GLAXOSMITHKLINE PLC
Form 6-K
July 11, 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 July 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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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 positive initial data from phase III study of dolutegravir-based regimen vs Atripla in HIV

London, United Kingdom, 11 July 2012: Shionogi-ViiV Healthcare LLC today announced that initial results have been received from the Phase III SINGLE (ING114467) study of the investigational integrase inhibitor dolutegravir in treatment-naïve adults with HIV-1. The study demonstrated superiority of the dolutegravir-based regimen compared to the single tablet regimen Atripla®. At 48 weeks, 88% of study participants on the dolutegravir regimen were virologically suppressed (<50 copies/mL) vs. 81% of participants on the single tablet regimen Atripla [difference and 95% CI; 7.4% (+2.5% to +12.3%); difference in the primary endpoint was statistically significant, p=0.003]. Differences in efficacy were primarily driven by a higher rate of discontinuation due to adverse events on the Atripla arm. The SINGLE study was designed to demonstrate non-inferiority of the dolutegravir-based regimen versus Atripla, and the primary analysis met this criterion. Statistical superiority was concluded as part of a subsequent, pre-specified testing procedure.

SINGLE is an ongoing double blind, double dummy study designed to compare the efficacy and safety of two antiretroviral regimens: dolutegravir 50mg plus abacavir/lamivudine (Kivexa®/Epzicom®) versus Atripla® tenofovir/emtricitabine/efavirenz). The primary endpoint was the proportion of study participants with undetectable HIV-1 RNA (<50c/mL) at 48 weeks; 414 treatment-naïve study participants were randomised and exposed to the dolutegravir-based regimen and 419 to the Atripla arm. Overall, 2% of subjects on the dolutegravir-based regimen discontinued due to adverse events vs. 10% of those receiving the Atripla regimen. The most common drug related adverse events on Atripla were in the nervous system System Organ Class (reported by 41% of Atripla recipients, vs. 15% of participants receiving the dolutegravir-based regimen), while the most common drug related adverse events on the dolutegravir-based regimen were in the gastrointestinal system organ class (reported by 22% of subjects receiving the dolutegravir-based regimen and 22% of subjects receiving Atripla).

"Taken together with the results of the SPRING-2 trial, the SINGLE findings suggest that, if approved by regulators, a treatment regimen containing dolutegravir may offer people living with HIV an important additional first line option in the future" said Dr. Tsutae "Den" Nagata, Chief Medical Officer, Shionogi & Co., Ltd.

"This study represents an important milestone in the development of dolutegravir-based regimens, including a single-tablet regimen, and also for the Shionogi-ViiV Healthcare joint venture. We look forward to receiving further safety and efficacy data from two Phase III studies in treatment experienced patients to continue to build a comprehensive picture of the role of dolutegravir in the treatment of HIV" said Dr John Pottage, Chief Medical Officer, ViiV Healthcare.

Full results of this study, including key secondary endpoints, will be presented at upcoming scientific meetings. SINGLE is the second of four Phase III studies that are due to be reported in 2012. Data from the clinical trial SPRING-2 (ING113086) were announced in April 2012. Data from VIKING-3 (ING112574) and SAILING (ING111762) in treatment-experienced patients will be received later this year and will allow further characterization of the profile of dolutegravir. These studies are designed to support a future regulatory filing for dolutegravir.

V A Whyte
Company Secretary
11 July 2012

About SINGLE (ING114467)
SINGLE is an ongoing phase III, randomised, multi-centre, multinational, double-blind, double dummy study designed to compare the efficacy and safety of dolutegravir plus abacavir/lamivudine compared to Atripla® in treatment-naïve patients. The primary objective for SINGLE is to demonstrate the antiviral activity of dolutegravir plus abacavir/lamivudine once-daily therapy compared to Atripla over 48 weeks. As per study design, trial participants will continue on blinded therapy in order to assess the tolerability, long-term safety, and antiviral and immunologic activity of dolutegravir plus abacavir/lamivudine once-daily compared to Atripla over 96 weeks. Investigators will also evaluate viral resistance in patients experiencing virologic 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. Dolutegravir does not require an additional 'booster' drug be 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
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 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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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: July 11, 2012

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc