams per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	80	4	0	84	0	0	13	0	0	13
L	n	0	0	0	1	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	95	5	0	100	0	0	100	0	0	100
L	%	0	0	0	100	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hemoglobin Unit : Grams per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	1	90	7	0	98	0	0	14	1	0	15
L	n	0	0	2	3	0	5	0	0	0	0	0	0
-	n	0	0	1	0	0	1	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	92	7	0	100	0	0	93	7	0	100
L	%	0	0	40	60	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hematocrit Unit : Percentage
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	74	0	6	80	0	0	13	0	0	13
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	1	0	4	5	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	93	0	8	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	20	0	80	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hematocrit Unit : Percentage
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	0	89	0	7	96	0	0	13	0	1	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	4	0	5	9	0	0	0	0	1	1
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	93	0	7	100	0	0	93	0	7	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	44	0	56	100	0	0	0	0	100	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	0	0	0	1	0	0	0	0	0	0
I	n	0	1	77	5	0	83	0	0	14	0	0	14
L	n	0	0	0	2	0	2	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	0	0	0	0	0
I	%	0	1	93	6	0	100	0	0	100	0	0	100
L	%	0	0	0	100	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	1	0	0	2	0	0	0	0	0	0
I	n	0	1	93	3	0	97	0	0	14	0	0	14
L	n	0	0	3	4	0	7	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	0	1	96	3	0	100	0	0	100	0	0	100
L	%	0	0	43	57	0	100	0	0	0	100	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : White Blood Cell Count Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	0	73	8	0	81	0	0	12	1	0	13
L	n	0	0	3	1	0	4	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	90	10	0	100	0	0	92	8	0	100
L	%	0	0	75	25	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : White Blood Cell Count Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	89	10	0	99	0	0	9	3	0	12
L	n	0	0	7	0	0	7	0	0	1	2	0	3
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	90	10	0	100	0	0	75	25	0	100
L	%	0	0	100	0	0	100	0	0	33	67	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Platelets Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	2	83	0	0	85	0	1	13	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	7	93	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Platelets Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	4	0	0	5	0	1	0	0	0	1
I	n	0	3	97	0	0	100	0	1	13	0	0	14
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	20	80	0	0	100	0	100	0	0	0	100
I	%	0	3	97	0	0	100	0	7	93	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Basophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	86	0	0	86	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Basophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	106	0	0	106	0	0	15	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	1	2	0	0	3	0	1	0	0	0	1
H	n	0	0	5	1	0	6	0	0	1	0	0	1
I	n	0	3	67	2	0	72	0	1	10	0	0	11
L	n	0	0	5	0	0	5	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	33	67	0	0	100	0	100	0	0	0	100
H	%	0	0	83	17	0	100	0	0	100	0	0	100
I	%	0	4	93	3	0	100	0	9	91	0	0	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	2	0	1	0	0	3	0	0	0	0	0	0
H	n	0	1	6	0	0	7	0	0	0	0	0	0
I	n	0	2	86	2	0	90	0	0	13	1	0	14
L	n	0	0	4	2	0	6	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	67	0	33	0	0	100	0	0	0	0	0	0
H	%	0	14	86	0	0	100	0	0	0	0	0	0
I	%	0	2	96	2	0	100	0	0	93	7	0	100
L	%	0	0	67	33	0	100	0	0	0	100	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	2	0	0	0	0	2	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	2	1	81	0	0	84	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	100	0	0	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	2	1	96	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	1	0	102	1	0	104	0	0	14	0	0	14
L	n	0	0	1	0	0	1	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	1	0	98	1	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Monocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	70	10	0	80	0	0	9	1	0	10
L	n	0	0	4	2	0	6	0	0	4	0	0	4
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	88	13	0	100	0	0	90	10	0	100
L	%	0	0	67	33	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Monocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	78	13	0	91	0	0	13	1	0	14
L	n	0	0	10	4	0	14	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	86	14	0	100	0	0	93	7	0	100
L	%	0	0	71	29	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	2	0	75	2	3	82	0	0	12	0	1	13
L	n	0	0	1	0	0	1	0	0	1	0	0	1
-	n	0	0	2	0	0	2	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	2	0	91	2	4	100	0	0	92	0	8	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	1	0	0	1
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	1	0	97	2	1	101	0	0	10	1	3	14
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	3	0	0	3	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	100	0	0	100
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	1	0	96	2	1	100	0	0	71	7	21	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Sodium Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	3	82	0	0	85	0	0	13	0	0	13
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	4	96	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Sodium Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	1	103	1	0	105	0	0	16	0	0	16
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	98	1	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Potassium Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	2	84	0	0	86	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Potassium Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	3	102	0	0	105	0	0	16	0	0	16
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	2	83	0	0	85	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	5	99	1	0	105	0	1	15	0	0	16
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	5	94	1	0	100	0	6	94	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Creatinine Unit : Micromoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	86	0	0	86	0	0	14	0	0	14
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Creatinine Unit : Micromoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	105	0	0	105	0	0	15	0	0	15
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alkaline Phosphatase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	3	0	0	3	0	0	0	0	0	0
I	n	0	1	83	0	0	84	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alkaline Phosphatase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	3	1	0	0	4	0	0	1	0	0	1
I	n	0	1	101	1	0	103	0	1	14	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	75	25	0	0	100	0	0	100	0	0	100
I	%	0	1	98	1	0	100	0	7	93	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	2	85	0	0	87	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	0	0	0	1	0	1	0	0	0	1
I	n	0	2	104	0	0	106	0	2	13	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	100	0	0	0	100
I	%	0	2	98	0	0	100	0	13	87	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alanine Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	2	84	0	0	86	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alanine Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	1	0	0	2	0	1	0	0	0	1
I	n	0	0	105	0	0	105	0	2	13	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	100	0	0	0	100
I	%	0	0	100	0	0	100	0	13	87	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Total Bilirubin Unit : Micromoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	1	86	0	0	87	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Total Bilirubin Unit : Micromoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	1	0	0	2	0	0	1	0	0	1
I	n	0	0	105	0	0	105	0	0	15	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	100	0	0	100
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Glucose - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	39 (100.0%)	46 (100.0%)	85 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Blood - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	0 (0.0%)	1 (2.2%)	1 (1.2%)
2+	2 (5.1%)	0 (0.0%)	2 (2.4%)
3+	3 (7.7%)	1 (2.2%)	4 (4.7%)
Trace	1 (2.6%)	4 (8.7%)	5 (5.9%)
Number of Patients with Assessment	39 (100.0%)	46 (100.0%)	85 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Red Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
0-1	5 (12.8%)	6 (13.0%)	11 (12.9%)
1-3	1 (2.6%)	1 (2.2%)	2 (2.4%)
10-15	1 (2.6%)	1 (2.2%)	2 (2.4%)
25-50	1 (2.6%)	0 (0.0%)	1 (1.2%)
5-10	2 (5.1%)	1 (2.2%)	3 (3.5%)
INNUMERABLE	1 (2.6%)	0 (0.0%)	1 (1.2%)
NONE SEEN	36 (92.3%)	43 (93.5%)	79 (92.9%)
Number of Patients with Assessment	39 (100.0%)	46 (100.0%)	85 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine White Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
0-1	15 (38.5%)	20 (43.5%)	35 (41.2%)
1-3	3 (7.7%)	7 (15.2%)	10 (11.8%)
10-15	1 (2.6%)	0 (0.0%)	1 (1.2%)
15-25	0 (0.0%)	2 (4.3%)	2 (2.4%)
3-5	1 (2.6%)	1 (2.2%)	2 (2.4%)
5-10	4 (10.3%)	1 (2.2%)	5 (5.9%)
NONE SEEN	28 (71.8%)	26 (56.5%)	54 (63.5%)
Number of Patients with Assessment	39 (100.0%)	46 (100.0%)	85 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Bacteria

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	6 (85.7%)	9 (81.8%)	15 (83.3%)
Many	1 (14.3%)	0 (0.0%)	1 (5.6%)
MODERATE	1 (14.3%)	1 (9.1%)	2 (11.1%)
OCCASIONAL	0 (0.0%)	1 (9.1%)	1 (5.6%)
Number of Patients with Assessment	7 (100.0%)	11 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Protein - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	5 (12.8%)	1 (2.2%)	6 (7.1%)
3+	0 (0.0%)	1 (2.2%)	1 (1.2%)
Trace	4 (10.3%)	5 (10.9%)	9 (10.6%)
Number of Patients with Assessment	39 (100.0%)	46 (100.0%)	85 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Calcium Oxalate Crystals

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	8 (88.9%)	7 (70.0%)	15 (78.9%)
MODERATE	1 (11.1%)	3 (30.0%)	4 (21.1%)
Number of Patients with Assessment	9 (100.0%)	10 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Uric Acid Crystals

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	0 (0.0%)	3 (75.0%)	3 (60.0%)
Many	1 (100.0%)	1 (25.0%)	2 (40.0%)
Number of Patients with Assessment	1 (100.0%)	4 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Amorphous Sediment

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	23 (76.7%)	24 (77.4%)	47 (77.0%)
Many	8 (26.7%)	5 (16.1%)	13 (21.3%)
MODERATE	4 (13.3%)	5 (16.1%)	9 (14.8%)
Number of Patients with Assessment	30 (100.0%)	31 (100.0%)	61 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Generic - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1	13 (15.7%)	9 (8.4%)	22 (11.6%)
2	76 (91.6%)	105 (98.1%)	181 (95.3%)
Number of Patients with Assessment	83 (100.0%)	107 (100.0%)	190 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Hyaline Casts

Result	Acute Study Treatment Group: Placebo	Total
3-5	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Mucous Threads

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	20 (83.3%)	31 (100.0%)	51 (92.7%)
Many	1 (4.2%)	0 (0.0%)	1 (1.8%)
MODERATE	5 (20.8%)	0 (0.0%)	5 (9.1%)
Number of Patients with Assessment	24 (100.0%)	31 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Squamous Epithelial Cells

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
FEW (1-5)	19 (100.0%)	17 (85.0%)	36 (92.3%)
MANY (21 OR GREATER)	3 (15.8%)	1 (5.0%)	4 (10.3%)
MODERATE (6-20)	3 (15.8%)	3 (15.0%)	6 (15.4%)
OCCASIONAL	1 (5.3%)	1 (5.0%)	2 (5.1%)
Number of Patients with Assessment	19 (100.0%)	20 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Yeast

Result	Acute Study Treatment Group: Placebo	Total
Few	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Glucose - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	3 (100.0%)	11 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Blood - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
3+	0 (0.0%)	1 (9.1%)	1 (7.1%)
Number of Patients with Assessment	3 (100.0%)	11 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Red Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
25-50	0 (0.0%)	1 (9.1%)	1 (7.1%)
3-5	0 (0.0%)	1 (9.1%)	1 (7.1%)
NONE SEEN	3 (100.0%)	9 (81.8%)	12 (85.7%)
Number of Patients with Assessment	3 (100.0%)	11 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine White Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
0-1	0 (0.0%)	5 (45.5%)	5 (35.7%)
NONE SEEN	3 (100.0%)	6 (54.5%)	9 (64.3%)
Number of Patients with Assessment	3 (100.0%)	11 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Bacteria

Result	Acute Study Treatment Group: Placebo	Total
Few	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Protein - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	0 (0.0%)	2 (18.2%)	2 (14.3%)
TRACE	1 (33.3%)	0 (0.0%)	1 (7.1%)
Number of Patients with Assessment	3 (100.0%)	11 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Amorphous Sediment

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	2 (100.0%)	3 (50.0%)	5 (62.5%)
MANY	0 (0.0%)	1 (16.7%)	1 (12.5%)
MODERATE	0 (0.0%)	2 (33.3%)	2 (25.0%)
Number of Patients with Assessment	2 (100.0%)	6 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Generic - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1	0 (0.0%)	2 (11.8%)	2 (6.5%)
2	14 (100.0%)	15 (88.2%)	29 (93.5%)
Number of Patients with Assessment	14 (100.0%)	17 (100.0%)	31 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Mucous Threads

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	2 (100.0%)	5 (100.0%)	7 (100.0%)
Number of Patients with Assessment	2 (100.0%)	5 (100.0%)	7 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Squamous Epithelial Cells

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
FEW (1-5)	2 (100.0%)	6 (100.0%)	8 (100.0%)
Number of Patients with Assessment	2 (100.0%)	6 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	94	16.32979	6.409650	15.00000	6.0000	47.0000
		Week 24	37	20.00000	13.731553	15.00000	7.0000	84.0000
		Change to Week 24	37	4.89189	13.029419	2.00000	-9.0000	69.0000
		Endpoint	87	18.67816	10.997351	16.00000	7.0000	84.0000
		Change to Endpoint	87	2.35632	10.796185	1.00000	-15.0000	69.0000
Alkaline Phosphatase	IU/L	Acute Baseline	94	227.57447	88.977645	233.50000	64.0000	452.0000
		Week 24	37	199.72973	81.339702	204.00000	74.0000	367.0000
		Change to Week 24	37	-21.62162	38.133065	-25.00000	-158.0000	72.0000
		Endpoint	87	208.43678	87.872887	210.00000	63.0000	453.0000
		Change to Endpoint	87	-20.45977	40.973561	-18.00000	-158.0000	80.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	94	23.06383	6.024696	23.00000	12.0000	38.0000
		Week 24	37	25.67568	10.096903	25.00000	15.0000	69.0000
		Change to Week 24	37	2.86486	10.050324	1.00000	-6.0000	49.0000
		Endpoint	87	25.18391	8.123364	24.00000	14.0000	69.0000
		Change to Endpoint	87	2.04598	7.445786	1.00000	-8.0000	49.0000
Basophils Absolute	10^9/L	Acute Baseline	93	0.02097	0.016156	0.02000	0.0000	0.1100
		Week 24	37	0.01676	0.010289	0.02000	0.0000	0.0500
		Change to Week 24	37	-0.00703	0.023078	0.00000	-0.0900	0.0200
		Endpoint	87	0.01667	0.010418	0.02000	0.0000	0.0500
		Change to Endpoint	86	-0.00477	0.018517	0.00000	-0.0900	0.0300
Blood Urea Nitrogen	MMOL/L	Acute Baseline	94	4.58023	1.171396	4.28400	2.8560	7.8540
		Week 24	37	4.64100	1.338419	4.28400	2.4990	7.8540
		Change to Week 24	37	0.09649	1.305340	0.35700	-2.1420	3.9270
		Endpoint	87	4.68203	1.175777	4.28400	2.4990	7.8540
		Change to Endpoint	87	0.11490	1.240865	0.00000	-2.8560	3.9270
Creatinine	UMOL/L	Acute Baseline	94	51.81745	14.758087	53.04000	26.5200	88.4000
		Week 24	37	54.95135	16.291514	53.04000	26.5200	97.2400
		Change to Week 24	37	2.38919	11.345365	0.00000	-26.5200	35.3600
		Endpoint	87	54.97057	15.395682	53.04000	26.5200	97.2400
		Change to Endpoint	87	3.45471	10.814679	0.00000	-26.5200	35.3600
Eosinophils Absolute	10^9/L	Acute Baseline	93	0.27290	0.209817	0.22000	0.0000	0.9600
		Week 24	37	0.21405	0.140386	0.19000	0.0500	0.5800
		Change to Week 24	37	-0.09378	0.216889	-0.06000	-0.6200	0.2800
		Endpoint	87	0.23379	0.160879	0.20000	0.0000	0.7900
		Change to Endpoint	86	-0.03581	0.188102	-0.00500	-0.6000	0.4300

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	93	5.73824	0.630836	5.72880	4.1118	7.6384
Hematocrit	%	Acute Baseline	93	39.70860	3.206944	39.30000	32.5000	52.5000
		Week 24	37	40.06757	2.869771	39.70000	35.2000	46.7000
		Change to Week 24	37	-0.65135	2.519658	-0.80000	-5.0000	6.1000
		Endpoint	87	38.91609	3.347782	38.50000	31.5000	47.2000
		Change to Endpoint	86	-0.76977	2.611967	-0.80000	-8.1000	6.2000
Hemoglobin	G/L	Acute Baseline	93	134.19355	10.168427	134.00000	106.0000	164.0000
		Week 24	37	135.29730	9.811741	135.00000	120.0000	162.0000
		Change to Week 24	37	-2.18919	7.210478	-2.00000	-16.0000	14.0000
		Endpoint	87	131.52874	11.366862	131.00000	101.0000	162.0000
		Change to Endpoint	86	-2.48837	7.421343	-3.00000	-17.0000	18.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	93	2.58785	0.797106	2.51000	1.3900	5.8000
		Week 24	37	2.37432	0.844609	2.19000	1.3200	5.0600
		Change to Week 24	37	-0.21919	0.703501	-0.31000	-1.3500	1.6100
		Endpoint	87	2.38977	0.803497	2.25000	1.0100	5.0600
		Change to Endpoint	86	-0.20163	0.711603	-0.27000	-2.4400	1.6100
Monocytes Absolute	10^9/L	Acute Baseline	93	0.42237	0.191768	0.39000	0.0600	0.9200
		Week 24	37	0.36081	0.180453	0.31000	0.1400	0.8900
		Change to Week 24	37	-0.09351	0.194354	-0.06000	-0.7300	0.4300
		Endpoint	87	0.36701	0.180298	0.34000	0.0500	0.8900
		Change to Endpoint	86	-0.06535	0.194529	-0.05000	-0.7300	0.4400
Neutrophils Absolute	10^9/L	Acute Baseline	93	3.86161	1.445365	3.72000	0.8900	8.6100
		Week 24	37	3.79649	1.795990	3.49000	1.4700	9.3700
		Change to Week 24	37	-0.01784	1.463408	-0.05000	-3.3900	3.8900
		Endpoint	87	3.94747	1.642108	3.70000	1.1500	9.3700
		Change to Endpoint	86	0.02558	1.485875	-0.02000	-3.4600	3.8900
Platelets	10^9/L	Acute Baseline	93	286.07527	58.489173	287.00000	154.0000	425.0000
		Week 24	37	281.70270	65.032413	284.00000	181.0000	411.0000
		Change to Week 24	37	-8.21622	49.767311	-13.00000	-107.0000	171.0000
		Endpoint	87	276.22989	59.171352	283.00000	135.0000	411.0000
		Change to Endpoint	86	-12.33721	45.958961	-14.50000	-145.0000	171.0000
Potassium	MMOL/L	Acute Baseline	94	4.31064	0.353924	4.20000	3.6000	5.6000
		Week 24	36	4.34167	0.354864	4.30000	3.8000	5.3000
		Change to Week 24	36	0.02778	0.516920	0.00000	-1.8000	1.2000
		Endpoint	87	4.32184	0.455311	4.20000	3.6000	6.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	87	0.02184	0.529902	0.00000	-1.8000	2.1000
Red Blood Cell Count	10^12/L	Acute Baseline	93	4.63978	0.330724	4.60000	4.0000	5.6000
		Week 24	37	4.67838	0.344912	4.70000	3.9000	5.4000
		Change to Week 24	37	-0.04324	0.257704	-0.10000	-0.5000	0.7000
		Endpoint	87	4.54598	0.351013	4.50000	3.9000	5.4000
		Change to Endpoint	86	-0.08140	0.268552	-0.10000	-0.7000	0.7000
Sodium	MMOL/L	Acute Baseline	94	141.75532	2.113379	142.00000	137.0000	149.0000
		Week 24	37	141.37838	2.325599	141.00000	137.0000	147.0000
		Change to Week 24	37	-0.35135	3.216418	-1.00000	-7.0000	8.0000
		Endpoint	87	141.67816	2.259318	141.00000	137.0000	148.0000
		Change to Endpoint	87	-0.04598	3.136092	0.00000	-7.0000	9.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	94	2.41489	1.804711	2.20000	0.1000	17.0000
Total Bilirubin	UMOL/L	Acute Baseline	94	8.04064	4.073161	6.84000	0.0000	22.2300
		Week 24	36	7.22000	4.130604	5.13000	3.4200	23.9400
		Change to Week 24	36	-0.71250	3.710008	-0.85500	-11.9700	6.8400
		Endpoint	87	7.52793	3.958762	6.84000	3.4200	23.9400
		Change to Endpoint	87	-0.43241	3.341741	0.00000	-11.9700	6.8400
Total Free Thyroxine	PMOL/L	Acute Baseline	91	13.60879	1.944663	12.90000	10.3200	20.6400
White Blood Cell Count	10^9/L	Acute Baseline	93	7.15914	2.013608	6.90000	3.9000	14.9000
		Week 24	37	6.76216	2.221530	6.60000	3.4000	12.6000
		Change to Week 24	37	-0.41892	1.769940	-0.70000	-3.5000	5.2000
		Endpoint	87	6.95402	2.142092	6.80000	2.8000	13.3000
		Change to Endpoint	86	-0.27558	1.912555	-0.30000	-6.5000	5.2000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	127	16.71654	8.254770	14.00000	7.0000	59.0000
		Week 24	29	18.31034	9.250882	16.00000	8.0000	47.0000
		Change to Week 24	29	1.93103	6.755585	1.00000	-12.0000	27.0000
		Endpoint	107	18.56075	9.315414	17.00000	6.0000	79.0000
		Change to Endpoint	107	2.00000	7.061722	2.00000	-19.0000	33.0000
Alkaline Phosphatase	IU/L	Acute Baseline	127	235.93701	93.984695	235.00000	49.0000	512.0000
		Week 24	29	204.62069	99.886154	218.00000	74.0000	528.0000
		Change to Week 24	29	-17.93103	33.902098	-13.00000	-112.0000	64.0000
		Endpoint	107	213.06542	95.464235	218.00000	30.0000	528.0000
		Change to Endpoint	107	-22.50467	43.897044	-17.00000	-207.0000	93.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	127	24.40157	6.542001	24.00000	12.0000	47.0000
		Week 24	29	24.96552	7.466510	23.00000	15.0000	53.0000
		Change to Week 24	29	1.20690	7.203071	0.00000	-16.0000	28.0000
		Endpoint	107	26.28972	7.972842	26.00000	13.0000	59.0000
		Change to Endpoint	107	2.00000	5.830952	1.00000	-16.0000	28.0000
Basophils Absolute	10^9/L	Acute Baseline	127	0.02024	0.012691	0.02000	0.0000	0.0700
		Week 24	30	0.01667	0.013730	0.01000	0.0000	0.0700
		Change to Week 24	30	-0.00433	0.015466	-0.00500	-0.0300	0.0300
		Endpoint	106	0.01991	0.020213	0.02000	0.0000	0.1800
		Change to Endpoint	106	-0.00047	0.023518	0.00000	-0.0300	0.1700
Blood Urea Nitrogen	MMOL/L	Acute Baseline	127	4.37114	1.298695	4.28400	1.4280	8.9250
		Week 24	29	4.56714	1.413195	4.28400	2.1420	8.5680
		Change to Week 24	29	0.28314	1.256327	0.35700	-2.8560	2.4990
		Endpoint	107	4.71774	1.358998	4.64100	2.1420	8.5680
		Change to Endpoint	107	0.32030	1.290852	0.35700	-2.8560	4.2840
Creatinine	UMOL/L	Acute Baseline	127	51.71748	14.652234	53.04000	26.5200	132.6000
		Week 24	29	54.56414	10.042802	53.04000	35.3600	79.5600
		Change to Week 24	29	4.26759	9.337666	0.00000	-17.6800	26.5200
		Endpoint	107	53.94879	13.017863	53.04000	26.5200	88.4000
		Change to Endpoint	107	1.98280	12.578568	0.00000	-79.5600	44.2000
Eosinophils Absolute	10^9/L	Acute Baseline	127	0.24504	0.202147	0.18000	0.0000	1.3300
		Week 24	30	0.21267	0.126353	0.19000	0.0000	0.5400
		Change to Week 24	30	-0.04167	0.173286	-0.03000	-0.5400	0.2900
		Endpoint	106	0.25821	0.189394	0.19500	0.0000	1.2800
		Change to Endpoint	106	0.00415	0.178357	-0.00500	-0.5400	0.5600

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	124	5.66198	0.663780	5.68260	3.7422	8.0388
Hematocrit	%	Acute Baseline	127	39.22283	3.399631	38.90000	31.8000	48.8000
		Week 24	30	38.76667	4.018949	38.55000	29.0000	47.2000
		Change to Week 24	30	-0.78000	2.655430	-0.45000	-6.1000	4.7000
		Endpoint	106	38.73774	3.205604	38.50000	29.0000	47.2000
		Change to Endpoint	106	-0.36604	2.477245	0.00000	-7.1000	6.2000
Hemoglobin	G/L	Acute Baseline	127	132.17323	11.332699	131.00000	104.0000	163.0000
		Week 24	30	130.40000	15.486590	129.00000	86.0000	162.0000
		Change to Week 24	30	-1.73333	9.996321	-1.50000	-20.0000	20.0000
		Endpoint	106	130.55660	11.317984	129.00000	86.0000	162.0000
		Change to Endpoint	106	-1.30189	7.885091	-1.00000	-24.0000	20.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	127	2.36213	0.661211	2.31000	0.8000	4.8700
		Week 24	30	2.31467	0.641215	2.19500	1.2900	3.4500
		Change to Week 24	30	-0.00500	0.516171	-0.04500	-1.0300	1.0500
		Endpoint	106	2.26189	0.680683	2.15500	0.7000	5.3800
		Change to Endpoint	106	-0.04189	0.602874	-0.06500	-2.4600	2.4200
Monocytes Absolute	10^9/L	Acute Baseline	127	0.35638	0.188278	0.34000	0.0000	1.4000
		Week 24	30	0.35767	0.165689	0.35000	0.0600	0.9100
		Change to Week 24	30	0.01133	0.193796	-0.02500	-0.4100	0.5200
		Endpoint	106	0.34642	0.166082	0.34500	0.0000	0.9100
		Change to Endpoint	106	-0.01255	0.194520	-0.02500	-0.9700	0.5400
Neutrophils Absolute	10^9/L	Acute Baseline	127	3.83299	1.391697	3.76000	1.4600	8.6500
		Week 24	30	3.71667	1.446852	3.53500	1.4400	7.0700
		Change to Week 24	30	0.02933	1.546462	0.03500	-2.6200	2.9100
		Endpoint	106	3.79481	1.419930	3.58000	1.4400	9.7900
		Change to Endpoint	106	0.06104	1.573434	0.08500	-4.1100	4.8000
Platelets	10^9/L	Acute Baseline	127	294.67717	63.205119	282.00000	115.0000	468.0000
		Week 24	30	293.26667	53.783688	295.50000	216.0000	415.0000
		Change to Week 24	30	12.46667	44.553519	10.50000	-43.0000	130.0000
		Endpoint	106	291.80189	59.718454	293.50000	154.0000	450.0000
		Change to Endpoint	106	-1.57547	45.991500	1.50000	-154.0000	130.0000
Potassium	MMOL/L	Acute Baseline	127	4.40157	0.383175	4.40000	3.3000	6.1000
		Week 24	29	4.33448	0.361817	4.20000	3.9000	5.1000
		Change to Week 24	29	-0.10690	0.374100	-0.10000	-0.9000	0.8000
		Endpoint	107	4.34486	0.390991	4.20000	3.9000	5.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	107	-0.08131	0.420272	-0.10000	-1.6000	1.4000
Red Blood Cell Count	10^12/L	Acute Baseline	127	4.57087	0.376304	4.60000	3.7000	5.4000
		Week 24	30	4.54333	0.434450	4.45000	3.9000	5.5000
		Change to Week 24	30	-0.05667	0.293238	-0.05000	-0.6000	0.5000
		Endpoint	106	4.52264	0.368079	4.50000	3.7000	5.5000
		Change to Endpoint	106	-0.03491	0.259686	0.00000	-0.8000	0.5000
Sodium	MMOL/L	Acute Baseline	127	141.76378	2.212722	142.00000	137.0000	149.0000
		Week 24	29	141.24138	2.029341	141.00000	137.0000	145.0000
		Change to Week 24	29	-0.75862	3.302112	0.00000	-8.0000	5.0000
		Endpoint	107	141.25234	2.101632	141.00000	134.0000	148.0000
		Change to Endpoint	107	-0.48598	2.963184	0.00000	-8.0000	7.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	127	2.30079	1.269827	2.00000	0.5000	11.7000
Total Bilirubin	UMOL/L	Acute Baseline	127	7.28433	3.956195	6.84000	3.4200	34.2000
		Week 24	29	7.48862	3.308681	6.84000	3.4200	13.6800
		Change to Week 24	29	0.41276	2.530370	0.00000	-3.4200	5.1300
		Endpoint	107	7.12766	3.129250	6.84000	3.4200	25.6500
		Change to Endpoint	107	-0.17579	3.237130	0.00000	-18.8100	5.1300
Total Free Thyroxine	PMOL/L	Acute Baseline	125	13.73592	1.933307	14.19000	9.0300	19.3500
White Blood Cell Count	10^9/L	Acute Baseline	127	6.81575	1.763673	6.50000	3.8000	13.2000
		Week 24	30	6.62000	1.683264	6.55000	3.0000	10.2000
		Change to Week 24	30	-0.00667	1.832830	0.00000	-3.7000	3.4000
		Endpoint	106	6.68113	1.767382	6.40000	3.0000	12.5000
		Change to Endpoint	106	0.01132	1.770355	0.05000	-4.2000	5.8000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	221	16.55204	7.512006	15.00000	6.0000	59.0000
		Week 24	66	19.25758	11.916776	15.50000	7.0000	84.0000
		Change to Week 24	66	3.59091	10.764582	2.00000	-12.0000	69.0000
		Endpoint	194	18.61340	10.077422	16.00000	6.0000	84.0000
		Change to Endpoint	194	2.15979	8.908297	1.50000	-19.0000	69.0000
Alkaline Phosphatase	IU/L	Acute Baseline	221	232.38009	91.776261	234.00000	49.0000	512.0000
		Week 24	66	201.87879	89.264777	211.00000	74.0000	528.0000
		Change to Week 24	66	-20.00000	36.109236	-22.50000	-158.0000	72.0000
		Endpoint	194	210.98969	91.931265	217.00000	30.0000	528.0000
		Change to Endpoint	194	-21.58763	42.514064	-18.00000	-207.0000	93.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	221	23.83258	6.347800	23.00000	12.0000	47.0000
		Week 24	66	25.36364	8.977984	24.00000	15.0000	69.0000
		Change to Week 24	66	2.13636	8.887132	0.00000	-16.0000	49.0000
		Endpoint	194	25.79381	8.038686	25.00000	13.0000	69.0000
		Change to Endpoint	194	2.02062	6.586183	1.00000	-16.0000	49.0000
Basophils Absolute	10^9/L	Acute Baseline	220	0.02055	0.014228	0.02000	0.0000	0.1100
		Week 24	67	0.01672	0.011856	0.02000	0.0000	0.0700
		Change to Week 24	67	-0.00582	0.019935	0.00000	-0.0900	0.0300
		Endpoint	193	0.01845	0.016573	0.02000	0.0000	0.1800
		Change to Endpoint	192	-0.00240	0.021477	0.00000	-0.0900	0.1700
Blood Urea Nitrogen	MMOL/L	Acute Baseline	221	4.46008	1.247700	4.28400	1.4280	8.9250
		Week 24	66	4.60855	1.361545	4.28400	2.1420	8.5680
		Change to Week 24	66	0.17850	1.277626	0.35700	-2.8560	3.9270
		Endpoint	194	4.70173	1.276980	4.46250	2.1420	8.5680
		Change to Endpoint	194	0.22819	1.269552	0.35700	-2.8560	4.2840
Creatinine	UMOL/L	Acute Baseline	221	51.76000	14.663921	53.04000	26.5200	132.6000
		Week 24	66	54.78121	13.801528	53.04000	26.5200	97.2400
		Change to Week 24	66	3.21455	10.475291	0.00000	-26.5200	35.3600
		Endpoint	194	54.40701	14.105025	53.04000	26.5200	97.2400
		Change to Endpoint	194	2.64289	11.813237	0.00000	-79.5600	44.2000
Eosinophils Absolute	10^9/L	Acute Baseline	220	0.25682	0.205413	0.20000	0.0000	1.3300
		Week 24	67	0.21343	0.133287	0.19000	0.0000	0.5800
		Change to Week 24	67	-0.07045	0.198833	-0.04000	-0.6200	0.2900
		Endpoint	193	0.24720	0.177081	0.20000	0.0000	1.2800
		Change to Endpoint	192	-0.01375	0.183387	-0.00500	-0.6000	0.5600

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	217	5.69466	0.649484	5.71340	3.7422	8.0388
Hematocrit	%	Acute Baseline	220	39.42818	3.320811	39.15000	31.8000	52.5000
		Week 24	67	39.48507	3.466124	39.10000	29.0000	47.2000
		Change to Week 24	67	-0.70896	2.562298	-0.80000	-6.1000	6.1000
		Endpoint	193	38.81813	3.263072	38.50000	29.0000	47.2000
		Change to Endpoint	192	-0.54687	2.539735	-0.40000	-8.1000	6.2000
Hemoglobin	G/L	Acute Baseline	220	133.02727	10.877868	132.00000	104.0000	164.0000
		Week 24	67	133.10448	12.802858	133.00000	86.0000	162.0000
		Change to Week 24	67	-1.98507	8.503996	-2.00000	-20.0000	20.0000
		Endpoint	193	130.99482	11.320841	130.00000	86.0000	162.0000
		Change to Endpoint	192	-1.83333	7.683758	-2.00000	-24.0000	20.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	220	2.45755	0.728661	2.35000	0.8000	5.8000
		Week 24	67	2.34761	0.755421	2.19000	1.2900	5.0600
		Change to Week 24	67	-0.12328	0.631298	-0.20000	-1.3500	1.6100
		Endpoint	193	2.31953	0.739345	2.21000	0.7000	5.3800
		Change to Endpoint	192	-0.11344	0.656888	-0.13000	-2.4600	2.4200
Monocytes Absolute	10^9/L	Acute Baseline	220	0.38427	0.192123	0.35000	0.0000	1.4000
		Week 24	67	0.35940	0.172705	0.32000	0.0600	0.9100
		Change to Week 24	67	-0.04657	0.199663	-0.04000	-0.7300	0.5200
		Endpoint	193	0.35570	0.172484	0.34000	0.0000	0.9100
		Change to Endpoint	192	-0.03620	0.195792	-0.04000	-0.9700	0.5400
Neutrophils Absolute	10^9/L	Acute Baseline	220	3.84509	1.411432	3.72000	0.8900	8.6500
		Week 24	67	3.76075	1.637323	3.49000	1.4400	9.3700
		Change to Week 24	67	0.00328	1.489803	-0.02000	-3.3900	3.8900
		Endpoint	193	3.86363	1.521915	3.68000	1.1500	9.7900
		Change to Endpoint	192	0.04516	1.530959	0.04000	-4.1100	4.8000
Platelets	10^9/L	Acute Baseline	220	291.04091	61.267384	282.50000	115.0000	468.0000
		Week 24	67	286.88060	60.095258	285.00000	181.0000	415.0000
		Change to Week 24	67	1.04478	48.275859	-3.00000	-107.0000	171.0000
		Endpoint	193	284.78238	59.824172	291.00000	135.0000	450.0000
		Change to Endpoint	192	-6.39583	46.169272	-7.50000	-154.0000	171.0000
Potassium	MMOL/L	Acute Baseline	221	4.36290	0.372923	4.30000	3.3000	6.1000
		Week 24	65	4.33846	0.355181	4.30000	3.8000	5.3000
		Change to Week 24	65	-0.03231	0.460335	0.00000	-1.8000	1.2000
		Endpoint	194	4.33454	0.420083	4.20000	3.6000	6.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	194	-0.03505	0.474105	-0.10000	-1.8000	2.1000
Red Blood Cell Count	10^12/L	Acute Baseline	220	4.60000	0.358587	4.60000	3.7000	5.6000
		Week 24	67	4.61791	0.390387	4.60000	3.9000	5.5000
		Change to Week 24	67	-0.04925	0.272126	-0.10000	-0.6000	0.7000
		Endpoint	193	4.53316	0.359744	4.50000	3.7000	5.5000
		Change to Endpoint	192	-0.05573	0.264017	-0.10000	-0.8000	0.7000
Sodium	MMOL/L	Acute Baseline	221	141.76018	2.166155	142.00000	137.0000	149.0000
		Week 24	66	141.31818	2.184977	141.00000	137.0000	147.0000
		Change to Week 24	66	-0.53030	3.235475	-1.00000	-8.0000	8.0000
		Endpoint	194	141.44330	2.178411	141.00000	134.0000	148.0000
		Change to Endpoint	194	-0.28866	3.041880	0.00000	-8.0000	9.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	221	2.34932	1.517732	2.10000	0.1000	17.0000
Total Bilirubin	UMOL/L	Acute Baseline	221	7.60602	4.014697	6.84000	0.0000	34.2000
		Week 24	65	7.33985	3.760094	6.84000	3.4200	23.9400
		Change to Week 24	65	-0.21046	3.262860	0.00000	-11.9700	6.8400
		Endpoint	194	7.30716	3.521537	6.84000	3.4200	25.6500
		Change to Endpoint	194	-0.29088	3.278377	0.00000	-18.8100	6.8400
Total Free Thyroxine	PMOL/L	Acute Baseline	216	13.68236	1.934602	12.90000	9.0300	20.6400
White Blood Cell Count	10^9/L	Acute Baseline	220	6.96091	1.876658	6.80000	3.8000	14.9000
		Week 24	67	6.69851	1.985439	6.60000	3.0000	12.6000
		Change to Week 24	67	-0.23433	1.796508	-0.30000	-3.7000	5.2000
		Endpoint	193	6.80415	1.944753	6.60000	2.8000	13.3000
		Change to Endpoint	192	-0.11719	1.836103	-0.20000	-6.5000	5.8000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

BRL 29060 - 716
Interim Output
Table 15.4.1

Number (%) of Patients by ECG Assessment by Acute Study Treatment Group

All Patients

Visit		Acute Treatement Group: Paroxetine (N=96)	Placebo (N=127)	Total (N=223)
Acute Study Screening	Abnormal	0	0	0
	Normal	96 (100.0%)	126 (100.0%)	222 (100.0%)
	Missing	0	0	0
	Total	96 (100.0%)	126 (100.0%)	222 (100.0%)
Acute Study Baseline	Abnormal	0	0	0
	Normal	1 (2.2%)	0	1 (0.9%)
	Unknown*	0	0	0
	Not Applicable**	44 (97.8%)	61 (100.0%)	105 (99.1%)
	Total	45 (100.0%)	61 (100.0%)	106 (100.0%)
716 Baseline	Abnormal	0	0	0
	Normal	10 (10.6%)	18 (14.2%)	28 (12.7%)
	Unknown*	0	0	0
	Not Applicable**	84 (89.4%)	109 (85.8%)	193 (87.3%)
	Total	94 (100.0%)	127 (100.0%)	221 (100.0%)
Last Study 716 Treatment ECG	Abnormal	0	0	0
	Normal	28 (93.3%)	28 (100.0%)	56 (96.6%)
	Missing	2 (6.7%)	0	2 (3.4%)
	Total	30 (100.0%)	28 (100.0%)	58 (100.0%)
Early Withdrawals ECG	Abnormal	0	0	0
	Normal	5 (55.6%)	27 (87.1%)	32 (80.0%)
	Missing	4 (44.4%)	3 (9.7%)	7 (17.5%)
	Not Applicable**	0	1 (3.2%)	1 (2.5%)
	Total	9 (100.0%)	31 (100.0%)	40 (100.0%)
Taper End ECG	Abnormal	0	0	0
	Normal	6 (40.0%)	7 (41.2%)	13 (40.6%)
	Missing	0	1 (5.9%)	1 (3.1%)
	Unknown*	0	0	0
	Not Applicable**	9 (60.0%)	9 (52.9%)	18 (56.3%)
	Total	15 (100.0%)	17 (100.0%)	32 (100.0%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit

(ECGs at timepoints other than Acute Study Screening, Last Study 716 Treatment and Early Withdrawal are performed only on patients who previously had an abnormal ECG)

Note: Percentages are based on number of patients with an assessment at that visit
Note: ECG's at Acute Study Baseline are only taken in Study 704

BRL 29060 - 716
Interim Output
Table 15.4.1

Number (%) of Patients by ECG Assessment by Acute Study Treatment Group

All Patients

Visit		Acute Treatement Group: Paroxetine (N=96)	Placebo (N=127)	Total (N=223)
Follow Up ECG	Abnormal	1 (1.8%)	1 (1.3%)	2 (1.5%)
	Normal	11 (20.0%)	10 (13.0%)	21 (15.9%)
	Missing	3 (5.5%)	1 (1.3%)	4 (3.0%)
	Unknown*	1 (1.8%)	5 (6.5%)	6 (4.5%)
	Not Applicable**	39 (70.9%)	60 (77.9%)	99 (75.0%)
	Total	55 (100.0%)	77 (100.0%)	132 (100.0%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit

(ECGs at timepoints other than Acute Study Screening, Last Study 716 Treatment and Early Withdrawal are performed only on patients who previously had an abnormal ECG)

Note: Percentages are based on number of patients with an assessment at that visit
Note: ECG's at Acute Study Baseline are only taken in Study 704

13 Errata

Table/Listing.	Error
Listings 13.9.1, Appendix B and 15.1.4, Appendix D	Patient 716.176.25794 received treatment for syncope on day 62 according to Listing 15.1.4, but no treatment for this date is recorded in the concomitant medication Listing 13.9.1.
Table 13.9.1, Section 11; Listing 13.9.1, Appendix B	Patient 716.055.28172 had a drug of "otc lotrimin" which was not coded. This drug has been listed and included in the summary tables with a missing generic term.
Table 13.9.1, Section 11; Listing 13.9.1, Appendix B	Patient 716.004.25403 received a one-a-day vitamin for nutrition as a concomitant medication starting during study 704 and continuing into study 716. However, this concomitant medication is not recorded in Table 13.9.1 or Listing 13.9.1.
Table 13.10.1, Section 11; Listing 13.10.1, Appendix B	Patient 716.176.27170 had 'unknown' entered for compliance question, missed > 3 consecutive days of study medication. This has been listed in Listing 13.10.1 as 'unk' and treated as missing in Table 13.10.1.
Table 13.10.2, Section 11; Listing 13.10.1, Appendix B	Patient 716.043.27694 received a dose of 15 mg/day between April 18, 2001 and May 25, 2001. This has been listed in Listing 13.10.1 as 15 mg and 15 mg has been used in the tablet accountability Table 13.10.2. The patient took one and a half 10 mg tablets.
Table 13.10.2, Section 11; Listing 13.10.1, Appendix B	Patient 716.159.25628 is databased as receiving a dose of 2mg/day between September 21, 2000 and October 16, 2000 according to the CRF. This has been queried and it should be 20mg/day. This has been listed in Listing 13.10.1 as 2mg and 2mg has been used in the tablet accountability Table 13.10.2. This error will be fixed for the final clinical study report.

Table/Listing.	Error
Tables 13.10.3 and 13.10.6, Section 11	Patient 716.043.27694 received a 15mg/day dose between April 18, 2001 and May 25, 2001. In dosing table 13.10.3 this 15 mg dose has been excluded from the table, and in table 13.10.6 the 15mg dose has been used.
Tables 13.10.3 and 13.10.6, Section 11	Patient 716.159.25628 is databased as received a 2mg/day dose between September 21, 2000 and October 16, 2000 according to the CRF. This has been queried and it should be 20mg/day. In dosing tables 13.10.3 and 13.10.6 this 2mg dose has been changed to 20mg/day. This error in the database will be fixed for the final clinical study report.
Listing 15.1.1, Appendix E	Patient 716.026.27047 has an AE of 'dehydration' which has a missing intensity.
Listings 15.1.1 and 15.1.4, Appendix E	Patient 716.004.25403 has "no" under corrective treatment for the adverse event manic symptoms, but according to the concomitant medication listing (Listing13.9.1, Appendix B), the patient received Risperdal (beginning on the day of withdrawal) for hypomanic symptoms. On the adverse event page of the CRF, the corrective therapy box for this adverse event has been entered as "no".
Table 15.4.1, Section 13; Listing 15.4.1, Appendix E	Patients 716.172.25619 and 716.014.25353 had an on-treatment ECG with a baseline page CRF, which cannot be assigned to a visit window. These ECGs have been listed, but not included in the summary tables.
Table 15.4.1, Section 13; Listing 15.4.1, Appendix E	Patient 716.010.28172 had an on-treatment ECG with a follow-up page CRF, which cannot be assigned to a visit window. These ECGs have been listed, but not included in the summary tables.
Table 15.4.1, Section 13; Listing 15.4.1, Appendix E	Patient 716.165.25664 had an abnormal ECG recorded as an adverse event with action drug stopped, but the ECG was recorded as normal on the ECG page of the CRF.

Table/Listing.	Error
Listing 15.1.4, Appendix D	In listing 15.1.4 all 33 patients who withdrew due to an AE are listed, however patients 716.020.25458 and 716.028.27685 don't have any AE's with an action of "Study medication Stopped". These patients are included because the study conclusion page has adverse event as the primary cause of withdrawal.
Listing 15.1.4, Appendix D	Patient 716.047.27156 received their first dose of open-label study medication on March 27, 2001. In listing 15.1.4 of study 716 "somnolence (drowsiness)" is recorded with an onset date of January 9, 2001. This event had a duration of 21 days which means it should have resolved by January 30, 2001 (two months before the start of study 716). This event is recorded in acute study 704 adverse event Listing 15.1.1, but is said to be "continuing". The duration of 21 days should have been recorded in 704 and this event should not be recorded in study 716 output. This will be corrected for the final clinical study report.
Table 15.1.4, Appendix D	Patient 716.015.27403 received amoxicillin to treat pleurisy, but pleurisy is not listed as adverse event for this patient.
Table 15.1.5.1, Section 13	Patient 716.019.25753 had an adverse event with an action of study medication stopped and is therefore included in Table 15.1.5.1 as withdrawing because of an adverse event. However, according to Table 13.3.1b patient 716.019.25753 was withdrawn for "other" reason, given as "did not want to give blood".
Table 15.1.5.1, Section 13	Patients 716.020.25458 and 716.028.27685 withdrew due to an adverse event, but don't have a corresponding adverse event with an action of "study medication stopped" and are therefore not included in the summary table.

Table/Listing.	Error
Table 15.1.5.1, Section 13	The following patients withdrew due to an AE, but their corresponding adverse event with an action of "study medication stopped" was not in the open-label treatment phase and they are therefore not included in the summary table: 716. 008.25644, 716.010.25606, 716.015.25464, 716.176.25794 and 716.010.25371.