GLAXOSMITHKLINE PLC
Form 6-K
April 09, 2019

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 09 April 2019

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: 8 April 2019, London UK - LSE Announcement

US FDA approves ViiV Healthcare's Dovato (dolutegravir/lamivudine), the first, once-daily, single-tablet, two-drug regimen for treatment-naïve HIV-1 adults

Approval based on GEMINI pivotal trials in which Dovato achieved non-inferior efficacy compared to a dolutegravir-based, traditional, three-drug regimen through 48 weeks, with no cases of resistance1

Dovato strengthens ViiV Healthcare's industry-leading portfolio of innovative treatment approaches for people living with HIV

London, 8 April 2019 - ViiV Healthcare today announced that the US Food and Drug Administration (FDA) approved Dovato, a complete, once-daily, single-tablet regimen of dolutegravir (DTG) 50 mg and lamivudine (3TC) 300 mg for the treatment of HIV-1 infection in adults with no antiretroviral (ARV) treatment history and with no known resistance to either DTG or 3TC. Dovato, a two-drug regimen (2DR), reduces exposure to the number of ARVs from the start of treatment, while still maintaining the efficacy and high barrier to resistance of a traditional DTG-based three-drug regimen.1

Deborah Waterhouse, CEO, ViiV Healthcare, said: "Building on our innovative portfolio of medicines, Dovato is powered by dolutegravir, an antiretroviral included in multiple combination therapies and the most prescribed integrase inhibitor in the world, 2 coupled with the established profile of lamivudine. With Dovato, the first complete, single-tablet, two-drug regimen for treatment-naïve adults, ViiV Healthcare is delivering what patients are requesting-a chance to treat their HIV-1 infection with as few drugs as possible, marking a significant step in HIV treatment."

The approval of Dovato is supported by the landmark global GEMINI 1 and 2 studies that included more than 1,400 HIV-1 infected adults. In these studies, DTG + 3TC demonstrated non-inferiority based on plasma HIV-1 RNA <50 copies per milliliter (c/mL), a standard measure of HIV-1 control, at Week 48 when compared to a three-drug regimen of DTG and two nucleoside reverse transcriptase inhibitors (NRTIs), tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in treatment-naïve, HIV-1 infected adults. The safety results for DTG + 3TC seen in GEMINI 1 and 2 were consistent with the product labelling for DTG and 3TC. No patient who experienced virologic failure in either treatment arm developed treatment-emergent resistance.1

Pedro Cahn, principal investigator for the GEMINI study program said: "People are now living longer with HIV and will spend a lifetime taking drugs to suppress their virus. The approval of the fixed dose combination of dolutegravir and lamivudine, a complete, single-tablet, two-drug regimen, marks a pivotal moment in the treatment of HIV-1. Treatment-naïve people living with the virus have a powerful option that delivers non-inferior efficacy to a dolutegravir-based three-drug regimen, allowing them to take fewer ARVs and get and remain suppressed."

Jeff Berry, Test Positive Aware Network (TPAN), said: "The approval of Dovato is a welcome paradigm shift, as it brings an innovative treatment approach to newly diagnosed adults with HIV-1. By exposing patients to fewer drugs at the start of treatment, the hope is to help address concerns arising from overall management of prolonged ARV therapy."

DTG/3TC as a complete, once-daily, single-tablet, two-drug regimen for HIV-1 therapy is currently under review by the European Medicines Agency (EMA) and regulatory authorities in Canada, Australia, Switzerland, and South Africa and several additional submissions are planned throughout 2019.

Notes to editors

About Dovato (dolutegravir/lamivudine)
Dovato is approved as a complete regimen for the treatment of HIV-1 infection in adults with no known antiretroviral treatment history and with no known substitutions associated with resistance to either dolutegravir or lamivudine.Dovato is a once-daily, single-tablet, two-drug regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir (Tivicay, 50 mg) with the nucleoside analogue reverse transcriptase inhibitor (NRTI) lamivudine (Epivir, 300 mg).

Like a DTG-based three-drug regimen, Dovato uses only two drugs to inhibit the viral cycle at two different sites. INSTIs, like dolutegravir, inhibit 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. Lamivudine is an NRTI that works by interfering with the conversion of viral RNA into DNA which in turn stops the virus from multiplying.

GEMINI 1 and 2 study design
GEMINI 1 (204861) and GEMINI 2 (205543) are duplicate, Phase III, randomized, double-blind, multicenter, 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 milliliter. The trials are designed to study the efficacy and safety of once-daily dolutegravir and lamivudine compared to once-daily dolutegravir and the fixed-dose combination of TDF/FTC at 48 weeks in HIV-1-infected, ART-naïve adult participants. The GEMINI studies are ongoing for 148 weeks. For more information, please search for NCT02831673 (GEMINI 1) or NCT02831764 (GEMINI 2) on www.clinicaltrials.gov.

IMPORTANT SAFETY INFORMATION (ISI)

The following ISI is based on the Highlights section of the Prescribing Information for Dovato. Please consult the full Prescribing Information for all the labeled safety information for Dovato.

WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV-1): EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment

DOSAGE AND ADMINISTRATION

Prior to or when initiating DOVATO, test patients for HBV infection.

Pregnancy Testing: Perform pregnancy testing before initiation of DOVATO in individuals of childbearing potential.

One tablet taken orally once daily with or without food.

The dolutegravir dose (50 mg) in DOVATO is insufficient when coadministered with carbamazepine or rifampin. If DOVATO is coadministered with carbamazepine or rifampin, take one tablet of DOVATO once daily, followed by an additional dolutegravir 50-mg tablet, approximately 12 hours from the dose of DOVATO.

CONTRAINDICATIONS

Prior hypersensitivity reaction to dolutegravir or lamivudine.

Coadministration with dofetilide.

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury, have been reported with dolutegravir. Discontinue DOVATO 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 a dolutegravir-containing regimen. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with DOVATO. Monitoring for hepatotoxicity is recommended.

Embryo-fetal toxicity may occur when used at the time of conception and in early pregnancy. Avoid use of DOVATO at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects. Advise individuals of childbearing potential to use effective contraception.

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

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

ADVERSE REACTIONS
The most common adverse reactions (all grades) observed in ≥2% (in those receiving DOVATO) were headache, diarrhea, nausea, insomnia, and fatigue.

DRUG INTERACTIONS

DOVATO is a complete regimen for the treatment of HIV-1 infection; therefore, coadministration with other antiretroviral drugs for the treatment of HIV-1 infection is not recommended.

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

USE IN SPECIFIC POPULATIONS

Pregnancy: Avoid use of DOVATO at the time of conception through the first trimester due to the risk of neural tube defects.

Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission.

Females and males of reproductive potential: Pregnancy testing and contraception are recommended in individuals of childbearing potential.

Renal Impairment: DOVATO is not recommended in patients with creatinine clearance less than 50 mL/min.

Hepatic Impairment: DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C).

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. ViiV'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. This year marks 10 years of ViiV Healthcare innovating on behalf of people living with HIV and advancing our efforts to leave no person living with HIV behind.

For more information on the company, its management, portfolio, pipeline and commitment, please visit www.viivhealthcare.com.

About ViiV Healthcare's Patient Assistance Program

ViiV Healthcare is committed to providing assistance to eligible people living with HIV who need our medicines. ViiV Healthcare's centralized service, ViiV Connect, provides comprehensive information on access and coverage to help patients get their prescribed ViiV Healthcare medicines whether they are insured, underinsured or uninsured. ViiV Connect provides one-on-one support from dedicated access coordinators, as well as having an integrated website, one site with many resources, including a portal. For more information on ViiV Connect, visit www.viivconnect.com.

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. 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 2018.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com.

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References

1. Dovato (dolutegravir/lamivudine) Prescribing Information. U.S. Approval 2019.
2. Number of Patients on Dolutegravir, Worldwide, IMS data. August 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: April 09, 2019

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc