GLAXOSMITHKLINE PLC
Form 6-K
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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 January 2014

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:

ViiV Healthcare's new HIV medicine TivicayTM (dolutegravir) is approved in Europe

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London, UK, 21 January 2014- ViiV Healthcare today announced that the European Commission has approved TivicayTM (dolutegravir), an integrase inhibitor, for use in combination with other anti-retroviral medicinal products for the treatment of HIV infected adults and adolescents above 12 years of age.

The Tivicay clinical development programme was comprehensive in its breadth, including people living with HIV who were new to treatment (naive), as well as those who had already been treated with other HIV medicines (experienced) and those who were infected with a virus that had developed resistance to previously available integrase inhibitors. The submission supporting today's approval included data from four pivotal Phase III clinical trials in which 2,557 adults received treatment with Tivicay or a comparator1-4. The submission also included data from a fifth study in children aged 12 years and older5.

"Today's approval of Tivicay is an important advance, opening the door to new treatment combinations for people living with HIV in Europe. Tivicay's clinical development programme was only possible through partnerships with the people living with HIV and healthcare professionals who participated in it, and we aim to move forward together with them based on an absolute commitment to the HIV/AIDS global response," said Dr Dominique Limet, Chief Executive Officer, ViiV Healthcare.

Today's approval of Tivicay is the European regulatory authorisation to market the medicine in each member state of the European Union. Tivicay will become available in each country as pricing and reimbursement processes are completed, with availability in some of the first countries anticipated in the immediate future.

The efficacy of Tivicay - as a 'third agent' - was statistically superior to its comparator in two pivotal Phase III studies1,2 and non-inferior in a third comparator study3. In clinical trials1-4, Tivicay had low rates of discontinuation due to adverse events (1-3%) in both treatment-naive and treatment-experienced patients.

"HIV treatment is not a question of 'one-size fits all' - especially now that treatment is something that patients will live with for many years," said Dr John Pottage, Chief Medical Officer, ViiV Healthcare. "We continue to find measurable clinical differences among the treatments now available for use in combination therapy to combat HIV. Using the clinical data for Tivicay, doctors and people living with HIV can fully consider the effectiveness against the virus and the side effect profile that Tivicay may bring."

The safety profile is based on pooled data from Phase IIb and Phase III clinical studies in 980 previously untreated patients, 357 previously treated patients unexposed to integrase inhibitors and 234 patients with prior treatment failure that included an integrase inhibitor (including integrase class resistance). The most commonly seen treatment emergent adverse reactions were nausea (15%), diarrhoea (16%) and headache (14%). The most severe adverse reaction, seen in an individual patient, was a hypersensitivity reaction that included rash and severe liver effects.

Tivicay inhibits an enzyme used by the HIV virus during its replication cycle, known as integrase. By binding to the site where integrase acts, it blocks the "strand transfer" step of the HIV replication process - stopping the viral DNA from forming a new virus. The recommended dose of Tivicay for most patients is one 50 mg tablet once daily. For

patients with documented or clinically suspected resistance to the integrase class, or when co-administered with certain medicines, the recommended dose of Tivicay is 50 mg twice daily. Please refer to the full European Summary of Product Characteristics for full prescribing information, including contraindications, special warnings and precautions for use6.

Important Safety Information for Tivicay in the European Union:

The decision to use dolutegravir in the presence of integrase class resistance should take into account that the activity of dolutegravir is considerably compromised for viral strains harbouring Q148 plus two or more secondary mutations from G140A/C/S, E138A/K/T, L74I. To what extent dolutegravir provides added efficacy in the presence of such integrase class resistance is uncertain.

Co-administration of dolutegravir with dofetilide is contraindicated.

Hypersensitivity reactions have been reported with dolutegravir, and were characterised by rash, constitutional findings, and sometimes, organ dysfunction, including severe liver reactions. Dolutegravir and other suspect agents should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop.

In HIV-infected patients with severe immune deficiency at the time of institution of combination antiretroviral therapy (CART), an inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Typically, such reactions have been observed within the first few weeks or months of initiation of CART.

Liver biochemistry elevations consistent with immune reconstitution syndrome were observed in some hepatitis B and/or C co-infected patients at the start of dolutegravir therapy.

Patients should be advised that dolutegravir or any other antiretroviral therapy does not cure HIV infection and that they may still develop opportunistic infections and other complications of HIV infection.

Factors that decrease dolutegravir exposure should be avoided in the presence of integrase class resistance. This includes co-administration with medicinal products that reduce dolutegravir exposure. Also, metformin concentrations may be increased by dolutegravir.

Cases of osteonecrosis have been reported in patients with advanced HIV-disease and/or long-term exposure to CART. Patients should be advised to seek medical advice if they experience joint aches and pain, joint stiffness or difficulty in movement.

Please refer to the full European Summary of Product Characteristics for full prescribing information, including contraindications, special warnings and precautions for use6.

About the Phase III Clinical Trial Programme

SINGLE1was a study evaluating once-daily Tivicay plus abacavir/lamivudine versus the single tablet regimen Atripla®* in 833 HIV-infected, treatment-naive patients. Virologic suppression among patients treated with a regimen comprising Tivicay, abacavir (ABC) and lamivudine (3TC) was 88% (n=414), which was statistically superior to the result for those treated with efavirenz (EFV), tenofovir (TDF) and emtricitabine (FTC) (81% at week 48, n=419, p=0.003 - a difference driven primarily by treatment discontinuations due to adverse events). 2% of subjects on the Tivicay-based regimen discontinued due to adverse events versus 10% of those receiving the comparator (EFV/TDF/FTC - Atripla®*). For Tivicay, treatment-emergent adverse drug reactions of at least moderate intensity (Grades 2 to 4) and ≥2% frequency were insomnia (3%) and headache (2%), and for Atripla® were rash (6%),

dizziness (5%), nausea (3%), and insomnia, abnormal dreams, headache, diarrhoea, and vertigo (2%).

No treatment-emergent genotypic resistance that resulted in reduced susceptibility to either Tivicay or the background regimen was seen in the arm containing Tivicay in SINGLE at week 48.

SAILING2 was a study evaluating once-daily Tivicay versus twice-daily raltegravir in 719 patients with HIV who were failing on current therapy, but had not been treated with an integrase inhibitor, in each case in combination with an investigator-selected background regimen consisting of up to two agents, including at least one fully active agent. Virologic suppression among those treated with a combination containing Tivicay (71%, n=354) was statistically superior to the result for those treated with a combination containing raltegravir (64%, n=361), at week 48 (p=0.03). Overall, the tolerability of Tivicay was similar to that of raltegravir, with adverse events leading to withdrawal in 3% of patients on the Tivicay regimen versus 4% among those taking the raltegravir regimen. There were no treatment-emergent adverse drug reactions of at least moderate intensity (Grades 2 to 4) and ≥2% frequency in the arm containing Tivicay compared with diarrhoea in 2% of patients in the raltegravir arm.

Viruses from five of 15 subjects with post-baseline resistance data in the arm containing Tivicay had evidence of treatment-emergent genetic changes (integrase substitutions). However, none of these patients had decreases in susceptibility to either Tivicay or raltegravir.

SPRING-23 was a study evaluating once-daily Tivicay versus twice-daily raltegravir in 822 HIV-infected, treatment-naive patients, in each case in combination with a fixed-dose dual-NRTI treatment. 88% of patients treated with a combination containing Tivicay 50 mg once daily (n=411) achieved virologic suppression (HIV-1 RNA <50 copies/mL), compared to 85% of patients in the raltegravir 400 mg twice-daily group (n=411) at 48 weeks, meeting the 10% non-inferiority criteria. The tolerability of Tivicay was similar to that of raltegravir, with adverse events leading to withdrawal in 2% of patients in both arms. There were no treatment-emergent adverse drug reactions of at least moderate intensity (Grades 2 to 4) and ≥2% frequency in the Tivicay or raltegravir arms.

No treatment-emergent genotypic resistance to Tivicay or the background regimen was seen in the arm containing Tivicay in SPRING-2 at week 48.

VIKING-34 was a study evaluating twice-daily Tivicay in 183 HIV-infected adults currently on medication whose HIV was resistant to multiple classes of HIV medicines, including integrase inhibitors (raltegravir and/or elvitegravir). In the study, mean HIV RNA levels declined by 1.4 log10 c/mL after seven days of treatment with the addition of Tivicay to their background regimen. The proportion of study participants who were subsequently virologically suppressed (HIV-1 RNA <50 c/mL) with Tivicay plus an optimized background regimen was 63% at week 24. However, poor virologic response was observed in subjects treated with Tivicay twice daily with an integrase inhibitor (INI) resistance-associated substitution called Q148 plus two or more additional secondary INI resistance substitutions. The rate of adverse events leading to discontinuation was 3% of subjects at week 24. Treatment-emergent adverse drug reactions in VIKING-3 were generally similar compared with observations with the once-daily, 50-mg dose in Phase III trials of adult patients.

The indication in children aged 12 years and older is based on an evaluation of safety, pharmacokinetics, and efficacy through 24 weeks in a multi-centre, open-label trial in paediatric patients aged 12-<18 years old who had not previously been treated with integrase inhibitors5.

About Tivicay (dolutegravir)
Please refer to local country prescribing information (the European SmPC for those in Europe6). Tivicay® is the first new treatment delivered by ViiV Healthcare. It was approved by the U.S. FDA in August 2013, by Health Canada in October 2013 and regulatory applications are being evaluated in other countries worldwide. It is a human immunodeficiency virus type 1 (HIV-1) integrase inhibitor. 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.

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 Walmsley S, Antela A, Clumeck N et al. Dolutegravir plus abacavir/lamivudine for the initial treatment of HIV-1 infection. N Engl J Med 2013;369:1807-18.

2 Cahn P, Pozniak AL, Mingrone H et al. Dolutegravir versus raltegravir in antiretroviral-experienced, integrase-inhibitor-naive adults with HIV: week 48 results from the randomised, double-blind, non-inferiority SAILING study.
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3 Raffi F, Rachlis A, Stellbrink H-J et al. Once-daily dolutegravir versus raltegravir in antiretroviral-naive adults with HIV-1 infection: 48 week results from the randomised, double-blind, non-inferiority SPRING-2 study. Lancet 2013;381(9868):735-743.

4 Eron JJ, Clotet B, Durant J et al. Safety and efficacy of dolutegravir in treatment-experienced subjects with raltegravir-resistant HIV type 1 infection: 24-week results of the VIKING study. J Infect Dis. 2013;207(5):740-748.

5 Hazra R, Viani R, Acosta E et al. Pharmacokinetics, safety and efficacy of dolutegravir (DTG; S/GSK1349572) in HIV-1-positive adolescents: preliminary analysis from IMPAACT P1093. 19th International AIDS Conference (IAC), 2012. Abstract TUAB0203.

6 Tivicay (dolutegravir) Summary of Product Characteristics (SmPC). Available at www.viivhealthcare.com/our-medicines.aspx

*Atripla is a registered trademark of Bristol-Myers Squibb and Gilead Sciences, LLC.

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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 the company'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: January 21, 2014

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc