GLAXOSMITHKLINE PLC
Form 6-K
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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 08 February 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 8 February, 2018, London UK

PRESS RELEASE
ViiV Healthcare launches eighth phase III study in two-drug regimen programme for HIV-1 treatment

TANGO study will investigate dolutegravir (TIVICAY) and lamivudine (EPIVIR) in patients with HIV who have achieved viral suppression on a tenofovir alafenamide fumarate-based regimen

London, UK 8 February 2018 - Today ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, announced the start of a phase III study designed to establish if adults with HIV-1 with current virologic suppression on a tenofovir alafenamide fumarate (TAF)-based regimen of at least three drugs are able to maintain viral suppression upon switching to a two-drug regimen (2DR) of dolutegravir (TIVICAY) and lamivudine (EPIVIR). TANGO will seek to enrol approximately 550 adults with HIV-1, from clinical trial sites in North America, Europe, Australia, and Japan.

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 the number of drugs to which a patient is exposed, while maintaining the level of efficacy achieved with three-drug regimens.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, said: "We are asking a simple question in the TANGO study - can virally suppressed people with HIV reduce the number of medicines in their HIV treatment regimen while maintaining viral suppression? If the data show the answer to be yes, this may allow healthcare providers to address issues of long-term toxicity by reducing exposure to antiviral agents over a lifetime of treatment. We believe that with its high barrier to resistance, dolutegravir has the right clinical profile to be a core part of 2DRs for the treatment of HIV-1 and look forward to seeing the results of TANGO in 2019."

The TANGO trial is designed to demonstrate the non-inferior antiviral activity of switching to dolutegravir and lamivudine compared to continuation of a TAF-based regimen over 48 weeks in virologically suppressed subjects. TANGO will characterise patient satisfaction as well as the long-term antiviral activity, tolerability and safety of a 2DR of dolutegravir and lamivudine through to 96 weeks.

The TANGO study follows the GEMINI studies' investigation of the 2DR of dolutegravir and lamivudine in treatment-naïve patients with HIV-1. Results from those trials are anticipated later this year.
TIVICAY and EPIVIR are trademarks owned by or licensed to the ViiV Healthcare group of companies.

Notes to editors

About TANGO (this study does not yet have an NCT number)
TANGO is a phase III, randomised, open-label, active-controlled, multicentre, parallel-group study to assess the non-inferior antiviral activity and safety of a two-drug regimen of dolutegravir and lamivudine compared to continuation on a TAF-based regimen in HIV-infected adults who are virologically suppressed and stable on a TAF-based regimen. Approximately 550 HIV-1 infected adults who are on a stable TAF-based regimen will be randomised 1:1 to switch to dolutegravir and lamivudine once daily for up to 96 weeks, or to continue their TAF-based regimen for 48 weeks. For patients in the TAF-based arm, if the HIV-1 RNA is <50 c/ml at the Week 48 visit, these study participants will switch to dolutegravir and lamivudine for the remainder of the study.

The primary endpoint for the study is the proportion of participants who meet the Snapshot virologic failure criteria at Week 48 using the Intent-to-Treat Exposed (ITT-E) population.

Other studies in ViiV Healthcare's phase III 2DR programme:

SWORD 1 and 2 (NCT02429791 and NCT02422797) - Two identical studies evaluating the safety and efficacy of switching virologically suppressed patients from a three- or four-drug antiretroviral regimen to a two-drug regimen of dolutegravir and rilpivirine (Janssen Sciences Ireland UC). Results presented at CROI 2017.
GEMINI 1 and 2 (NCT02831673 and NCT02831764) - Two identical studies comparing a two-drug regimen of dolutegravir plus lamivudine with a three-drug regimen of dolutegravir plus the fixed-dose tablet tenofovir/emtricitabine in treatment-naïve adults living with HIV. Results are anticipated in 2018.
ATLAS (NCT02951052) - Study evaluating the efficacy and safety of a two-drug regimen of long-acting, injectable cabotegravir and rilpivirine (Janssen Sciences Ireland UC) administered every 4 weeks compared to continuation of current ART of two nucleoside reverse transcriptase inhibitors (NRTIs) plus an integrase inhibitor (INI), non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor (PI). Results are anticipated in 2018.
FLAIR (NCT02938520) - Study evaluating the safety and efficacy of a two-drug regimen of intramuscular, long-acting, injectable cabotegravir and rilpivirine (Janssen Sciences Ireland UC) administered every four weeks in treatment-naïve adults living with HIV. Results are anticipated in 2018.
ATLAS 2M (NCT03299049) - Study evaluating the safety and efficacy of long-acting cabotegravir and long-acting rilpivirine (Janssen Sciences Ireland UC) administered every 8 weeks compared to long-acting cabotegravir and long-acting rilpivirine (Janssen Sciences Ireland UC) administered every 4 weeks. Results are anticipated in 2019.

About EPIVIR
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 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
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
CONTRAINDICATIONS:

TIVICAY is contraindicated in patients:

with previous hypersensitivity reaction to dolutegravir

receiving dofetilide (antiarrhythmic)

WARNINGS AND PRECAUTIONS:

Hypersensitivity Reactions:

Hypersensitivity reactions have been reported and were characterized 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

Hepatotoxicity:

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

Cases of hepatic toxicity, including elevated serum liver biochemistries, hepatitis, and acute liver failure, have also been reported in patients receiving a dolutegravir-containing regimen who had no pre-existing hepatic disease or other identifiable risk factors. Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ (abacavir, dolutegravir, and lamivudine)

Monitoring for hepatotoxicity is recommended

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

The concomitant use of TIVICAY and other drugs may result in known or potentially significant drug interactions (see Contraindications or Drug Interactions).

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

USE IN SPECIFIC POPULATIONS:

Pregnancy:

There are insufficient human data on the use of TIVICAY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.

Lactation:

Breastfeeding is not recommended due to the potential for HIV transmission and developing viral resistance in HIV-positive infants.

Pediatric Use:
Safety and efficacy of TIVICAY have not been established in pediatric patients weighing less than 30 kg or in any pediatric patients who are INSTI-experienced.

EPIVIR (lamivudine) tablets
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.
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPIVIR safely and effectively. See full prescribing information for EPIVIR.

EPIVIR (lamivudine) tablets for oral use
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 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.

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 HBV.

DOSAGE AND ADMINISTRATION

Adults: 300 mg daily, administered as either 150 mg twice daily or 300 mg once daily.

Pediatric Patients Aged 3 Months and Older: Administered either once or twice daily. Dose should be calculated on body weight (kg) and should not exceed 300 mg daily.

Patients with Renal Impairment: Doses of EPIVIR must be adjusted in accordance with renal function.

DOSAGE FORMS AND STRENGTHS

Tablets: 150 mg, scored.

Tablets: 300 mg.

Oral Solution: 10 mg per mL.

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. 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.

To report SUSPECTED ADVERSE REACTIONS, contact ViiV Healthcare at 1-888-844-8872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding not recommended.

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.

GSK - 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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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 2016.

[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 February 2018
[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 February 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: February 08, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc