

### **Pre-Quarterly Results Communication Q3 2013**

### **New information for Q3 2013**

#### **Share repurchases:**

During Q3 2013 we repurchased 34.1m shares at a cost of £560m including a quarter-end accrual. This brings the total shares repurchased year to date to 59.4m at a cost of £980m including a Q3 quarter-end accrual.

# GlaxoSmithKline plc - Continuation of Share Buy-Back Programme during close period (LSE announcement 30 September 2013)

GlaxoSmithKline plc (the "Company") announces that it has today, put in place an irrevocable, non-discretionary programme for the purchase of its Ordinary shares during the close period which precedes the 2013 third quarter results announcement, expected to be made on 23 October 2013. The shares to be purchased on behalf of the Company will either be cancelled or held in treasury. <a href="http://www.londonstockexchange.com/exchange/news/market-news/market-news-detail.html?announcementId=11726466">http://www.londonstockexchange.com/exchange/news/market-news/market-news-detail.html?announcementId=11726466</a>

### **Basic Weighted Average Number of Shares (WANS):**

The basic weighted number of shares in issue during Q3 2013 was 4,837m compared with 4,897m in Q3 2012 (a reduction of 1.2%).

The basic weighted number of shares in issue during 9M 2013 was 4,842m compared with 4,935m in 9M 2012 (a reduction of 1.9%).

In millions	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	2012	2012	2012	2012	2013	2013	2013
WANS: Quarter	4,963	4,945	4,897	4,843	4,834	4,855	4,837
<b>WANS</b> : Cumulative - Year to date	4,963	4,954	4,935	4,912	4,834	4,844	4,842
Period end shares *	4,962	4,910	4,864	4,827	4,844	4,845	4,818

<sup>\*</sup>excludes Treasury shares and shares held by ESOP Trusts

### Foreign Exchange:

Average rates for the quarter ended 30<sup>th</sup> September 2013 were \$1.55/£, €1.18/£ and Yen 155/£. On the basis of these rates, it is expected that the impact of foreign exchange on Q3 2013 sales will be around -1%.

Average rates for the nine months ended 30<sup>th</sup> September 2013 were \$1.55/£, €1.18/£ and Yen 149/£. On the basis of these rates, it is expected that the impact of foreign exchange on 9M 2013 sales will be around +0%.



Average rates	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	2012	2012	2012	2012	2013	2013	2013
Quarter							
US\$	1.58	1.58	1.58	1.62	1.56	1.54	1.55
€	1.20	1.24	1.25	1.23	1.19	1.17	1.18
Yen	125	125	125	133	142	150	155
FX impact on	-1%	-2%	-3%	-3%	-1%	+0%	-1%
Turnover							
	Q1	H1	9M	Full Year	Q1	H1	9M
	2012	2012	2012	2012	2013	2013	2013
Cumulative - YTD							
US\$	1.58	1.58	1.58	1.59	1.56	1.55	1.55
€	1.20	1.22	1.23	1.23	1.19	1.18	1.18
Yen	125	125	125	127	142	146	149
FX impact on	-1%	-2%	-2%	-2%	-1%	+0%	+0%
Turnover							

### **Exchange Gains and Losses (EGOLs)**

Sharp movements and volatility in currencies during a quarter can result in Exchange Gains and Losses (EGOLs) which are recorded in SG&A. In Q1 there was an EGOL credit of £82m, while in Q2 there were losses of £46m. During Q3 2013 there was continued volatility in number of currencies relative to sterling including in particular the US\$.

EGOLS £m (as reported)	Q1	Q2	Q3	Q4	Full year
2012	(17)	(2)	2	(9)	(26)
2013	82	(46)			

### Ready-reckoner

At the 2012 results presentation on 6<sup>th</sup> February 2013, the following ready-reckoner was provided in one of the slides to help estimate the expected impact of foreign exchange movements on core EPS\*:

Currency	Impact on 2013 Full Year EPS
US Dollar	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-3.5%
Euro	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-2.5%
Japanese Yen	10 Yen movement in average exchange rate for full year impacts EPS by approximately +/-1.0%

<sup>\*</sup>Please note that the ready-reckoner does not include the impact of inter-company Exchange Gains and Losses



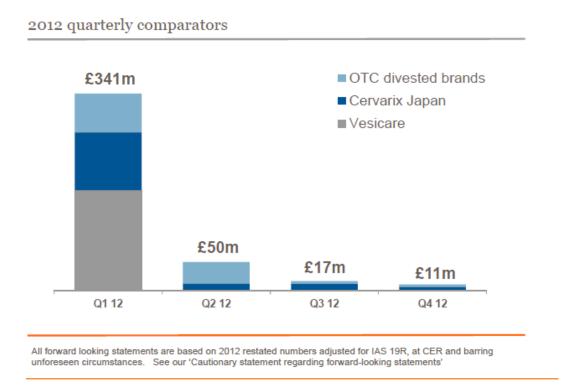
### **Factors impacting the Quarter**

As usual there were a number of events in Q3 2012 and since then which impact the year on year comparison for Q3 2013. The following include several noteworthy items which you may wish to consider in your modelling.

EPS for Q3 2012 was 26.2p when restated for IAS 19 (revised) – see later for further details.

Please note that the items listed below are not intended to be a complete list of all items that may impact the comparisons for Q3 2013 versus Q3 2012.

In our Full Year 2012 results presentation on 6 February 2013 we included the following slide:



Link to 2012 Results London Stock Exchange announcements and presentations: <a href="http://www.gsk.com/investors/quarterly-results.html">http://www.gsk.com/investors/quarterly-results.html</a>



### **Acquisitions and Divestments - Historic information**

### **OTC divestments**

During 2012, we divested the non-core tail of OTC products in three tranches. The divestments included:

- North American brands (2011 sales of circa £126 million), which was substantially completed at the end of January 2012;
- International brands (total 2011 sales of circa £60 million), which was substantially completed in April 2012; and
- European brands (total 2011 sales of circa £185 million), which was substantially completed in May 2012 (Europe business was sold to Omega).

Sales £m (as reported)	Q1 2012	Q2 2012	Q3 2012	Q4 2012	FY 2012	Q1 2013	Q2 2013
Ongoing Consumer Healthcare	1,269	1,220	1,263	1,245	4,997	1,346	1,309
Divested OTC products	67	37	5	4	113	1	0
Total Consumer Healthcare	1,336	1,257	1,268	1,249	5,110	1,347	1,309
CER growth*							
Ongoing Consumer Healthcare	+4%	+5%	+5%	+7%	+5%	+6%	+5%
Total Consumer Healthcare	+1%	+0%	-2%	+0%	+0%	+1%	+2%

### **Vesicare:**

In Q1 2012 the Group benefited from incremental revenue related to the conclusion of the copromotion agreement for Vesicare in the US. There were no associated COGS with Vesicare. There will be no Vesicare sales going forward.

Sales £m (as reported)	Q1	Q2	Q3	Q4	Full year
2012	174	0	0	1	175
2013	0	0			



#### **Items Impacting Recent Quarterly Comparisons**

### **Emerging Markets:**

Vaccines in Emerging Markets are particularly vulnerable to volatility on a quarterly basis. Here are the published quarterly results for Pharma and Vaccines in Emerging Markets:

Sales £m (as reported)	Q1	Q2	Q3	Q4	FY	Q1	Q2
	2012	2012	2012	2012	2012	2013	2013
Pharma	842	892	902	993	3,629	894	958
Vaccines	210	277	301	319	1,107	225	247
Pharma + Vaccines	1,052	1,169	1,203	1,312	4,736	1,119	1,205
CER growth*							
Pharma	+6%	+7%	+10%	+11%	+8%	+8%	+7%
Vaccines**	-9%	+15%	+13%	+39%	+14%	+7%	-13%
Pharma + Vaccines	+2%	+9%	+11%	+16%	+10%	+8%	+2%

<sup>\*\*</sup>In the 2013 Q2 results presentation on 24 July Simon Dingemans (Chief Financial Officer) made the following comments:

"In EMAP, reported Q2 sales grew 2%. This particularly reflects the affected phasing of vaccine tenders and a tough comparator last year resulting in a 13% decline in vaccine sales in the quarter. We are expecting a better Vaccines performance overall in the second half but, as with last year, tenders will likely be weighted to Q4 relative to Q3. Remember, both quarters offer tough comparators as well."

The full results announcements along with links to related webcasts and presentations can be found at: <a href="http://www.gsk.com/investors/quarterly-results.html">http://www.gsk.com/investors/quarterly-results.html</a>

### **Cost performance**

In the 2013 Q2 results presentation on 24 July Simon Dingemans (Chief Financial Officer) made the following comment on costs:

"Cost of goods remains an area of pressure as we initiate commercial volumes of new products.

Restructuring benefits have had more of an impact on our SG&A expenses which remain broadly flat, excluding the one-off benefits last year and our restructuring programmes are particularly helping us to be significantly more flexible in how we allocate our resources and how we can re-allocate them behind the pipeline in particular.

I should remind you also that during the second half of last year we had a number of similar one-off benefits that reduced our operating costs including a £290 million favourable pension adjustment recorded in Q4. I expect the combination of ongoing cost management benefits, including savings from existing programmes plus other one-off value opportunities to largely offset the comparator drag during the second half of 2013.

R&D expense was down 6% in the quarter, primarily reflecting restructuring savings coming through, productivity improvements but also the phasing of trial and study costs, particularly as a number of late-stage projects move to filing and complete their development phases. However, I am currently expecting R&D expense to pick up again in the second half and to be higher relative to first half."



## <u>Acquisitions and Divestments – Historic London Stock Exchange announcements (LSE announcements) and press releases</u>

## GlaxoSmithKline reaches agreement with Aspen to divest thrombosis brands and related manufacturing site for £0.7 billion (LSE announcement 30 September 2013)

GlaxoSmithKline (LSE:GSK) today announced it has reached agreement to sell its thrombosis brands, Arixtra® and Fraxiparine®, and the Notre-Dame de Bondeville (NDB) manufacturing site to The Aspen Group (Aspen), the South African pharmaceuticals company, for £0.7 billion in cash, of which £0.1 billion relates to inventory. The agreement is a further example of GSK's commitment to increase focus on products with the most growth potential and the delivery of its late-stage pipeline.

The net cash proceeds from the transaction after tax and transaction costs are expected to be approximately £0.6 billion. The proceeds will be used for general corporate purposes. The net profit on disposal will be excluded from core operating profit and core EPS in 2013.

GSK already has an 18.6% holding in Aspen, a leading generics manufacturer in the southern hemisphere and Africa's largest pharmaceutical manufacturer

## GSK reaches agreement to divest Lucozade and Ribena for £1.35 billion (LSE announcement 9 September 2013)

GlaxoSmithKline (LSE:GSK) today announced it has reached agreement to sell its nutritional drinks brands Lucozade and Ribena to Suntory Beverage & Food Ltd (SBF), the Japanese consumer goods company, for £1.35 billion in cash. It is expected that the transaction will be completed by the end of the year, subject to regulatory approvals.

GSK's Consumer Healthcare business has been increasing its focus around a core portfolio of healthcare brands, with a particular emphasis on emerging markets. As part of this, the company initiated a strategic review of Lucozade and Ribena in February 2013 and subsequently announced its decision to divest the brands, subject to the realisation of appropriate shareholder value.

The net proceeds of the transaction after tax, fees and costs are estimated to be approximately £1.3 billion. The net profit will be excluded from core operating profit and EPS in 2013. The proceeds will be used to reduce debt and for general corporate purposes.

Annual sales of the two brands were approximately £0.5 billion in 2012.

### Update on GSK Consumer Nigeria plc Scheme of Arrangement (LSE announcement 22 July 2013)

GlaxoSmithKline plc ("GSK") (LSE:GSK) and GlaxoSmithKline Consumer Nigeria PLC ("GSK Nigeria") today announced that they have agreed that the scheme of arrangement proposed to GSK Nigeria's shareholders in the scheme document dated 24 June 2013, under which it was proposed that GSK would increase its indirect ownership in GSK Nigeria to 75%, will be withdrawn. Following this withdrawal, at the meeting of its shareholders scheduled for July 23, 2012, GSK Nigeria will be suspending the proposed scheme of arrangement.

GSK and GSK Nigeria believe that the suspension of the scheme of arrangement is necessary to consider appropriate amendments to the proposal for GSK to increase its indirect ownership in GSK Nigeria. In particular, GSK and GSK Nigeria have agreed to consult shareholders and the Securities



and Exchange Commission about the proposal including whether it should be implemented by way of a tender offer. There can be no assurance that the proposal will proceed by way of a tender offer or otherwise.

Furthermore, as disclosed in the scheme document, GSK has announced its intention to dispose of its global Lucozade and Ribena brands. GSK and GSK Nigeria have commenced work towards the formalisation of updated long term arrangements that would allow GSK Nigeria to continue to distribute these brands in Nigeria and certain countries in West Africa. GSK and GSK Nigeria believe it is important that these arrangements are concluded and disclosed before any revised proposal is put to GSK Nigeria shareholders.

### Acquisition of Okairos AG (LSE announcement 29 May 2013)

### GSK to further expand its vaccines platform technology expertise through strategic acquisition

GlaxoSmithKline (GSK) today announced that it has acquired Okairos AG (Okairos), a specialist developer of vaccine platform technologies for €250 million (approximately £215 million/\$325 million) in cash. Swiss-based Okairos, a private company, has developed a novel vaccine platform technology which is expected to play an important role in GSK's development of new prophylactic vaccines (designed to prevent infection) as well as new classes of therapeutic vaccines (designed to treat infection or disease). Okairos' technology complements GSK's existing vaccine technology and expertise and will enable GSK to continue its work developing the next generation of vaccines. The deal also includes a small number of early stage assets.

## GlaxoSmithKline and Impax Pharmaceuticals terminate their collaboration on IPX066 (29 April 2013)

GlaxoSmithKline (GSK) plc and Impax Pharmaceuticals today announced that they are terminating their collaboration for the development and commercialisation of IPX066 outside the United States and Taiwan. IPX066 is a carbidopa-levodopa extended release product in Phase III development for the symptomatic treatment of Parkinson's disease and is not approved anywhere in the world.

#### GSK Consumer India – Increase in stake: (LSE announcement 5 February 2013)

GSK increases stake in its publicly-listed Consumer Healthcare subsidiary in India to 72.5 per cent GlaxoSmithKline plc (LSE: GSK) announced today that, pursuant to the voluntary open offer undertaken by its subsidiary, GlaxoSmithKline Pte. Ltd, GSK has successfully increased its stake in GlaxoSmithKline Consumer Healthcare Ltd, its publicly-listed Consumer Healthcare subsidiary in India, from 43.2% to 72.5%.

### HGS update comment from Q3 2012 Results announcement: (31 October 2012)

The integration is progressing well and potential cost savings of up to \$250 million have now been identified. The early emphasis has been on realising synergies in the commercial organisation. A number of additional opportunities within manufacturing have also now been identified and may rephase some of the synergy delivery. As a result, the acquisition is now expected to have a neutral effect on core earnings in 2013 and to be accretive thereafter.



### Shionogi/ViiV comment from Q3 2012 Press release (31 October 2012) and (LSE announcement 29 October 2012)

On 28 October 2012, GSK announced that ViiV Healthcare has acquired the 50% of the Shionogi-ViiV Healthcare Holdings joint venture previously held by Shionogi. As a result, GSK will record 100% of the sales of the products formerly held by the joint venture and Shionogi will take an additional non-controlling interest in ViiV Healthcare. As all of the development costs of the previous joint venture will now be fully consolidated, the acquisition is expected to be marginally dilutive to core EPS by up to 1p in each of 2013 and 2014 and accretive thereafter reflecting full consolidation of R&D costs.

### Australian Classic Brands (LSE announcement 15 August 2012)

### GlaxoSmithKline reaches agreement to divest majority of Classic Brands in Australia for £172m

GlaxoSmithKline plc (GSK) today announced that it has reached agreement to divest the majority of its "Classic Brands" (25 non-promoted and genericised products) in Australia to Aspen Global Incorporated (Aspen) for approximately £172 million in cash. The divested brands include Valtrex, Lamictal, Timentin, Amoxil and Aropax and generated total sales of approximately £83 million in 2011 and approximately £31 million in the first half of 2012.

On 30<sup>th</sup> November 2012, GSK completed the divestment of Classic Brands in Australia. The brands generated total sales in 2012 of £56m up to the date of completion.

### Toctino (LSE announcement 12 June 2012)

### Stiefel signs worldwide acquisition and license agreement for Toctino®

Stiefel, a GSK company, today announced that it has entered into a worldwide agreement to acquire Toctino (alitretinoin) from Basilea Pharmaceutica Ltd. (Basilea). Toctino is a once-daily oral retinoid and the only prescription medicine specifically approved for the treatment of severe chronic hand eczema unresponsive to potent topical steroids in adults. In 2011, worldwide sales of Toctino were £22m. Basilea will receive an initial payment of £146m in cash from Stiefel and is eligible to receive further payments of up to £50m upon FDA approval of the product in the US and double-digit success payments on US net sales, beginning three years after launch of the product in the US. The acquisition was completed at the end of July 2012.



#### News flow on Key Assets during the quarter – To date

Since the beginning of Q3 we have issued a number of LSE announcements and press releases, each of which can be accessed using the following link: http://www.gsk.com/media/press-releases.html

# Regulatory update – GSK and Genmab announce European submission to regulatory authorities for Arzerra® (ofatumumab) as 1st line treatment of Chronic Lymphocytic Leukaemia (CLL) (LSE announcement 4 October 2013)

GlaxoSmithKline plc and Genmab A/S [OMX: GEN] announced today the submission of a variation to the Marketing Authorisation to the European Medicines Agency (EMA) for the use of Arzerra (ofatumumab) in combination with an alkylator-based therapy, to be used for treatment of CLL patients who have not received prior treatment and are inappropriate for fludarabine-based therapy.

# GSK receives marketing authorisation from the European Commission for additional Revolade™ (eltrombopag) indication as the first approved treatment for chronic hepatitis C-associated thrombocytopenia (LSE announcement 20 September 2013)

GlaxoSmithKline plc announced today that the European Commission has granted an additional indication for Revolade™ (eltrombopag) as a treatment for low platelet counts (thrombocytopenia) in adult patients with chronic hepatitis C infection, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon (IFN)-based therapy.

# GSK and Prosensa announce primary endpoint not met in Phase III study of drisapersen in patients with Duchenne Muscular Dystrophy (LSE announcement 20 September 2013)

GlaxoSmithKline (GSK) and Prosensa today announced that GSK's Phase III clinical study of drisapersen, an investigational antisense oligonucleotide, for the treatment of Duchenne Muscular Dystrophy (DMD) patients with an amenable mutation, did not meet the primary endpoint of a statistically significant improvement in the 6 Minute Walking Distance (6MWD) test compared to placebo.

# RELVAR™ ELLIPTA™ gains approval in Japan for the treatment of asthma (LSE announcement 20 September 2013)

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved RELVAR™ ELLIPTA™ for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required). Relvar Ellipta is not indicated for the treatment of chronic obstructive pulmonary disease (COPD) in Japan

## RELVAR™ ELLIPTA™ receives positive opinion from the CHMP in Europe for the treatment of asthma and COPD (LSE announcement 19 September 2013)

GlaxoSmithKline plc (LSE/NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for fluticasone furoate/vilanterol (FF/VI) under the proposed brand name RELVAR™ ELLIPTA™ for;



**Asthma:** the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate:

 patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists

**COPD**: the symptomatic treatment of adults with Chronic Obstructive Pulmonary Disease (COPD) with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy

## GSK signs a multi-year agreement with BARDA to supply the US government with anthrax treatment (LSE announcement 19 September 2013)

GlaxoSmithKline (GSK) plc today announced a new four year contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the US Department of Health and Human Services (HHS), for the provision of its inhalation anthrax treatment, raxibacumab. The US government is purchasing the medicine as a counter measure against a potential bioterrorist attack

## GSK receives Priority Review from FDA for dabrafenib/trametinib combination in metastatic melanoma (LSE announcement 16 September 2013)

GlaxoSmithKline plc (LSE:GSK) today announced that the US Food and Drug Administration (FDA) has granted Priority Review designation to its supplemental New Drug Applications (sNDAs) for combined use of Tafinlar® (dabrafenib) and Mekinist® (trametinib) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 E or K mutation.

# FDA grants GSK and Genmab's Arzerra® (ofatumumab) Breakthrough Therapy designation for previously untreated chronic lymphocytic leukaemia (LSE announcement 13 September 2013)

GlaxoSmithKline plc (LSE:GSK) and Genmab A/S (OMX: GEN) announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for Arzerra® (ofatumumab) in combination with chlorambucil for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior treatment and are inappropriate for fludarabine-based therapy. Ofatumumab is not approved or licensed anywhere in the world for use in this treatment setting. Breakthrough Therapy Designation is the newest of the FDA's programs aimed at accelerating the development and review times of drugs for serious or life-threatening conditions.

### GSK statement in response to patent ruling reversal on Lovaza (LSE announcement 13 September 2013)

GlaxoSmithKline confirmed today that the Court of Appeals for the Federal Circuit has ruled against Pronova Biopharma Norge AS in its patent litigation regarding Lovaza® (omega-3-acid ethyl esters). Reversing a lower court ruling, the Appellate court found the asserted claims of Pronova's U.S. 5,656,667 patent invalid and remanded the case to the district court with orders to enter judgment in favour of the Appellant ANDA filers. Because the only other patent in the litigation, U.S. 5,502,077, had expired earlier this year, the court found it unnecessary to reach any issues regarding that patent.



# FDA Advisory Committee recommends approval in US of umeclidinium/vilanterol for the treatment of COPD (LSE announcement 10 September 2013)

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Pulmonary-Allergy Drugs Advisory Committee (PADAC) to the US Food and Drug Administration (FDA) voted 11 yes to 2 no that the efficacy and safety data provide substantial evidence to support approval of umeclidinium/vilanterol (UMEC/VI, 62.5/25mcg dose) for the long-term, once-daily, maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

### The investigational MAGE-A3 antigen-specific cancer immunotherapeutic does not meet first coprimary endpoint in Phase III melanoma clinical trial

- In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the DERMA trial until the second co-primary endpoint is assessed (LSE announcement 5 September 2013)

GlaxoSmithKline plc (LSE:GSK) today announced that an independent analysis of the DERMAi study, a Phase III randomised, blinded, placebo-controlled trial of the MAGE-A3 cancer immunotherapeutic, ii showed that the study did not meet its first co-primary endpoint as it did not significantly extend disease-free survival (DFSiii) when compared to placebo in the MAGE-A3 positive population.

# GSK receives marketing authorisation from the European Commission for Tafinlar™ (dabrafenib), an oral treatment for unresectable or metastatic melanoma in adult patients with a BRAF V600 mutation (LSE announcement 2 September 2013)

GlaxoSmithKline plc announced today that the European Commission has granted marketing authorisation for Tafinlar™ (dabrafenib) as an oral targeted treatment indicated in monotherapy for unresectable melanoma (melanoma that cannot be removed by surgery) or metastatic melanoma (melanoma which has spread to other parts of the body) in adult patients with a BRAF V600 mutation.1 Dabrafenib is not indicated for the treatment of patients with wild-type BRAF melanoma. Before taking dabrafenib, patients must have confirmation of a BRAF V600 mutation using a validated test.

## GSK announces phase III study of vercirnon in patients with moderate-to-severe Crohn's disease did not meet its primary endpoint (LSE announcement 23 August 2013)

GlaxoSmithKline (GSK) announced today that the first of four Phase III studies, the SHIELD-1 study, investigating vercirnon - an investigational CCR9 antagonist - in adult patients with moderately-to-severely active Crohn's disease did not achieve the primary endpoint of improvement in clinical response and the key secondary endpoint of clinical remission.

### Additional GlaxoSmithKline quadrivalent intramuscular influenza vaccine approved by FDA

GlaxoSmithKline plc [LSE/NYSE: GSK] announced today that the U.S. Food and Drug Administration (FDA) has approved FLULAVAL® QUADRIVALENT (Influenza Virus Vaccine) for the active immunization of persons three years of age and older to help prevent disease caused by seasonal influenza (flu) virus subtypes A and B contained in the vaccine. This is the second GSK intramuscular quadrivalent influenza vaccine approved by the FDA. GSK's Fluarix Quadrivalent was the first-ever intramuscular influenza vaccine approved by the FDA in December 2012, and is now shipping to customers.



# GSK receives marketing authorisation from the European Commission for additional indication: Tyverb™ (lapatinib) in combination with trastuzumab for patients with HER2-positive, HR-negative metastatic breast cancer (LSE announcement 14 August 2013)

GlaxoSmithKline announced today that the European Commission has granted an additional indication for Tyverb™ (lapatinib) to be used in combination with trastuzumab. This combination is indicated for adult patients with breast cancer whose tumours overexpress HER2 (ErbB2), with hormone receptor-negative (HR-) metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.

# ViiV Healthcare announces U.S. approval of Tivicay® (dolutegravir) for the treatment of HIV-1 (LSE announcement 12 August 2013)

ViiV Healthcare is pleased to announce today that the U.S. Food and Drug Administration (FDA) has approved Tivicay® (dolutegravir) 50-mg tablets. Tivicay is an integrase inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 in adults and children aged 12 years and older weighing at least 40 kg (approx. 88 lbs).

# Regulatory update – GSK announces EU submission for Cervarix® two dose schedule (LSE announcement 7 August 2013)

GlaxoSmithKline (GSK) plc today announced the submission of a regulatory application in the European Union for a two dosing schedule in 9-14 year old girls for its cervical cancer vaccine, Cervarix <sup>®</sup> [Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant].

# Regulatory Update - GSK announces EU submission seeking additional indication for Votrient® as maintenance therapy for advanced ovarian cancer (LSE announcement 6 August 2013)

GlaxoSmithKline (GSK) plc today announced submission to the European Medicines Agency of a variation to the Marketing Authorisation for Votrient® (pazopanib), adding the additional indication for the maintenance treatment of women with Stage II-IV ovarian, fallopian tube or primary peritoneal cancer who have not progressed after receiving first-line chemotherapy.

# Regulatory update: albiglutide US PDUFA date extended by three months (LSE announcement 2 August 2013)

GlaxoSmithKline plc (LSE:GSK) today announced that the US Prescription Drug User Fee Act (PDUFA) goal date for albiglutide, an investigational once-weekly treatment for adult patients with type 2 diabetes, has been extended by three months to 15 April 2014 to provide time for a full review of information submitted by GSK in response to the Food and Drug Administration's requests

# GSK receives positive CHMP opinion for REVOLADE in thrombocytopenia associated with chronic hepatitis C infection (LSE announcement 26 July 2013)

Today, GlaxoSmithKline plc (GSK) announced a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorisation for REVOLADETM (eltrombopag) as a treatment for low platelet counts (thrombocytopenia) in adult patients with chronic hepatitis C infection, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.



### Regulatory update: fluticasone furoate/vilanterol submission in Japan (LSE announcement 12 July 2013)

GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the licence application for the use of fluticasone furoate (FF) and vilanterol (VI) (proposed brand name RELVARTM ELLIPTATM) in patients with chronic obstructive pulmonary disease (COPD) has been withdrawn from the current Japanese New Drug Application (JNDA). The review of FF/VI for use in patients with asthma is continuing to progress through the normal Japanese regulatory process as part of this JNDA.

# Regulatory update: GSK announces US submission for dabrafenib/trametinib combination in metastatic melanoma (LSE announcement 9 July 2013)

GlaxoSmithKline (GSK) plc today announced submission of supplemental New Drug Applications (NDAs) to the US Food and Drug Administration for use of dabrafenib, a BRAF inhibitor, in combination with trametinib, a MEK inhibitor. Supplemental applications were submitted to each of the currently approved NDAs for the use of each drug in combination with the other, for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 E or K mutation.



### Revision of IAS 19 'Employee benefits' (LSE announcement 6 February 2013)

IAS 19 (Revised) was implemented by GSK from 1 January 2013. The main effect is that the expected returns on pension scheme assets are no longer recognised in the income statement, expected returns have been replaced by income calculated using the same discount rate as that used to measure the pension obligations. This discount rate is based on market rates for high quality corporate bonds. As a consequence, pension scheme costs are higher under IAS 19 (Revised). For 2013 reporting, the results for 2012 have been restated retrospectively, and the effect of the change, on 2012 results, has been to reduce core operating profit for the year by approximately £92 million and core EPS by approximately 1.3p. It is estimated that core operating profit in 2013 will be reduced by approximately £160 million and core EPS by approximately 2.5p by the change.

In conjunction with our 2012 full year results announcement we issued an LSE announcement outlining the changes:

http://www.gsk.com/content/dam/gsk/globals/documents/pdf/Investors/quarterly-results/2012/Amended-Accounting-Standard-on-Employee-Benefits.pdf

£m	2011	Q1'12	Q2'12	Q3'12	Q4'12	2012	Q1'13	Q2′13
Group Turnover	27,387	6,640	6,462	6,527	6,802	26,431	6,471	6,618
COGS	(7,284)	(1,719)	(1,698)	(1,855)	(1,837)	(7,109)	(1,847)	(1,818)
as a % of sales	26.6%	25.9%	26.3%	28.4%	27.0%	26.9%	28.5%	27.5%
Gross profit	20,103	4,921	4,764	4,672	4,965	19,322	4,624	4,800
Gross margin	73.4%	74.1%	73.7%	71.6%	73.0%	73.1%	71.5%	72.5%
SG&A	(7,993)	(2,050)	(1,969)	(1,946)	(1,940)	(7,905)	(1,955)	(2,092)
as a % of sales	29.2%	30.9%	30.5%	29.8%	28.5%	29.9%	30.2%	31.6%
R&D	(3,689)	(895)	(882)	(871)	(837)	(3,485)	(857)	(847)
as a % of sales	13.5%	13.5%	13.6%	13.3%	12.3%	13.2%	13.2%	12.8%
Royalties	309	72	66	92	76	306	113	82
as a % of sales	-1.1%	-1.1%	-1.0%	-1.4%	-1.1%	-1.2%	-1.6%	-1.3%
Operating profit	8,730	2,048	1,979	1,947	2,264	8,238	1,925	1,943
Margin	31.9%	30.8%	30.6%	29.8%	33.3%	31.2%	29.7%	29.4%
NFI	(707)	(168)	(184)	(178)	(194)	(724)	(176)	(183)
Associates	15	10	0	9	10	29	11	7
Pre-tax profit	8,038	1,890	1,795	1,778	2,080	7,543	1,760	1,767
Tax	(2,084)	(489)	(457)	(431)	(461)	(1,838)	(394)	(424)
Tax rate	25.9%	25.9%	25.5%	24.2%	22.2%	24.4%	22.4%	24.0%
Profit after tax	5,954	1,401	1,338	1,347	1,619	5,705	1,366	1,343
Minorities	(197)	(65)	(48)	(64)	(58)	(235)	(68)	(64)
Attributable profit	5,757	1,336	1,290	1,283	1,561	5,470	1,298	1,279
WANS (m)	5,028	4,963	4,945	4,897	4,843	4,912	4,834	4,855
Core EPS (p)	114.5	26.9	26.1	26.2	32.2	111.4	26.9	26.3
DPS (p)	70.0	17.0	17.0	18.0	22.0	74.0	18.0	18.0



### \* CER growth

In order to illustrate underlying performance, it is the Group's practice to discuss its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Sterling had remained unchanged from those used in the comparative period. All commentaries are presented in terms of CER growth, unless otherwise stated.

Analyst/Investor enquiries: Ziba Shamsi + 44 (0) 20 8047 3289 (London)

Tom Curry + 1 215 751 5419 (Philadelphia)

Gary Davies + 44 (0) 20 8047 5503 (London)

James Dodwell + 44 (0) 20 8047 2406 (London)

Jeff McLaughlin + 1 215 751 7002 (Philadelphia)

Lucy Singah +44 (0) 20 8047 2248 (London)

### Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this document, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.