GLAXOSMITHKLINE PLC
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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 21 May 2018

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

Issued: 21 may 2018, London UK - LSE Announcement

ViiV Healthcare receives EU marketing authorisation for Juluca (dolutegravir/rilpivirine), the first 2-drug regimen, once-daily, single-pill for the treatment of HIV

Juluca maintains viral suppression with two drugs in the smallest single pill regimen
London, 21 May 2018 - ViiV Healthcare, the global specialist HIV company, majority owned by GlaxoSmithKline, with Pfizer Inc. and Shionogi Limited as shareholders, today announced that the European Commission has granted marketing authorisation for Juluca (dolutegravir 50mg/rilpivirine 25mg) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor or integrase inhibitor.[1] Juluca is a 2-drug regimen of dolutegravir (ViiV Healthcare), the most widely prescribed integrase inhibitor worldwide,[2] and rilpivirine (Janssen Sciences Ireland UC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson).1

Deborah Waterhouse, CEO ViiV Healthcare said, "The European Commission Decision for Juluca is very positive news for people living with HIV (PLHIV) across Europe, who will now have the opportunity to maintain their viral suppression with a complete treatment regimen composed of only two drugs within a single-pill. Thanks to advances in treatment, many PLHIV who are on therapy are living longer, with near-normal life expectancies. We listened to their concerns about the potential long-term effects of being on treatment for decades, and have developed a solution aligned with a preference to streamline care by taking fewer antiretrovirals to manage their HIV." [3]

This approval brings another treatment option to the estimated 810,000 PLHIV in Europe.[4] It follows the Positive Opinion from the European Medicines Agency's (EMA) Committee for Human use of Medicinal Products (CHMP) on 22 March 2018.[5] Juluca was approved by the US Food and Drug Administration (FDA) in November 2017 and Health Canada on 18 May 2018.[6],[7]

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "We are delighted to be able to provide dolutegravir with rilpivirine in a once-daily 2-drug regimen for PLHIV. ViiV Healthcare is committed to delivering innovative advances to meet the unmet needs of PLHIV and our robust clinical research programme has the potential to revolutionalise how we care for PLHIV for the long-term. With the advent of Juluca, we have found a way to reduce the number of antiretrovirals whilst maintaining the efficacy of the traditional 3-drug regimen. This is already being recognised by the European AIDS Society (EACS 2017) guidelines recommending a dolutegravir and rilpivirine regimen as a switch option for virologically suppressed patients."[8]

Data from the SWORD studies, presented at the Conference for Retroviruses and Opportunistic Infections (CROI) 2017 and later published in The Lancet, showed that the dolutegravir and rilpivirine regimen is non-inferior to traditional three and four drug regimens in maintaining virologic suppression (HIV-1 RNA <50 copies/mL) through 48 weeks in adults who are infected with HIV-1, in both pooled and individual analyses of the SWORD-1 and SWORD-2 studies (dolutegravir+rilpivirine 486/513 [95%] current antiretroviral regimen 485/511 [95%], [adjusted difference -0.2% (95% confidence interval:
-3.0%, 2.5%), pooled analysis]). The most commonly reported (>5%) adverse events in the dolutegravir+rilpivirine arm were nasopharyngitis, headache, diarrhoea and upper respiratory tract infection. Participating adults had stable plasma HIV-1 RNA (viral load <50 copies/mL) for 6 months or longer at screening, with no resistance-associated major integrase inhibitor, protease inhibitor, nucleoside and non-nucleoside reverse transcriptase inhibitor mutations.[9]

- Ends -

Notes to editors
In June 2014, ViiV Healthcare and Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced a collaboration to investigate the potential of combining dolutegravir and rilpivirine in a single tablet in order to expand the treatment options available to people living with HIV.

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. There is no cure for HIV, but effective treatment can control the virus so that people with HIV can enjoy healthy and productive lives.

HIV has largely become a chronic treatable disease with improved access to antiretroviral treatment. This has led to a 22% drop in global HIV mortality between 2009 and 2013,[10] but more can be done for the estimated 36.7 million people living with HIV[11] of which 160,000 were newly diagnosed in the Europe region alone in 2016.[12]

About Juluca (dolutegravir/rilpivirine)
Juluca was approved by the US Food and Drug Administration (FDA) on 21 November 2017, as a complete regimen for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of dolutegravir/rilpivirine.6

Juluca is a 2-drug regimen, single pill that combines the integrase inhibitor (INI) dolutegravir (50mg), with the non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine (25mg) taken once-daily as a complete HIV regimen for people living with HIV who are virologically suppressed.1,6

Two essential steps in the HIV life cycle include reverse transcription - when the virus turns its RNA (ribonucleic acid) copy into DNA (deoxyribonucleic acid) - and integration - the moment when viral DNA becomes part of the host cell's DNA. These processes require two enzymes called nucleoside reverse transcriptase and integrase. NNRTIs and INIs interfere with the action of these two enzymes to prevent the virus from replicating. This decrease in replication can lead to less virus being available to cause subsequent infection of uninfected cells.

ViiV Healthcare has also submitted regulatory marketing applications in other countries worldwide.

About the SWORD phase III programme for dolutegravir (Tivicay) and rilpivirine (Edurant)
The SWORD phase III programme evaluates the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine from current integrase inhibitor-, non-nucleoside reverse transcriptase inhibitor-, or boosted protease inhibitor-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed with a three or four-drug regimen. SWORD-1 (NCT02429791) and SWORD-2 (NCT02422797) are replicate 148-week, randomised, open-label, non-inferiority studies to assess the antiviral activity and safety of a two-drug, daily oral regimen of dolutegravir plus rilpivirine compared with current antiretroviral therapy (100-week data will be shared in Q3 2018 with the full 148-week data being shared in 2019). In the SWORD clinical trials, dolutegravir and rilpivirine are provided as individual tablets.[13],[14]

The primary endpoint is the proportion of patients with plasma HIV-1 RNA <50 copies per millilitre (c/mL) at week 48. Key secondary endpoints include evaluation of the development of viral resistance, measurements of safety and tolerability, and changes in renal, bone and cardiovascular biomarkers. The studies also include exploratory measures to assess change in health-related quality of life, willingness to switch and adherence to treatment regimens.13, 14

For more information on the trials please visit: www.clinicaltrials.gov

Juluca and Tivicay are trademarks owned by the ViiV Healthcare group of companies.

Edurant is a registered trademark of Janssen Sciences Ireland UC.

Safety Information for Juluca in the European Union:1
Juluca (dolutegravir 50mg, rilpivirine 25mg) is contraindicated in any patient with hypersensitivity to the active substances dolutegravir or rilpivirine or to any of the excipients.

Juluca is contraindicated in patients taking:
- dofetilide
- the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- the antimycobacterials rifampicin, rifapentine
- proton pump inhibitors, such as omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole
- the systemic glucocorticoid dexamethasone, except as a single dose treatment
- St John's wort (Hypericum perforatum)

Factors that decrease the exposure of the components of Juluca should be avoided. Juluca should not be taken with any other medicinal products containing dolutegravir or rilpivirine or antiretroviral medicinal products used for the treatment of HIV.

The safety and efficacy of Juluca has not yet been established in patients <18 years and/or in women who are pregnant. Use of Juluca in these patient populations is not recommended.

No dosage adjustment is required in patients with mild or moderate renal impairment. In patients with severe or end stage renal disease, the combination of Juluca with a strong CYP3A inhibitor should only be used if the benefit outweighs the risk. No data are available in subjects receiving dialysis although differences in pharmacokinetics are not expected in this population.

No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh score A or B). Juluca should be used with caution in patients with moderate hepatic impairment. No data are available in patients with severe hepatic impairment (Child-Pugh score C); therefore Juluca is not recommended in these patients.

Hypersensitivity reactions have been reported with dolutegravir and were characterised by rash, constitutional findings, and sometimes, organ dysfunction, including severe liver reactions. Juluca should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by raised liver enzymes, fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial oedema, eosinophilia, angioedema). Clinical status including liver aminotransferases and bilirubin should be monitored. Delay in stopping treatment with Juluca after the onset of hypersensitivity may result in a life-threatening allergic reaction.

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. Relevant examples are cytomegalovirus retinitis, generalised and/or focal mycobacterial infections, and Pneumocystis jirovecii pneumonia. Any inflammatory symptoms should be evaluated and treatment instituted when necessary. Autoimmune disorders (such as Graves' disease) have also been reported to occur in the setting of immune reconstitution, however, the reported time to onset is more variable and these events can occur many months after initiation of treatment.

Monitoring of liver function is recommended in patients with hepatitis B and/or C co-infection. No clinical data are available in patients with hepatitis B co-infection. Physicians should refer to current treatment guidelines for the management of HIV infection in patients co-infected with hepatitis B virus. Limited data is available in patients with

hepatitis C co-infection. A higher incidence of liver chemistry elevations (Grade 1) were observed in patients treated with dolutegravir and rilpivirine co-infected with hepatitis C compared to those who were not co-infected.
Patients should be advised that Juluca does not cure HIV infection and that they may still develop opportunistic infections and other complications of HIV infection. Therefore, patients should remain under close clinical observation by physicians experienced in the treatment of these associated HIV diseases.

Although the aetiology is considered to be multifactorial (including corticosteroid use, biphosphonates, alcohol consumption, severe immunosuppression, higher body mass index), 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.

At supra-therapeutic doses (75 and 300 mg once daily), rilpivirine has been associated with prolongation of the QTc interval of the electrocardiogram (ECG). Rilpivirine at the recommended dose of 25 mg once daily is not associated with a clinically relevant effect on QTc. Juluca should be used with caution when co-administered with medicinal products with a known risk of Torsade de Pointes.

Please refer to the full European Summary of Product Characteristics for full prescribing information, including contraindications, special warnings and precautions for use.1

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 and for people who are at risk of becoming infected with HIV. Shionogi joined 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 innovative medicines for HIV treatment and prevention, 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.

About GSK
GSK - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.
Cautionary statement regarding forward-looking statements
ViiV Healthcare Limited, the global specialist HIV company, is majority owned by GlaxoSmithKline plc, with Pfizer Inc. and Shionogi Limited. 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. Such factors include, but are not limited to, those described under Item 3.D 'Principal risks and uncertainties' in the company's Annual Report on Form 20-F for 2017.

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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: 21 May, 2018

By: VICTORIA WHYTE

Victoria Whyte

Authorised Signatory for and on
behalf of GlaxoSmithKline plc