GLAXOSMITHKLINE PLC
Form 6-K
November 22, 2017

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 22 November 2017

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

PRESS RELEASE

Juluca® (dolutegravir and rilpivirine) approved in US as first 2-drug regimen, once-daily, single pill - a complete regimen for the maintenance treatment of virologically suppressed HIV-1 infection

London, 21 November 2017 - ViiV Healthcare, the global specialist HIV company, majority owned by GlaxoSmithKline, with Pfizer Inc. and Shionogi Limited as shareholders, today announced that the US Food and Drug Administration (FDA) has approved Juluca®, indicated as a complete regimen for the maintenance treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral (ART) regimen for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.[1]

Juluca is the first 2-drug regimen (2DR) comprising dolutegravir 50mg (ViiV Healthcare), an integrase strand transfer inhibitor and rilpivirine 25mg (Janssen Therapeutics, Division of Janssen Products LP), a non-nucleoside reverse transcriptase inhibitor.

Deborah Waterhouse, CEO ViiV Healthcare said, "The FDA approval of Juluca marks an important milestone in our commitment to deliver innovative advances in HIV care by providing new treatment options that challenge the traditional approach to care. This is the start of a new era in HIV treatment. We are delighted to be able to provide the first 2-drug regimen to physicians and people living with HIV in the US, to support the reduction of long-term ART exposure as they receive life-long treatment for their chronic condition."

This FDA approval is based primarily upon data from two pivotal phase III clinical trials, SWORD-12 and SWORD-2,2 which showed the 2-drug regimen achieved non-inferior viral suppression (HIV-1 RNA less than 50 copies per mL) at 48 weeks compared with a three- or four-drug regimen in both pooled and individual analyses of the SWORD-1 and SWORD-2 studies (CAR 485/511 [95%], dolutegravir + rilpivirine 486/513 [95%] [adjusted difference -0.2% (95% confidence interval CI: 3.0%, 2.5%), pooled analysis]).2 Virologic suppression rates were similar between treatment arms.2 Drug related adverse events and adverse events leading to withdrawal occurred in low frequencies in both arms of the study, but more frequently in the investigational arm.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "Based on the fundamental principle that no one should have to take more medicines than necessary, ViiV Healthcare has put in place a comprehensive 2-drug regimen research and development programme built around the characteristics of dolutegravir. Juluca, our new 2-drug regimen, once-daily, single pill, now provides people living with HIV who are virologically suppressed, the option to reduce the number of antiretrovirals they take, while maintaining the efficacy of a traditional three-drug regimen."

Juluca is the first medicine in our 2-drug regimen pipeline, which looks to help lessen the lifetime burden of treatment for people living with HIV. Our R&D efforts are exploring the potential of two further 2-drug regimens both in phase III development, a once-daily, single pill containing dolutegravir/lamivudine for treatment naïve patients, as well as cabotegravir/rilpivirine long-acting injectable for treatment-experienced and naïve patients.

- 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 partnership 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 leading to a 22% drop in global HIV mortality between 2009 and 2013,3 but more can be done for the estimated 36.7 million people living with HIV and 1.8 million individuals newly infected each year worldwide.4

About Juluca
Juluca is a 2-drug regimen, once-daily, single pill that combines the INSTI dolutegravir (50mg), with the NNRTI rilpivirine (25mg) taken once-daily as a complete HIV regimen for people living with HIV who are virologically suppressed.

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 INSTIs 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.

Juluca was approved by the US Food and Drug Administration (FDA) on 21st 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 Juluca. Juluca is expected to be available in pharmacies in the US from 11th December 2017.

ViiV Healthcare has also submitted regulatory marketing applications in Europe, Canada, Australia and Switzerland.

About the SWORD phase III program for dolutegravir (Tivicay®) and rilpivirine (Edurant®)
The SWORD phase III program 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 (full 148-week data will be shared in 2018). In the SWORD clinical trials, dolutegravir and rilpivirine are provided as individual tablets.

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.

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

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

*Edurant is a registered trademark of Janssen Sciences Ireland UC.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use JULUCA safely and effectively. See full prescribing information for JULUCA.

JULUCA (dolutegravir and rilpivirine) tablets, for oral use Initial U.S. Approval: 2017

INDICATIONS AND USAGE
JULUCA, a two-drug combination of dolutegravir, a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, a HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those 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 JULUCA.

DOSAGE AND ADMINISTRATION

One tablet taken orally once daily with a meal.

Rifabutin coadministration: Take an additional 25-mg tablet of rilpivirine with JULUCA once daily with a meal for the duration of the rifabutin coadministration.

DOSAGE FORMS AND STRENGTHS
Each tablet contains: 50 mg of dolutegravir (equivalent to 52.6 mg dolutegravir sodium) and 25 mg of rilpivirine (equivalent to 27.5 mg rilpivirine hydrochloride).

CONTRAINDICATIONS

Previous hypersensitivity reaction to dolutegravir or rilpivirine.

Coadministration with dofetilide.

Coadministration with drugs where significant decreases in rilpivirine plasma concentrations may occur, which may result in loss of virologic response.

WARNINGS AND PRECAUTIONS

Severe skin and hypersensitivity reactions characterised by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported with the individual components. Discontinue JULUCA immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in

alife-threatening reaction.

Hepatotoxicity has been reported in patients receiving a dolutegravir- or rilpivirine-containing regimen. Monitoring for hepatotoxicity is recommended.

Depressive disorders have been reported with the use of rilpivirine- or dolutegravir-containing regimens. Immediate medical evaluation is recommended for severe depressive symptoms.

ADVERSE REACTIONS
The most common adverse reactions (all Grades) observed in at least 2% of subjects were diarrhoea and headache.

To report SUSPECTED ADVERSE REACTIONS, contact ViiV Healthcare at 1-888-844-8872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Because JULUCA is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

Refer to the full prescribing information for important drug interactions with JULUCA.

Drugs that induce or inhibit CYP3A4 or UGT1A1 may affect the plasma concentrations of the components of JULUCA.

Drugs that increase gastric pH or containing polyvalent cations may decrease plasma concentrations of the components of JULUCA

Consider alternatives to prescribing JULUCA with drugs with a known risk of Torsade de Pointes.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended due to the potential for HIV transmission.

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.

Inside Information
The information contained in this announcement is inside information.

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.


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References


1. Juluca US label information
2. Llibre JM, Hung C-C, Brinson C, et al. SWORD 1 & 2: Switch to DTG + RPV maintains virologic suppression through 48 weeks, a Phase III study. Presented at: Conference on Retroviruses and Opportunistic Infections; February 13-16, 2017; Seattle, WA, USA.
3. World Health Organization. Global Update on the health sector response to HIV, 2014. July 2014. Available at: http://apps.who.int/iris/bitstream/10665/128494/1/9789241507585_eng.pdf?ua=1. Last accessed November 2017.
4. World Health Organization. HIV/AIDS Fact Sheet. Available at: http://www.who.int/mediacentre/factsheets/fs360/en/. Last accessed November 2017.


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: November 22, 2017

By: VICTORIA WHYTE
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Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc