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GLAXOSMITHKLINE CLARIFIES AVAILABILITY OF CLINICAL TRIAL DATA ON PAROXETINE IN ADOLESCENT AND PAEDIATRIC PATIENTS

GlaxoSmithKline's policy is to ensure transparency of the clinical data the company collects on its marketed medicines. Specifically, we endorse the PhRMA principles that call for timely publication of meaningful trial results.

With regard to clinical trial data on paroxetine, GSK has already provided data that were collected during clinical trials in adolescent and paediatric patients to the US, UK, European and other regulatory agencies.

In addition, data have previously been made available to healthcare professionals through publication in peer-reviewed journals, poster presentations at scientific meetings, and medical letters to physicians. This approach is accepted standard practice for making data available.

However, in order to clarify the nature of these data, GSK will shortly be making available full study reports of the safety and efficacy data from the clinical studies conducted with paroxetine in adolescent and paediatric patients, as well as a bibliography of public communications derived from these studies, and the US letter to physicians summarising these data. This information will be available through the media room on the company's corporate website (www.gsk.com).

Paroxetine has not been approved in Europe or North America for treatment of patients younger than 18 years of age. It is GlaxoSmithKline's policy not to promote off label use of any of our medicines.

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. For more information on GlaxoSmithKline visit www.gsk.com.

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