GLAXOSMITHKLINE PLC
Form 6-K
August 16, 2016

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 16 August 2016

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

ViiV Healthcare launches phase III programme evaluating a two-drug regimen combining dolutegravir and lamivudine for HIV-1 treatment

London, UK, 15 August 2016 - ViiV Healthcare today announced the start of a phase III programme to support regulatory filings for a two-drug regimen of dolutegravir (Tivicay®) and lamivudine (Epivir®) as a treatment for HIV-1 infection in adults who have not received prior antiretroviral therapy.

The phase III programme comprises two identical studies (GEMINI 1 and 2) comparing a two-drug regimen of dolutegravir plus lamivudine with a three-drug regimen of dolutegravir plus the fixed-dose tablet tenofovir/emtricitabine (Truvada®). The studies together will include approximately 1,400 men and women living with HIV and are being conducted at research centres in Europe, Central and South America, North America, South Africa and Asia Pacific.

HIV care is a long-term prospect for those living with the disease, requiring life-long adherence to treatment. Since the introduction of highly active antiretroviral therapy 20 years ago, HIV treatment regimens have predominantly included three antiretroviral drugs.[1],[2] ViiV Healthcare is looking to the future and exploring how HIV treatment could evolve to reduce drug exposure and improve treatment adherence, while maintaining the level of efficacy achieved with three-drug regimens.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "We believe the clinical profile for dolutegravir presents an important opportunity to investigate the possibility of first-line treatment of HIV with a two-drug regimen. With this ambitious phase III programme, we will explore whether this two-drug regimen can fundamentally change the existing HIV treatment strategy, reducing the number of medications and potentially streamlining treatment regimens for people living with HIV."

The GEMINI trials are the third development programme undertaken by ViiV Healthcare to investigate a two-drug regimen for the treatment of HIV.

GEMINI 1 & 2: Study design
Each study is a randomised, double-blind study and will compare the safety, efficacy, and tolerability of a two-drug regimen of dolutegravir plus lamivudine administered once daily, against dolutegravir plus two nucleoside reverse transcriptase inhibitors (tenofovir/emtricitabine fixed-dose combination) administered once daily in HIV-1 infected adult subjects that have not previously received antiretroviral therapy.

Each study will include approximately 700 subjects who will be randomised 1:1 to receive dolutegravir plus lamivudine or dolutegravir plus tenofovir/emtricitabine fixed-dose combination. Both studies are designed to demonstrate the non-inferior antiviral activity of a dolutegravir plus lamivudine regimen to that of dolutegravir plus tenofovir/emtricitabine fixed-dose combination. The primary efficacy endpoint will be measured at Week 48 and the study will continue to evaluate the long term antiviral activity, tolerability and safety of dolutegravir plus lamivudine through Week 148.
For more information please search for NCT02831673 (GEMINI 1) or NCT02831764 (GEMINI 2) on www.clinicaltrials.gov.

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.

About 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.

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. 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 new HIV medicines, 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.

TIVICAY® (dolutegravir) tablets
Professional Indication(s) and Important Safety Information
Note: this is taken from the US label and local variations apply. Please refer to applicable local labelling

FDA 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.

Limitations of Use:
Use of TIVICAY in INSTI-experienced patients should be guided by the number and type of baseline INSTI substitutions. The efficacy of TIVICAY 50 mg twice daily is reduced in patients with an INSTI-resistance Q148 substitution plus 2 or more additional INSTI-resistance substitutions including T66A, L74I/M, E138A/K/T, G140S/A/C, Y143R/C/H, E157Q, G163S/E/K/Q, or G193E/R

Important Safety Information
Contraindications:
TIVICAY is contraindicated in patients:
with previous hypersensitivity reaction to dolutegravir
receiving dofetilide (antiarrhythmic)

Hypersensitivity Reactions:
Hypersensitivity reactions have been reported and were characterised by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. The events were reported in <1% of subjects receiving TIVICAY in Phase 3 clinical trials
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. Monitor clinical status, including liver aminotransferases, and initiate appropriate therapy if hypersensitivity reaction is suspected
Effects on Serum Liver Biochemistries in Patients with Hepatitis B or C Co-infection:
Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of TIVICAY. 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

Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during therapy with TIVICAY are recommended in patients with underlying hepatic disease such as hepatitis B or C
Fat Redistribution or accumulation has been observed in patients receiving antiretroviral therapy

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported

Adverse Reactions: The most commonly reported (≥2%) adverse reactions of moderate to severe intensity in treatment-naïve adult subjects in any one trial receiving TIVICAY in a combination regimen were insomnia (3%), fatigue (2%), and headache (2%).

Drug Interactions:

Coadministration of TIVICAY with certain inducers of UGT1A and/or CYP3A may reduce plasma concentrations of dolutegravir and require dose adjustments of TIVICAY

Administer TIVICAY 2 hours before or 6 hours after taking polyvalent 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 with food

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

Pregnancy: TIVICAY should be used during pregnancy only if the potential benefit justifies the potential risk. An Antiretroviral Pregnancy Registry has been established.

Nursing Mothers: Breastfeeding is not recommended due to the potential for HIV transmission and the potential for adverse reactions in nursing infants.

EPIVIR® (lamivudine) tablets
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 for hepatitis B virus (HBV).

Important Safety Information (ISI)
The following ISI is based on the Highlights section of the US Prescribing Information for EPIVIR. Please consult the full Prescribing Information for all the labeled safety information for EPIVIR.

BOXED WARNING: LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, EXACERBATIONS OF HEPATITIS B, and DIFFERENT FORMULATIONS OF EPIVIR
See full prescribing information for complete boxed warning.

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

Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with 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.

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.

Immune reconstitution syndrome and redistribution/accumulation of body fat have 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.

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.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding not recommended.

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[1] Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents; p. F-4. Available at www.aidsinfo.nih.gov/guidelines Last accessed August 2016

[2] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach - Second edition. WHO June 2016; p. 97. Available at http://www.who.int/hiv/pub/arv/arv-2016/en/ Last accessed August 2016

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: August 16, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc