GLAXOSMITHKLINE PLC
Form 6-K
April 02, 2012

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending April 2012

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the
Securities Exchange Act of 1934.

Yes No x

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Issued: 2 April 2012 London UK

Phase lll study of dolutegravir in HIV announced

GlaxoSmithKline plc (GSK) today announced that Shionogi-ViiV Healthcare LLC, a joint venture between ViiV Healthcare Ltd (a global specialist HIV company established by GlaxoSmithKline and Pfizer, Inc.) and Shionogi & Co., Ltd, is issuing the following statement today:

Shionogi-ViiV Healthcare Announces Initial Data from Pivotal Phase III Study of Dolutegravir in HIV

SPRING-2 study meets primary endpoint of non-inferiority of dolutegravir compared to raltegravir over 48 weeks in treatment-naïve HIV patients

London, United Kingdom, 2 April 2012 ViiV Healthcare and Shionogi & Co., Ltd. today announced that initial results have been received from the SPRING-2 (ING113086) Phase III study of the investigational integrase inhibitor dolutegravir in treatment-naïve adults with HIV-1. The study met its primary objective, demonstrating non-inferiority of dolutegravir to raltegravir. Through 48 weeks, 88% of study participants on dolutegravir were virologically suppressed (<50 copies/mL) vs. 85% of participants on raltegravir [with a 95% confidence interval (CI) for the difference, -2.2% to + 7.1%; the lower end of the CI (-2.2%) was above the prespecified -10% non-inferiority limit].

SPRING-2 is an ongoing non-inferiority study designed to compare the efficacy and safety of dolutegravir 50mg administered once-daily versus raltegravir 400mg administered twice daily, both with two nucleoside reverse transcriptase inhibitors(NRTIs); 411 treatment-naïve study participants were randomised in each arm. The primary endpoint of the study was the proportion of study participants with undetectable HIV-1 RNA (<50c/mL) through 48 weeks. The tolerability of dolutegravir was similar to that of raltegravir, with rates of adverse events leading to withdrawal at 2% in both arms. Drug-related nausea was reported by 10% of patients in each arm; no other adverse events related to study medication were reported by more than 5% of participants in either arm.

"The SPRING-2 findings indicate that once daily unboosted dolutegravir may offer people living with HIV an additional treatment option in the future. These are the first large-scale safety and efficacy data in naïve patients, and we look forward to seeing further data in 2012 to build a more comprehensive picture of the role of dolutegravir" said Dr John Pottage, Chief Medical Officer, ViiV Healthcare.

"At ViiV Healthcare we have a total focus on the needs of people living with HIV, and as a result we see the continued need for new, effective and convenient therapies. We are committed to building connections and collaborations, like the Shionogi-ViiV Healthcare dolutegravir programme, to meet these needs." said Dr. Dominique Limet, Chief Executive Officer, ViiV Healthcare.

"The SPRING-2 study has met its primary endpoint for dolutegravir in treatment-naïve patients. This marks an important milestone for the development of dolutegravir and the Shionogi-ViiV Healthcare joint venture. We look forward to completing further Phase III studies in a variety of clinical settings in order to fully understand the potential clinical benefit for a range of HIV patient populations" said Dr. Tsutae "Den" Nagata, Chief Medical Officer, Shionogi & Co., Ltd.

Full results of this study, including the full results of the secondary endpoints, will be presented at an upcoming scientific meeting. SPRING-2 is the first of four Phase III studies that are due to be reported in 2012. Data from the clinical trials SINGLE (ING114467), VIKING-3 (ING112574) and SAILING (ING111762), will be received throughout the year and will allow further determination of the profile of dolutegravir. These studies are designed to support a future regulatory file for dolutegravir.

V A Whyte
Company Secretary

2 April 2012

About SPRING-2

SPRING-2 (ING113086) is a Phase III, randomized, double-blind, multicentre, parallel group, non-inferiority study. The study included 822 HIV-1 infected treatment-naïve participants. The study compares the efficacy and safety of dolutegravir and raltegravir as part of an overall treatment regimen; both treatment arms are administered with investigator-selected dual nucleoside reverse transcriptase inhibitor therapy (either abacavir + lamivudine or tenofovir + emtricitabine).

The primary objective for SPRING-2 is to demonstrate the antiviral activity of dolutegravir 50mg administered once-daily compared to raltegravir 400mg administered twice daily over 48-weeks. Secondary objectives include the assessment of antiviral activity of dolutegravir compared to raltegravir at 96-weeks, to compare the tolerability, long-term safety and antiviral and immunologic activity of dolutegravir to raltegravir and to evaluate viral resistance in study participants experiencing virological failure.

About Dolutegravir
S/GSK1349572 (dolutegravir) is an investigational integrase inhibitor (INI) currently in development by Shionogi-ViiV Healthcare LLC for the treatment of HIV. It is currently the only once-daily, unboosted INI in Phase III clinical development. Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Given the stage of development of this investigational HIV therapy, the full picture of the efficacy and safety of dolutegravir has not been conclusively determined.

About Shionogi-ViiV Healthcare LLC
The Shionogi-ViiV Healthcare LLC is a joint venture between Shionogi & Co., Ltd. and ViiV Healthcare Ltd., a global company with a sole focus on HIV established in 2009 by GlaxoSmithKline and Pfizer, Inc. Dolutegravir is the lead compound in the Shionogi-ViiV Healthcare LLC partnership. Shionogi-ViiV Healthcare LLC is also developing another integrase inhibitor which is at an earlier stage of development.

About Shionogi & Co., Ltd
Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company is the originator of innovative medicines which have been successfully delivered to millions of patients worldwide. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp. For more information on Shionogi Inc. headquartered in Florham Park, NJ, please visit www.shionogi.com.

About ViiV Healthcare
ViiV Healthcare Ltd. is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV. The company's aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and take a new approach to deliver effective and new HIV medicines as well as support communities affected by HIV. For more

information on the company, its management, portfolio, pipeline and commitment, please visit www.viivhealthcare.com.

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Cautionary statement regarding forward-looking statements
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, 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 'Risk factors' in the 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

Pfizer disclosure notice: Pfizer assumes no obligation to update any forward-looking statements contained in this release as a result of new information or future events or developments. This release contains forward-looking information about Pfizer, GlaxoSmithKline and ViiV Healthcare and about the prospects of the companies, including revenues from in-line products and the potential benefits of product candidates that will be contributed to that company, as well as the potential financial impact of the transaction. Such information involves substantial risks and uncertainties including, among other things, decisions by regulatory authorities regarding whether and when to approve any drug applications that have been or may be filed for such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report of Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

Shionogi forward-looking statement: This announcementcontains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise. Thisannouncement contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.

Registered in England & Wales:
No. 3888792

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TW8 9GS

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: April 2, 2012

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc