

GLAXOSMITHKLINE PLC  
Form 6-K  
October 04, 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 October 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  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

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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 completion of initial clinical registration package for dolutegravir in HIV

London, United Kingdom, 4 October 2012: Shionogi-ViiV Healthcare LLC today announced that the phase III data required for initial regulatory filings of the investigational integrase inhibitor dolutegravir in adults infected with HIV are in house. Data from the two phase III studies in treatment-experienced patients (VIKING-3 and SAILING) have been received and will be the subject of future presentations at scientific meetings. Together with previously disclosed data from the SPRING-2 and SINGLE studies in treatment-naïve patients, these additional study data support Shionogi-ViiV Healthcare's plans to commence global regulatory submissions for dolutegravir before the end of 2012. Dolutegravir is not yet approved as a treatment for HIV or any other indication anywhere in the world.

About the VIKING-3 and SAILING studies in treatment-experienced adults with HIV-1 VIKING-3 (ING112574) is an ongoing Phase III, multicentre, open-label, single arm study to assess the antiviral activity and safety of dolutegravir 50mg twice-daily in treatment-experienced adults with HIV-1 and historical or current evidence of resistance to raltegravir or elvitegravir.

SAILING (ING111762) is an ongoing Phase III, multicentre, double blind, double dummy study to compare the efficacy and safety of dolutegravir 50mg once-daily to raltegravir 400mg twice-daily in treatment-experienced, integrase inhibitor-naïve adults with HIV-1.

The full results of these studies will be presented at upcoming scientific meetings.

About the SPRING-2 and SINGLE studies in treatment-naïve adults with HIV-1 SPRING-2 (ING113086) is an ongoing Phase III, multicentre, double blind, double dummy study to compare the efficacy and safety of dolutegravir 50mg once-daily to raltegravir 400mg twice-daily in treatment-naïve adults with HIV-1. Full 48-week data from SPRING-2 were presented at the International AIDS Conference in July 2012. SINGLE (ING114467) is an ongoing Phase III, multicentre, double blind, double dummy study to compare the efficacy and safety of once-daily dolutegravir 50mg plus abacavir/lamivudine versus Atripla (tenofovir/emtricitabine/efavirenz). Full 48-week data from SINGLE were presented at ICAAC in September 2012. Together with data from an ongoing bioequivalence study (ING114580), SINGLE is designed to support additional regulatory submissions for a fixed dose combination of dolutegravir/abacavir/lamivudine.

V A Whyte  
Company Secretary  
04 October 2012

About Dolutegravir

S/GSK1349572 (dolutegravir) is an investigational integrase inhibitor (INI) currently in development by Shionogi-ViiV Healthcare LLC for the treatment of HIV for use in combination with other HIV medicines. Dolutegravir is being evaluated for safety and efficacy without an additional 'booster' drug being added to the regimen. 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

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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](http://www.shionogi.co.jp). For more information on Shionogi Inc. headquartered in Florham Park, NJ, please visit [www.shionogi.com](http://www.shionogi.com).

### About ViiV Healthcare

ViiV Healthcare 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](http://www.viivhealthcare.com).

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Shionogi forward-looking statement: This announcement contains 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.

This announcement 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.

#### GlaxoSmithKline 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.

#### 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: October 04, 2012

By: VICTORIA WHYTE  
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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc