GLAXOSMITHKLINE PLC
Form 6-K
August 22, 2014

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 August 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 HIVcompany with GlaxoSmithKline, Pfizer, Inc. and Shionogi Limited as shareholders) is issuing the following statement today:

ViiV Healthcare receives FDA approval for Triumeq® (abacavir, dolutegravir and lamivudine), a new single-pill regimen for the treatment of HIV-1 infection

London, UK, 22 August, 2014 – ViiV Healthcare announced today that the US Food and Drug Administration (FDA) has approved Triumeq® (abacavir 600mg, dolutegravir 50mg and lamivudine 300mg) tablets for the treatment of HIV-1 infection.1 Triumeq is ViiV Healthcare's first dolutegravir-based fixed-dose combination, offering many people living with HIV the option of a single-pill regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir, with the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir and lamivudine.

Triumeq alone is not recommended for use in patients with current or past history of resistance to any components of Triumeq. Triumeq alone is not recommended in patients with resistance-associated integrase substitutions or clinically suspected INSTI resistance because the dose of dolutegravir in Triumeq is insufficient in these populations. Before initiating treatment with abacavir-containing products, screening for the presence of a genetic marker, the HLA-B*5701 allele, should be performed in any HIV-infected patient, irrespective of racial origin. Products containing abacavir should not be used in patients known to carry the HLA-B*5701 allele.1

Dr Dominique Limet, Chief Executive Officer, ViiV Healthcare, said: "Today's approval of Triumeq offers many people living with HIV in the US the first single-pill regimen containing dolutegravir. ViiV Healthcare is committed to delivering advances in care and new treatment options to physicians and people living with HIV. We are proud to announce this important milestone, marking the second new treatment to be approved in the US from our pipeline of medicines."

This FDA approval is based primarily upon data from two clinical trials:

- the Phase III study (SINGLE) of treatment-naïve adults, conducted with dolutegravir and abacavir/lamivudine as separate pills2,3
- a bioequivalence study of the fixed-dose combination of abacavir, dolutegravir and lamivudine when taken as a single pill compared to the administration of dolutegravir and abacavir/lamivudine as separate pills.4

In the SINGLE study, a non-inferiority trial with a pre-specified superiority analysis, more patients were undetectable (HIV-1 RNA <50 copies/mL) in the dolutegravir and abacavir/lamivudine arm (the separate components of Triumeq) than in the Atripla®† (efavirenz, emtricitabine and tenofovir) arm, the most commonly used single-pill regimen. The difference was statistically significant and met the pre-specified test for superiority. The difference was driven by a higher rate of discontinuation due to adverse events in the Atripla arm.2, 3

- At 96 weeks, 80% of participants on the dolutegravir-based regimen were virologically suppressed compared to 72% of participants on Atripla. Grade 2-4 treatment emergent adverse reactions occurring in 2% or more participants taking the dolutegavir-based regimen were insomnia (3%), headache (2%) and fatigue (2%).3

About HIV

HIV stands for the Human Immunodeficiency Virus. Unlike some other viruses, the human body cannot get rid of HIV, so once someone has HIV they have it for life.5-7

HIV infects specific cells of the immune system, called CD4 cells or T-cells. Over time, HIV can destroy so many of these cells that the body cannot fight off infections and disease. When this happens, HIV infection leads to Acquired Immunodeficiency Syndrome (AIDS) which is the final stage of HIV infection. There is no cure for HIV, but with early diagnosis and effective treatment most people with HIV will not go on to develop AIDS.5-7

An estimated 1.1 million people in the US are living with HIV. However, only 33 percent are taking the medication they need.8

About Triumeq
Triumeq is a fixed-dose combination containing the INSTI dolutegravir and the NRTIs abacavir and lamivudine.

Two essential steps in the HIV life cycle are replication – when the virus turns its RNA copy into DNA – and integration – the moment when viral DNA becomes part of the host cell's DNA. These processes require two enzymes called reverse transcriptase and integrase. NRTIs and integrase inhibitors interfere with the action of the two enzymes to prevent the virus from replicating and further infecting cells.

Dolutegravir was approved in the US in August 2013 and in Europe in January 2014 under the brand name Tivicay®. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted a positive opinion on the Marketing Authorisation Application (MAA) for Triumeq on 26 June 2014. Regulatory applications are also being evaluated in other markets worldwide, including Australia, Brazil and Canada.

Important Safety Information (ISI) for Triumeq (abacavir, dolutegravir and lamivudine) tablets

The following ISI is based on the Highlights section of the Prescribing Information for Triumeq. Please consult the full Prescribing Information for all the labeled safety information for Triumeq.

BOXED WARNING: RISK OF HYPERSENSITIVITY REACTIONS, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, AND EXACERBATIONS OF HEPATITIS B
See full Prescribing Information for complete boxed warning.

- Serious and sometimes fatal hypersensitivity reactions have been associated with abacavir-containing products.
  - Hypersensitivity to abacavir is a multi-organ clinical syndrome.
- Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir.
- Discontinue Triumeq as soon as a hypersensitivity reaction is suspected. Regardless of HLA-B*5701 status, permanently discontinue Triumeq if hypersensitivity cannot be ruled out, even when other diagnoses are possible.
- Following a hypersensitivity reaction to abacavir, NEVER restart Triumeq or any other abacavir-containing product.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.
- Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) -1 and have discontinued lamivudine, a component of Triumeq. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.

CONTRAINDICATIONS

- Presence of HLA-B*5701 allele.
- Previous hypersensitivity reaction to abacavir, dolutegravir or lamivudine.
- Co-administration with dofetilide.
- Moderate or severe hepatic impairment.

WARNINGS AND PRECAUTIONS

- Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of Triumeq. Appropriate laboratory testing prior to initiating therapy and monitoring for

hepatotoxicity during therapy with Triumeq is recommended in patients with underlying hepatic disease such as hepatitis B or C.

- Hepatic decompensation, some fatal, has occurred in HIV-1/Hepatitis C Virus (HCV) co-infected patients receiving combination antiretroviral therapy and interferon alfa with or without ribavirin. Discontinue Triumeq as medically appropriate and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both.
- Immune reconstitution syndrome and redistribution/accumulation of body fat have been reported in patients treated with combination antiretroviral therapy.
- Administration of Triumeq is not recommended in patients receiving other products containing abacavir or lamivudine.

ADVERSE REACTIONS

The most commonly reported (≥2%) adverse reactions of at least moderate intensity in treatment-naïve adult subjects receiving Triumeq were insomnia (3%), headache (2%), and fatigue (2%).

DRUG INTERACTIONS

Co-administration of Triumeq with other drugs can alter the concentration of other drugs and other drugs may alter the concentrations of Triumeq. The potential drug-drug interactions must be considered prior to and during therapy.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Triumeq should be used during pregnancy only if the potential benefit justifies the potential risk.
- Nursing mothers: Breastfeeding is not recommended due to the potential for HIV transmission.
- Triumeq is not recommended in patients with creatinine clearance less than 50 mL per min.
- If a dose reduction of abacavir, a component of Triumeq, is required for patients with mild hepatic impairment, then the individual components should be used.

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 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:

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3. Walmsley S, Berenguer J, Khuong-Josses M, et al. Dolutegravir regimen statistically superior to efavirenz/tenofovir/emtricitabine: 96-week results from the SINGLE study (ING114467). Poster presented at: 21st Conference on Retroviruses and Opportunistic Infections; March 3-6, 2014; Boston, MA. Poster 543.
4. Weller S, Chen S, Borland J et al. Bioequivalence of a Dolutegravir, Abacavir and Lamivudine Fixed-Dose Combination Tablet and the Effect of Food. JAIDS. 2014 May doi:

10.1097/QAI.0000000000000193.http://journals.lww.com/jaids/Abstract/publishahead/Bioequivalence_of_a_Dolutegravir,_Ab
5. Centers for Disease Control and Prevention. HIV Basics. http://www.cdc.gov/hiv/basics/index.html. Accessed July 28, 2014.
6. NHS Choices, HIV & AIDS Overview. http://www.nhs.uk/conditions/HIV/Pages/Introduction.aspx. Accessed July 28, 2014.

7. Centers for Disease Control and Prevention. CDC Fact Sheet. HIV in the United States: The Stages of Care. http://www.cdc.gov/hiv/pdf/research_mmp_StagesofCare.pdf. Accessed July 28, 2014.
8. Centers for Disease Control and Prevention. Today's HIV/AIDS Epidemic. http://www.cdc.gov/nchhstp/newsroom/docs/HIVFactSheets/TodaysEpidemic-508.pdf. Accessed July 28, 2014.

†Atripla is a registered trademark of Bristol-Meyers Squibb and Gilead Sciences, LLC.

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GlaxoSmithKline 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 2013.

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: August 22, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc