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 24 July 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: Tuesday 24 July 2018, London UK - LSE Announcement

ViiV Healthcare announces SWORD 100-week data for Juluca (dolutegravir/rilpivirine) at AIDS 2018

- Juluca, the first 2-drug regimen, once daily, single pill regimen, maintains viral suppression through 100 weeks

London, 24 July 2018 - ViiV Healthcare today presented 100-week results from its phase III programme evaluating the safety and efficacy of switching virologically-suppressed people living with HIV from a three or four-drug antiretroviral regimen to a 2-drug regimen of dolutegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson.)1 These results were presented at the 22nd International AIDS Conference taking place 23-27 July 2018 in Amsterdam.

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "As we progress further into a new era of HIV treatment, these 100-week data from the SWORD studies add to the growing evidence base for Juluca and 2-drug regimens. The results confirm the ability of Juluca to maintain efficacy over a 100-week period and importantly support that the long-term safety profile of this regimen is consistent with the respective labels of the component medicines. This 100-week data should provide physicians with further confidence that they may be able to reduce the number of antiretroviral drugs required to effectively maintain virologic suppression in their patient's HIV."

In pooled data from the SWORD 1 and SWORD 2 studies, 89% (456/513) of participants on the 2-drug regimen of dolutegravir and rilpivirine for 100 weeks (n=513) maintained viral suppression, with a viral load of less than 50 copies/mL. A low rate of snapshot virologic non-response was observed (n=13; 3%) and 6 participants met the confirmed virologic withdrawal criterion. Three participants failed with NNRTI mutations, one that had pre-existing NNRTI mutations at baseline developed resistance to rilpivirine and was withdrawn; no participants developed integrase inhibitor resistance. There were no new safety findings in the second year of the study. A total 34 participants (7%) experienced adverse events that led to withdrawal through week 100.1

In the 'late switch' arm (n=477), where participants continued on their current antiretroviral regimen until week 52 before switching to the 2-drug regimen of dolutegravir and rilpivirine, 93% (n=444) of participants maintained viral suppression through week 100. Two participants (<1%) met the confirmed virologic withdrawal criterion, and the safety profile of the late switch group was comparable to the early switch group (dolutegravir and rilpivirine from day 1 to week 100). 30 participants (6%) experienced serious adverse events and 15 participants (3%) experienced adverse events that led to withdrawal.1

The SWORD clinical programme is part of ViiV Healthcare's ongoing commitment to lessening the burden of HIV treatment on PLHIV through research into 2-drug regimens. The 48-week results from the SWORD studies were presented at CROI 2017 and later published in The Lancet.2 Data from the SWORD studies as well as a pivotal bioequivalence study3 has led to successful regulatory approval of the 2-drug regimen in the United States, European Union, Canada and Australia, marketed under the trade name Juluca.4,5,6,7

- Ends -

Notes to editors

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 2013,8 but more can be done for the estimated 36.7 million people living with HIV9 of which 160,000 were newly diagnosed in the Europe region alone in 2016.10

About Juluca (dolutegravir/rilpivirine)
Juluca is ViiV Healthcare's first two-drug regimen (2DR), once-daily, single-pill that combines dolutegravir 50mg (ViiV Healthcare), the most widely prescribed integrase inhibitor (INI) worldwide, with the nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine 25mg (Janssen Sciences Ireland UC). Juluca was granted marketing authorisation by regulatory authorities in the United States in November 2017, the European Union and Canada in May 2018, and Australia in June 2018.4,5,6,7 ViiV Healthcare has also submitted regulatory marketing applications in other countries worldwide.

Juluca is indicated 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 NNRTI or INI.4

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.

About the SWORD phase III programme for Juluca
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.11,12 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 2-drug, daily oral regimen of dolutegravir plus rilpivirine compared with current antiretroviral therapy11,12 (the 148-week data will be shared in 2019). In the SWORD clinical trials, dolutegravir and rilpivirine are provided as individual tablets.11,12

The primary endpoint is the proportion of patients with plasma HIV-1 RNA <50 copies per millilitre (copies/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.11,12

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

U.S. IMPORTANT SAFETY INFORMATION: JULUCA (dolutegravir and rilpivirine) tablets

Professional Indication(s) and Important Safety Information

Indication and Usage for JULUCA
JULUCA is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of JULUCA.

Important Safety Information

CONTRAINDICATIONS
JULUCA is contraindicated in patients:

with previous hypersensitivity reaction to dolutegravir or rilpivirine.

receiving dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, systemic dexamethasone (>1 dose), St. John's wort, and proton pump inhibitors (e.g., esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole).

WARNINGS AND PRECAUTIONS

Skin and Hypersensitivity Reactions:
Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. These events were reported in <1% of subjects receiving dolutegravir in Phase 3 clinical trials.

Severe skin and hypersensitivity reactions have been reported during postmarketing experience, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), with rilpivirine-containing regimens and have been accompanied by fever and/or organ dysfunctions including elevations in hepatic serum biochemistries.

Discontinue JULUCA immediately if signs or symptoms of severe skin or hypersensitivity reactions develop (such as severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters or peeling of the skin, mucosal involvement, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, and difficulty breathing), as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including laboratory parameters with liver aminotransferases, should be monitored and appropriate therapy initiated.

Hepatotoxicity:

Hepatic adverse events have been reported, including cases of hepatic toxicity, in patients without pre-existing hepatic disease or other identifiable risk factors.

Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn.

Monitoring for hepatotoxicity is recommended.

Depressive Disorders:

Depressive disorders (including depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, and suicidal ideation) have been reported.

Promptly evaluate patients with severe depressive symptoms.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

The concomitant use of JULUCA and other drugs may result in known or potentially significant drug interactions, see Contraindications and Drug Interactions sections. Rilpivirine doses 3 and 12 times higher than the recommended dose can prolong the QTc interval. Consider alternatives to JULUCA when coadministered with a drug with a known risk of Torsade de Pointes. Consider the potential for drug interactions prior to and during therapy with JULUCA and monitor for adverse reactions.

ADVERSE REACTIONS: Most common adverse reactions with JULUCA (incidence ≥2%, all Grades) were diarrhea (2%) and headache (2%).

DRUG INTERACTIONS

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

Drugs that induce or inhibit CYP3A 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.

Consult the full Prescribing Information for JULUCA for more information on potentially significant drug interactions, including clinical comments.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are insufficient prospective pregnancy data to adequately assess the risk of birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.

Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission and the potential for adverse reactions in nursing infants.

DOSAGE AND ADMINISTRATION

Dosage: 1 tablet taken orally once daily with a meal for adult patients.

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

Full US prescribing information including is available at:
https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Juluca/pdf/JULUCA-PI-PI
For the EU Summary of Product Characteristics, please visit:
https://www.medicines.org.uk/emc/product/9246

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.

ViiV Healthcare Media enquiries:	Patricia O'Connor	+44 (0) 208 047 5982
GSK Global Media enquiries:	Simon Steel	+44 (0) 20 8047 5502
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 20 8047 5194
	Danielle Smith	+44 (0) 20 8047 0932
	James Dodwell	+44 (0) 20 8047 2406
	Jeff McLaughlin	+1 215 751 7002

References

1 Aboud M, Orkin C, Podzamczer D, et al. Durable Suppression 2 years after switch to DTG+RPV 2-Drug Regimen: SWORD 1&2 Studies. Presented at the 22nd International AIDS Conference (AIDS 2018), 23-27 July 2018, Amsterdam, The Netherlands.
2 Llibre JM, et al. Efficacy, safety, and tolerability of dolutegravir-rilpivirine for the maintenance of virological suppression in adults with HIV-1: phase 3, randomised, non-inferiority SWORD-1 and SWORD-2 studies. The Lancet. 2018 Mar 3;391(10123):839-849.
3 Metha R, et al. Bioequivalence of a fixed dose combination tablet of dolutegravir and rilpivirine in healthy subjects. Presented at the 18th Workshop on Clinical Pharmacology of Antiviral Therapy, 2017. Chicago, United States.
4 Juluca EU Summary of Product Characteristics www.ema.europa.eu.
5 Juluca (dolutegravir and rilpivirine) Prescribing Information. U.S Approval 2017.

6 Health Canada. Juluca certified product information document. 18 May 2018.
7 Australian Government. Department of Health Therapeutic Goods Administration. Juluca Product Information - ARTG ID 291356. Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-01956-1&d=20180629161146224 Last accessed July 2018.
8 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 May 2018.
9 World Health Organization. HIV AIDS Factsheet 2017. Available at: http://www.who.int/mediacentre/factsheets/fs360/en/ Last accessed July 2018.
10 World Health Organization. Infographic - Newly diagnosed HIV infections in the WHO European Region, 2016. Available at: http://www.euro.who.int/en/health-topics/communicable-diseases/hivaids/data-and-statistics/infographic-newly-diagnosed-hiv- accessed July 2018.
11 SWORD-1 - Regimen Switch to Dolutegravir + Rilpivirine From Current Antiretroviral Regimen in Human Immunodeficiency Virus Type 1 Infected and Virologically Suppressed Adults (SWORD-1). Available at: https://clinicaltrials.gov/ct2/show/NCT02429791?term=dolutegravir+AND+sword&cond=HIV&rank=3 Last accessed July 2018.
12 SWORD-2 - Regimen Switch to Dolutegravir + Rilpivirine From Current Antiretroviral Regimen in Human Immunodeficiency Virus Type 1 Infected and Virologically Suppressed Adults (SWORD-2). Available at: https://clinicaltrials.gov/ct2/show/NCT02422797?term=dolutegravir+AND+sword&cond=HIV&rank=1 Last accessed July 2018.

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: July 24, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc