GLAXOSMITHKLINE PLC
Form 6-K
September 03, 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 September 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 receives EU marketing authorisation for Triumeq® (dolutegravir/abacavir/lamivudine), a new once-daily single-pill regimen for the treatment of HIV

London, United Kingdom, 3 September, 2014 - ViiV Healthcare announced today that the European Commission (EC) has granted marketing authorisation for Triumeq® (dolutegravir 50mg / abacavir 600mg / lamivudine 300mg) tablets for the treatment of HIV in adults and adolescents aged 12 years and older and weighing at least 40kg. 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. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.

[1]Patients who carry this genetic marker are at high risk of experiencing a hypersensitivity reaction to abacavir.

Triumeq is ViiV Healthcare's first once-daily single-pill dolutegravir-based regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir, with the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir and lamivudine.

Dr Dominique Limet, Chief Executive Officer, ViiV Healthcare, said: "We are delighted with today's approval that offers people living with HIV in Europe the first single-pill regimen containing dolutegravir. Triumeq is a direct result of ViiV Healthcare's patient-centred approach to innovation. As a company that focuses 100% on HIV, our commitment is to continue to deliver new options for care and treatment for people living with HIV."

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

- the Phase III study (SINGLE) of treatment-naive adults, conducted with dolutegravir and abacavir/lamivudine as separate pills[2][3]
- a bioequivalence study of the fixed-dose combination of dolutegravir, abacavir 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 dolutegravir-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]

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.5 There is no cure for HIV, but with early diagnosis and effective treatment most people with HIV will not go on to develop AIDS.[6]

By the end of 2012, an estimated 35.3 million people were living with HIV worldwide, up 18% from 2001. 2.3 million people had new HIV infections contracted that year[7].An estimated 2.2 million people are living with HIV in the World Health Organisation (WHO) European Region in 2012 and around half are unaware of their diagnosis. In 2012, over 131,000 people were newly diagnosed with HIV in the region and over 29,000 of these were in the European Union or European Economic Area (EU/EEA).[8]

About Triumeq
Triumeq is a once-daily single-pill dolutegravir-based regimen, 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. This decrease in replication will lead to less virus being available to cause subsequent infection of uninfected cells.

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

Today's approval of Triumeq is the European regulatory authorisation to market the medicine in each member state of the European Union. Triumeq 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 US Food and Drug Administration (FDA) approved Triumeq on 22 August 2014. Regulatory applications are also being evaluated in other markets worldwide, including Australia, Brazil and Canada.

Dolutegravir was approved in the US in August 2013 and in Europe in January 2014 under the brand name Tivicay®.

Tivicay and Triumeq are registered trademarks of the ViiV Healthcare group of companies.

Safety Information for Triumeq in the European Union:1
The risk for abacavir hypersensitivity reactions (HSR) to occur is high in patients who test positive for a genetic marker, the HLA-B*5701 allele. Because Triumeq contains abacavir, before initiating treatment with Triumeq, screening for the presence of the HLA-B*5701 allele should be performed.

Dolutegravir has also been associated with a risk for HSR. Clinically it is not possible to determine whether an HSR with Triumeq is caused by abacavir or dolutegravir. However, HSR have been observed more commonly with

abacavir.

If an HSR is suspected, Triumeq must be stopped immediately. Any delay in stopping treatment with Triumeq after the onset of hypersensitivity may result in an immediate and life-threatening reaction.

After stopping treatment with Triumeq for reasons of a suspected HSR, Triumeq or any other medicinal product containing abacavir or dolutegravir must never be re-initiated.

Triumeq is contraindicated in any patient with hypersensitivity to dolutegravir, abacavir or lamivudine or to any of the excipients.

Co-administration with dofetilide is also contraindicated.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.

Triumeq is not recommended for use in patients with a creatinine clearance < 50 mL/min.

A dose reduction of abacavir may be required for patients with mild hepatic impairment (Child-Pugh grade A). As dose reduction is not possible with Triumeq, the separate preparations of dolutegravir, abacavir or lamivudine should be used when this is judged necessary.

Triumeq is not recommended in patients with moderate and severe hepatic impairment.

Triumeq includes lamivudine, which is active against hepatitis B. Abacavir and dolutegravir lacks such activity. Lamivudine monotherapy is generally not considered an adequate treatment for hepatitis B, since the risk for hepatitis B resistance development is high. If Triumeq is used in patients co-infected with hepatitis B an additional antiviral is therefore generally needed.

The safety and efficacy of Triumeq in children less than 12 years of age has not yet been established. No data are available.

Observational studies have shown an association between myocardial infarction and the use of abacavir. Data from clinical trials showed limited numbers of myocardial infarction and could not exclude a small increase in risk. Overall the available data from observational cohorts and from randomised trials show some inconsistency so can neither confirm nor refute a causal relationship between abacavir treatment and the risk of myocardial infarction. To date, there is no established biological mechanism to explain a potential increase in risk.

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.

Factors that decrease the exposure of the components of Triumeq (dolutegravir, abacavir and lamivudine) should be avoided. Triumeq should not be taken with any other medicinal products containing dolutegravir, abacavir, lamivudine or emtricitabine.

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.

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

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

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 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

†Atripla® is a registered trademark of Bristol-Myers 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.

References

[1] Triumeq Summary of Product Characteristics

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[5] Centers for Disease Control and Prevention. HIV Basics. http://www.cdc.gov/hiv/basics/index.html

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[6] NHS Choices, HIV & AIDS Overview http://www.nhs.uk/conditions/HIV/Pages/Introduction.aspx. (Accessed 18 August 2014)

[7] Terrence Higgins Trust. Facts and statistics about HIV.

http://www.tht.org.uk/our-charity/Facts-and-statistics-about-HIV/Worldwide. (Accessed August

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[8] Terrence Higgins Trust. Facts and statistics about HIV.

http://www.tht.org.uk/our-charity/Facts-and-statistics-about-HIV/Europe. (Accessed August 2014)

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: September 03, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc