GLAXOSMITHKLINE PLC
Form 6-K
October 18, 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 18 October 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

18 October 2018, London, UK - LSE Announcement

ViiV Healthcare submits New Drug Application to US FDA for single-tablet, two-drug regimen of dolutegravir and lamivudine for treatment of HIV

Priority review voucher used with NDA submission with anticipated target action date of six months

London, UK 18 October 2018 - ViiV Healthcare today announced it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for a single-tablet, two-drug regimen of dolutegravir (DTG) and lamivudine (3TC) for the treatment of HIV-1 infection.

The submission is based on the global GEMINI 1 & 2 studies that included more than 1400 HIV-1 infected adults with baseline viral loads up to 500,000 c/mL. The results of these studies were presented at the 2018 International AIDS Society meeting in July.

Deborah Waterhouse, CEO, ViiV Healthcare, said, "We have now entered an exciting new era of treatments for people living with HIV. ViiV Healthcare believes that a two-drug regimen has the potential to be an important option for many who may spend their lifetime taking drugs to control their virus. This regulatory submission is the next step in the two-drug regimen journey and reinforces our belief that many patients can control their disease with two drugs instead of three or more."

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer of ViiV Healthcare, said: "This NDA, if approved, will provide a single-tablet, two-drug regimen option with DTG and 3TC that we believe could have an impact on the existing HIV treatment strategy and serve as a valuable option for people living with HIV. ViiV Healthcare is committed to challenging the status quo with innovations that are based on our belief that no one should take more medicines than they need."

A priority review voucher was submitted to the FDA along with the NDA. Under the Prescription Drug User Fee Act, the anticipated target action date for this NDA with a priority review voucher is six months after receipt of the application by the FDA. A marketing authorisation application (MAA) to the European Medicines Agency (EMA) was submitted in September and other global regulatory submissions for DTG and 3TC as a single-tablet, two-drug regimen for HIV-1 therapy are anticipated in the coming months.

Notes to editors

GEMINI 1 & 2 study design
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 trials are designed to study the 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. 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.

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) 50 mg 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.

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

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

Lactation: Breastfeeding is not recommended.

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

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.

ViiV Healthcare Media enquiries:	Melinda Stubbee	+1 919 491 0831
	Audrey Abernathy	+1 919 605 4521
GSK Global Media enquiries:	Simon Steel	+44 (0) 20 8047 5502
	Sarah Spencer	+1 215 751 3335
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 20 8047 5194
	Mel Foster-Hawes	+44 (0) 20 8047 0674
	Danielle Smith	+44 (0) 20 8047 0932
	James Dodwell	+44 (0) 20 8047 2406
	Jeff McLaughlin	+1 215 751 7002

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: October 18, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc