GLAXOSMITHKLINE PLC
Form 6-K
March 07, 2013

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 March 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

Yes No x
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ViiV Healthcare presents data from Phase III study of dolutegravir vs raltegravir in treatment-experienced adults with HIV-1

· ViiV Healthcare presents 24-week interim results from Phase III SAILING study at the 20th Conference on Retroviruses and Opportunistic Infections (CROI)

Issued: London, United Kingdom - 6 March 2013 - LSE Announcement

ViiV Healthcare today announced 24-week data from the Phase III SAILING (ING111762) study evaluating the investigational integrase inhibitor dolutegravir in patients with HIV-1 who are failing on current therapy, but had not been treated with an integrase inhibitor. At 24 weeks, 79% of study participants receiving the once-daily dolutegravir regimen were virologically suppressed (HIV-1 RNA <50 c/mL) vs. 70% of participants on the twice-daily raltegravir regimen. This difference in response was statistically significant with a 95% confidence interval for the difference of 3.4% to 15.9% (p=0.003). The SAILING study was designed to demonstrate non-inferiority of a regimen containing dolutegravir versus raltegravir (both with up to two background agents) and the analysis met this criterion; statistical superiority was concluded as part of a pre-specified testing procedure. These data were presented at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta, Georgia.

Differences in treatment outcome in favour of the dolutegravir arm were driven by greater virologic response: at Week 24, 15% of patients receiving the dolutegravir regimen had virologic non-response vs. 24% of patients receiving the raltegravir regimen. In addition, fewer subjects failed therapy with integrase inhibitor resistance on dolutegravir (n=2) than on raltegravir (n=10, p=0.016).

Overall, the tolerability of dolutegravir (DTG) was similar to that of raltegravir (RAL). At 24 weeks, 2% of subjects on the dolutegravir regimen discontinued due to adverse events (AEs) vs. 4% of subjects on the raltegravir regimen. The rate of drug-related AEs was similar for both arms (DTG 20%, RAL 23%) and commonly reported AEs (defined as events that occurred in more than 10% of subjects) were similar on both arms, namely diarrhoea (20% DTG, 17% RAL) and upper respiratory tract infection (11% DTG, 8% RAL).

"People living with HIV who have developed resistance to more than one antiretroviral drug class face increasingly narrow treatment options and clinical decisions become increasingly complex. We welcome these initial results supporting the efficacy and tolerability of dolutegravir as a potentially useful addition in the management of HIV in treatment-experienced patients." said John Pottage, MD, Chief Scientific and Medical Officer, ViiV Healthcare. "These encouraging data were included as part of the comprehensive clinical data package supporting recent regulatory submissions for dolutegravir and we look forward to receiving the primary analysis at 48 weeks in due course."

V A Whyte
Company Secretary
6 March 2013

About the SAILING study
The primary objective of the ongoing double-blind, double-dummy phase III SAILING study is to demonstrate the antiviral activity of once-daily dolutegravir 50mg compared to twice-daily raltegravir 400mg over 48 weeks in HIV-1 infected, antiretroviral-experienced, integrase inhibitor-naïve adults. At baseline, 715 study participants were randomised 1:1 to receive either dolutegravir or raltegravir plus investigator-selected background regimen of no more

than 2 agents, one of which was fully active. All subjects had documented genotypic or phenotypic resistance to agents from at least two antiretroviral therapy drug classes, and ongoing virologic replication. Median baseline HIV-1 RNA levels were 4.18 log10 c/mL and median baseline CD4+ cell counts were 200 cells/mm3. The study population included 32% women, 42% were of African American/African heritage, and 46% of study participants were classified as CDC Class C (patients who have one or more AIDS-defining illness).The 48-week primary analysis of this study will be presented at a future scientific meeting.

About Dolutegravir and the Dolutegravir Clinical Trial Programme
S/GSK1349572 (dolutegravir, DTG) is an investigational integrase inhibitor currently in development for the treatment of HIV; it does not require an additional pharmacokinetic boosting drug to 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.

SAILING is the fourth Phase III dolutegravir study reporting in 2012 and 2013. Data from the two studies in treatment-naïve populations, SPRING-2 (ING113086) and SINGLE (ING114467), were announced in April and July of 2012 respectively. Data from VIKING-3 (ING112574) in integrase inhibitor-resistant patients were announced in November 2012. Dolutegravir is not yet approved as a treatment for HIV or any other indication anywhere in the world.

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 kind.

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: March 07, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on

behalf of GlaxoSmithKline plc