GLAXOSMITHKLINE PLC
Form 6-K
October 25, 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 October 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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GlaxoSmithKline plc (LSE:GSK) today announced that ViiV Healthcare Ltd (a global specialist HIV company with GlaxoSmithKline, Pfizer, Inc. and Shionogi Limited as shareholders) is issuing the following statement today:

PRESS RELEASE

For Immediate Release

ViiV Healthcare announces European regulatory submission for a single-tablet regimen combining dolutegravir with abacavir and lamivudine for people living with HIV

London, UK - 25 October 2013: ViiV Healthcare today announced the submission of a regulatory application in Europe for its investigational single-tablet regimen (STR) combining dolutegravir (DTG), abacavir (ABC) and lamivudine (3TC) for the treatment of people living with HIV. This Marketing Authorisation Application (MAA) follows the announcement earlier this week of a similar regulatory submission in the US1.

"People living with HIV and their doctors seek to use appropriate treatment options for the individual, while also trying to minimise the number of pills required for effective and acceptable antiretroviral treatment," said Dr John Pottage, Chief Medical Officer, ViiV Healthcare. "This submission, together with the New Drug Application submitted recently to the US Food and Drug Administration, aims to make a complete dolutegravir-based regimen available for the first time in a single once-daily pill."

Dolutegravir was approved by the US Food and Drug Administration in August 2013 under the brand name Tivicay® for use in combination with other antiretroviral agents for the treatment of HIV-1 in adults and children aged 12 years and older weighing at least 40 kg (approx. 88 lbs). The review of the MAA for dolutegravir (DTG), submitted in Europe in December 2012, is in progress with the European Medicines Agency (EMA). A fixed-dose combination of ABC/3TC for use in antiretroviral combination therapy is marketed by ViiV Healthcare in Europe under the brand name Kivexa®as a once-daily tablet. The investigational STR combining DTG/ABC/3TC has sometimes been referred to as "Trii".

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.

References

1 ViiV Healthcare announces US regulatory submission for a single-tablet regimen combining dolutegravir with abacavir and lamivudine for people living with HIV.
Press Release, 23 October 2013. Available at:
https://www.viivhealthcare.com/media/press-releases/2013/october/viiv-healthcare-announces-us-regulatory-submission-for-a-

US Prescribing information for Tivicay is available online at:

https://www.viivhealthcare.com/media/58599/us_tivicay.pdf

Please refer to country-specific Kivexa prescribing information.

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Cautionary statement regarding forward-looking statements

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 Item 3.D 'Risk factors' in GSK's Annual Report on Form 20-F for 2012.

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 25, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc