GLAXOSMITHKLINE PLC
Form 6-K
February 15, 2013

FORM 6-K/A

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 February 2013

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: Friday 15 February 2013, London UK - LSE Announcement

ViiV Healthcare announces FDA priority review designation for dolutegravir as a potential treatment for HIV infection

ViiV Healthcare today announced that the U.S. Food and Drug Administration (FDA) has granted a priority review designation to dolutegravir submitted for the treatment of HIV infection, in combination with other antiretroviral agents, in adults and adolescents. A priority review designation is granted to drugs that, if approved, have the potential to offer significant improvement compared to marketed products or provide a treatment where no adequate therapy exists. The FDA has assigned dolutegravir a Prescription Drug User Fee Act (PDUFA) target date of 17 August 2013.

The new drug application (NDA) for dolutegravir was received by the FDA on 17 December 2012, and includes the results of four pivotal phase III clinical trials that treated a total of 2553 patients with HIV/AIDS across the treatment spectrum, from therapy naïve to salvage patients. Dolutegravir is in development and subject to evaluation of the benefits and risks by the regulatory authorities before it can be approved and made available on prescription.

ViiV Healthcare submitted a Marketing Authorisation Application (MAA) for dolutegravir to the European Medicines Agency (EMA) on 17 December 2012.

V A Whyte

Company Secretary

15 February 2013

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. Shionogi joined as a 10% shareholder in October 2012. 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 labelling 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: February 15, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc