GLAXOSMITHKLINE PLC
Form 6-K
November 27, 2017

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 27 November 2017

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

PRESS RELEASE
ViiV Healthcare starts third phase III HIV treatment study investigating long-acting two-drug regimen of cabotegravir plus rilpivirine

The ATLAS-2M study will evaluate injections every two months in virally suppressed patients

London, UK 27 November 2017 - 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 with a two-drug regimen of long-acting, injectable cabotegravir (ViiV Healthcare) and long-acting injectable rilpivirine (Janssen Sciences Ireland UC) in virally suppressed adults with HIV-1 infection.

The ATLAS-2M study is designed to demonstrate the non-inferior antiviral activity, at 48 weeks of treatment, of long-acting cabotegravir and long-acting rilpivirine administered every eight weeks compared with long-acting cabotegravir and long-acting rilpivirine administered every four weeks. ATLAS-2M will also assess patient satisfaction and provide comparative data on antiviral activity, pharmacokinetics, safety and tolerability out to 96 weeks. Initial results from this study are anticipated in 2019.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare said: "We have a patient-centred approach to innovation that seeks to transform how HIV is treated. Our focus on 2-drug regimens is key to this strategy. HIV treatment regimens that do not require daily dosing could be an important part of making HIV feel like a smaller part of patients' lives and with the ATLAS-2M study, we are evaluating the possibility of maintaining viral suppression with six treatments per year of long-acting cabotegravir and long-acting rilpivirine."

This study follows the phase III ATLAS1 (virally suppressed patients) and FLAIR2 (treatment-naïve patients) studies of monthly dosing with long-acting cabotegravir and long-acting rilpivirine for the treatment of HIV-1 infection. Results from those trials are anticipated in 2018.

Notes to editors

About ATLAS-2M (NCT03299049)
The Antiretroviral Therapy as Long Acting Suppression every 2 Months (ATLAS-2M) study is designed to demonstrate the non-inferior antiviral activity and safety of long-acting cabotegravir and long-acting rilpivirine administered every 8 weeks (Q8W) compared with long-acting cabotegravir and long-acting rilpivirine administered every 4 weeks (Q4W) over a 48-week treatment period in adult HIV-1-infected participants. Participants will be enrolled from Australia, Argentina, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden and the United States.
Approximately half of the participants in ATLAS-2M will rollover from the ongoing ATLAS trial, which commenced in October 2016. Additional participants will be recruited to support a targeted total sample size of approximately 1,020 participants. Participants will be divided into two groups: Group 1 will include participants receiving current anti-retroviral standard of care (SOC) therapy whereas Group 2 will include participants currently receiving long-acting cabotegravir and long-acting rilpivirine Q4W in the ATLAS study. Participants in both groups will be randomised to receive long-acting cabotegravir and long-acting rilpivirine Q4W or Q8W. Following an oral lead in for SOC participants, the study will be carried out in three phases including a screening phase, maintenance phase and extension phase. Participants choosing not to enter the extension phase can complete their study participation at the Week 100 visit and enter the 52-week Long-Term Follow-Up Phase.

About cabotegravir

Cabotegravir is an investigational integrase strand transfer inhibitor (INSTI) and is not approved by regulatory authorities anywhere in the world. Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV and is currently being evaluated as a long-acting formulation for intramuscular injection (with a once-daily oral tablet being used to establish safety and tolerability in individuals prior to long-acting injection).

About rilpivirine
EDURANT® (rilpivirine), in combination with other antiretroviral agents, is a non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy.

The following points should be considered when initiating therapy with EDURANT®:

More EDURANT®-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥50 copies/mL) compared to EDURANT®-treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL

Regardless of HIV-1 RNA at the start of therapy, more EDURANT®-treated subjects with CD4+ cell count less than 200 cells/mm3 experienced virologic failure compared to EDURANT®-treated subjects with CD4+ cell count greater than or equal to 200 cells/mm3

The observed virologic failure rate in EDURANT®-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz

More subjects treated with EDURANT®developed tenofovir and lamivudine/emtricitabine-associated resistance compared to efavirenz

EDURANT® is not recommended for patients less than 12 years of age.

Important Safety Information

Contraindications

Coadministration of EDURANT® with the following drugs is contraindicated because significant decreases in rilpivirine plasma concentrations may occur due to CYP3A enzyme induction or gastric pH increase, which may result in loss of virologic response and possible resistance and cross-resistance: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, proton pump inhibitors such as esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole, systemic dexamethasone (more than a single dose), and products containing St. John's wort (Hypericum perforatum)

Warnings and Precautions

Skin and Hypersensitivity Reactions:Severe skin and hypersensitivity reactions have been reported during the postmarketing experience, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries. EDURANT® should be discontinued immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, including but not limited to, severe rash or rash accompanied by fever, blisters, mucosal involvement, conjunctivitis, facial edema, angioedema, hepatitis or eosinophilia. Clinical status including

laboratory parameters should be monitored and appropriate therapy should be initiated

Depressive Disorders: Severe depressive disorders, defined as depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, and suicidal ideation, have been reported with EDURANT®. Immediate medical evaluation is recommended for severe depressive symptoms

Hepatotoxicity: Hepatic adverse events were reported. Patients with underlying hepatic disease, including hepatitis B or C, or marked elevations in transaminases before treatment may be at increased risk for worsening or development of transaminase elevations. Monitor liver function tests (LFTs) before and during treatment. A few hepatotoxicity cases occurred in patients with no pre-existing hepatic disease or other identifiable risk factors; therefore, monitoring of LFTs should be considered in all patients

Fat Redistribution: Redistribution and/or accumulation of body fat have been observed in patients receiving ARV therapy. The causal relationship, mechanism, and long-term consequences of these events have not been established

Immune Reconstitution Syndrome has been reported in patients treated with combination ARV therapy, including EDURANT®. Autoimmune disorders (such as Graves disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment

Drug Interactions

EDURANT® should be used with caution when coadministered with drugs that may reduce the exposure of rilpivirine, such as antacids and H2-receptor antagonists

Concomitant use of EDURANT® with rifabutin may cause a decrease in the plasma concentrations of rilpivirine. Please read the Dosage and Administration Section of the Prescribing Information for more details regarding the concomitant use of EDURANT® and rifabutin

EDURANT® should be used with caution when coadministered with a drug with a known risk of Torsade de Pointes

EDURANT® should not be used in combination with NNRTIs

This is not a complete list of potential drug interactions.

Please see full Prescribing Information for more details.

Use in Specific Populations

Hepatic Impairment: EDURANT® should be used with caution in patients with severe hepatic impairment (Child-Pugh Class C) as pharmacokinetics of EDURANT® have not been evaluated in these patients

Pregnancy Category B: EDURANT® should be used during pregnancy only if the potential benefit justifies the potential risk. No adequate and well-controlled studies have been conducted in pregnant women

Adverse Reactions

The most common adverse drug reactions reported (incidence >2%) of at least moderate intensity (≥ Grade 2) in patients taking EDURANT® through 96 weeks were depressive disorders (5%), headache (3%), insomnia (3%), and rash (3%)

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.

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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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.

1Study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen in virologically suppressed HIV-1-infected adults. Available at: https://clinicaltrials.gov/ct2/show/NCT02951052?term=ATLAS+cabotegravir&rank=1. Last accessed November 2017.

2 Study to evaluate the efficacy, safety, and tolerability of long-acting intramuscular cabotegravir and rilpivirine for maintenance of virologic suppression following switch from an integrase inhibitor in HIV-1 infected therapy naïve participants. Available at: https://clinicaltrials.gov/ct2/show/NCT02938520?term=FLAIR+Cabotegravir&rank=1. Last accessed November 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: November 27, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc