GLAXOSMITHKLINE PLC
Form 6-K
July 24, 2018

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 presents phase III data at AIDS 2018 from landmark GEMINI studies showing two-drug regimen of dolutegravir and lamivudine has similar efficacy to a three-drug regimen in treatment naïve HIV patients, with no emergence of resistance.

GEMINI 1 & 2 studies meet primary endpoint, showing two-drug regimen to be effective across high and low viral loads.

London, 24 July 2018

ViiV Healthcare today presented at the 22nd International AIDS conference in Amsterdam 48-week results from the phase III GEMINI 1 & 2 studies, assessing the safety and efficacy of a two-drug regimen (2DR) of dolutegravir (DTG) and lamivudine (3TC) compared to a three-drug regimen of dolutegravir and two nucleoside reverse transcriptase inhibitors (NRTIs), tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in treatment naïve HIV-1 infected adults with baseline viral loads up to 500,000 copies per millilitre (c/mL).

The studies met their primary endpoint for non-inferiority based on plasma HIV-1 RNA <50c/mL, a standard measure of HIV control, at Week 48. In a pooled analysis, 91% (655/716) of patients taking DTG + 3TC had HIV-1 RNA<50 copies/mL compared with 93% (669/717) of patients taking DTG +TDF/FTC [adjusted difference -1.7% (95% CI: -4.4%, 1.1%)].
Pedro Cahn, principal investigator for the GEMINI study programme said: "For the last 15-20 years, the standard of care for HIV has revolved around three-drug regimens. Now that we have more potent drugs, the focus is shifting to tolerability and convenience. The GEMINI studies show that we can get the efficacy of three drugs in a two-drug regimen with the tolerability and drug interaction profile of DTG and 3TC. These are important findings for people living with HIV who will spend their lifetime taking drugs to suppress their virus. The studies have the potential to expand the treatment paradigm for first-line therapy of people living with HIV."

Results show broadly consistent results for virus suppression across individuals with higher viral load (more than 100,000 copies of viral RNA per millilitre of blood plasma [>100,000c/mL]) and lower viral load (<=100,000 c/mL) HIV-1 plasma RNA. Rates of virologic failure were ≤1% across all arms of the study. No patient who experienced virologic failure in either treatment arm developed treatment-emergent resistance.

The percentage of patients that withdrew due to adverse events was 2% in each study arm (GEMINI I DTG + 3TC arm: n=7, GEMINI I DTG + TDF/FTC arm n=8, GEMINI II DTG + 3TC arm = 8, GEMINI II DTG + TDF/FTC arm n = 8). Pooled results show that the most common (≥5%) adverse events across the studies were headache, diarrhoea and nasopharyngitis in both arms (DTG + 3TC arm: 10%, 9%, and 8%, respectively, DTG + TDF/FTC: 10%, 11%, and 11%, respectively).

Drug-related adverse events were less frequent in patients on the DTG/3TC regimen (126/716, 18%), compared with those on the DTG + TDF/FTC regimen (169/717, 24%).

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer of ViiV Healthcare, said: "These data we have presented at AIDS 2018 provide further evidence that we should be rethinking the traditional approach to HIV treatment of using three or more drugs. The results from the GEMINI programme support our belief that the two-drug

regimen of dolutegravir and lamivudine can be a valuable option for treatment-naïve patients and that no patient should take more medicine than they need."

ViiV Healthcare intends to seek regulatory approval for a fixed-dose combination of DTG and 3TC later this year. DTG and 3TC, as a 2DR, is not yet approved for use by the US FDA.

Notes to editors
GEMINI 1 & 2 study design
The GEMINI studies are part of ViiV Healthcare's innovative clinical trial programme, which seeks to increase the body of evidence supporting the use of two-drug regimens for the treatment of HIV, in order to ensure that no patient is taking more medication than they need. The GEMINI studies are ongoing for 148 weeks.

GEMINI 1 (204861) and GEMINI 2 (205543) are duplicate, phase III, randomised, double-blind, multicentre, parallel group, non-inferiority studies. These studies evaluate a two-drug regimen of dolutegravir and lamivudine compared with a three-drug, first-line regimen of DTG + TDF/FTC in HIV-1 infected, antiretroviral therapy (ART)-naïve adult participants with baseline HIV-1 viral loads up to 500,000 copies per ml. The studies are designed to demonstrate the non-inferior efficacy, safety, and tolerability of once-daily dolutegravir and lamivudine compared to once-daily dolutegravir and the fixed-dose combination of TDF/FDC at 48 weeks in HIV-1-infected, ART-naïve participants.
For more information please search for NCT02831673 (GEMINI 1) or NCT02831764 (GEMINI 2)
on www.clinicaltrials.gov.

U.S INDICATIONS AND IMPORTANT SAFETY INFORMATION

About Tivicay® (dolutegravir)
Dolutegravir (Tivicay) is an integrase strand transfer inhibitor (INSTI) for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Tivicay is approved in over 100 countries across North America, Europe, Asia, Australia, Africa and Latin America.

TIVICAY (dolutegravir tablets
Professional Indication(s) and Important Safety Information
U.S. Indications and Usage
TIVICAY is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with:

- other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 30 kg
- rilpivirine 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 < 50 copies per mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent.

Important safety information: Tivicay (dolutegravir)
The following ISI is based on the Highlights section of the Prescribing Information for Tivicay. Please consult the full Prescribing Information for all the labelled safety information for Tivicay.

Contraindications

- Previous hypersensitivity reaction to dolutegravir.
- Coadministration with dofetilide.

Warnings and precautions

Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported. Discontinue TIVICAY and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction.

Hepatotoxicity has been reported in patients receiving dolutegravir-containing regimens. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations. Monitoring for hepatoxicity is recommended.

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.

Adverse reactions
The most common adverse reactions of moderate to severe intensity and incidence at least 2% (in those receiving TIVICAY in any one adult trial) are insomnia, fatigue, and headache.
Drug interactions

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

Drugs that are metabolic inducers may decrease the plasma concentrations of dolutegravir.

TIVICAY should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, TIVICAY and supplements containing calcium or iron can be taken together with food.

Use in specific populations

Pregnancy: TIVICAY should be used during pregnancy only if the potential benefit justifies the potential risk.

Lactation: Breastfeeding is not recommended.

Full US prescribing information including is available at:
https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Tivicay/pdf/TIVICAY-PI-

For the EU Summary of Product Characteristics, please visit:
https://www.medicines.org.uk/emc/medicine/28545

About Epivir® (lamivudine)
Lamivudine is a nucleoside analogue used in combination with other antiretroviral agents for the treatment of HIV infection. Lamivudine is available in branded (Epivir) and generic forms. Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

EPIVIR 300mg TABLETS

Professional Indication(s) and Important Safety Information

U.S. Indications and Usage
EPIVIR is a nucleoside analogue reverse transcriptase inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Limitations of Use: The dosage of this product is for HIV-1 and not HBV.

Important safety information (ISI): Epivir (lamivudine) tablets
The following ISI is based on the Highlights section of the Prescribing Information for Epivir. Please consult the full Prescribing Information for all the labelled safety information for Epivir.

Warning: Exacerbations of Hepatitis B, and different formulations of Epivir
See full prescribing information for complete boxed warning.

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 EPIVIR. Monitor hepatic function closely

in these patients and, if appropriate, initiate anti-hepatitis B treatment.

Patients with HIV-1 infection should receive only dosage forms of EPIVIR appropriate for treatment of HIV-1.

Contraindications

EPIVIR is contraindicated in patients with previous hypersensitivity reaction to lamivudine.

Warnings and precautions

Co-infected HIV-1/HBV Patients: Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported.

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

Hepatic decompensation, some fatal, has occurred in HIV-1/HCV co-infected patients receiving interferon and ribavirin-based regimens. Monitor for treatment-associated toxicities. Discontinue EPIVIR as medically appropriate and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both.

Pancreatitis: Use with caution in pediatric patients with a history of pancreatitis or other significant risk factors for pancreatitis. Discontinue treatment as clinically appropriate. (5.4)

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.

Lower virologic suppression rates and increased risk of viral resistance were observed in pediatric subjects who received EPIVIR oral solution concomitantly with other antiretroviral oral solutions compared with those who received tablets. An all-tablet regimen should be used when possible.

Adverse reactions

The most common reported adverse reactions (incidence greater than or equal to 15%) in adults were headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough.

The most common reported adverse reactions (incidence greater than or equal to 15%) in pediatric subjects were fever and cough.

Drug interactions

Sorbitol: Coadministration of lamivudine and sorbitol may decrease lamivudine concentrations; when possible, avoid chronic coadministration.

Use in specific populations

Lactation: Women infected with HIV should be instructed not to breastfeed due to potential for HIV transmission.

Full US prescribing information including is available at:
https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Epivir/pdf/EPIVIR-PI-PIL

For the EU Summary of Product Characteristics, please visit:
https://www.medicines.org.uk/emc/product/943

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 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 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.

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.

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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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