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 29 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

Issued: 29 October 2018, London UK - LSE Announcement

ViiV Healthcare presents three-year data for investigational long-acting injectable, two-drug HIV regimen

LATTE-2 study shows high rates of virologic response and long-term durability with the long-acting, injectable, two-drug regimen over 160 weeks

London, UK 29 October 2018 - ViiV Healthcare today presented three-year results from LATTE-2,[1] a phase IIb study investigating a long-acting, two-drug, injectable regimen of cabotegravir and rilpivirine. At 160 weeks, the long-acting regimen, administered either every eight weeks or every four weeks, demonstrated high rates of virologic response, long-term durability of virologic response and good overall tolerability. These results were presented at the HIV Glasgow Drug Therapy meeting in Scotland.

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer, ViiV Healthcare, said, "Our two-drug regimen research efforts explore a number of treatment options that look beyond viral load and focus on addressing the unresolved issues that many people living with HIV face. The LATTE-2, three-year data show cabotegravir and rilpivirine as a long-acting injectable regimen may provide an alternative to daily pills, reducing the number of annual doses from 365 to 12. It is encouraging to see these long-term results."

At 160 weeks, 90% (104/115) and 83% (95/115) of the patients receiving the injectable regimen of cabotegravir and rilpivirine every eight and four weeks, respectively, remained virally suppressed. Of the patients on the oral comparator arm who elected to switch to the injectable regimen at Week 96, 97% (33/34) and 100% (10/10) remained virally suppressed on every eight- and four-week dosing schedule, respectively, at Week 160. Through Week 48, two patients developed protocol-defined virologic failure (PVDF) on the every-eight-week dosing arm, one with treatment-emergent, non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) resistance. No additional PVDF cases were observed on any arm between Week 48 and Week 160.[2]

A majority of participants reported an injection site reaction (ISR) through Week 160, of which 85% were mild and 14% were moderate. Eighty-seven percent of ISRs resolved within seven days. Excluding ISRs, the most common adverse events (AEs) were nasopharyngitis (38%), diarrhoea (22%), and headache (22%). Three percent (3/115; Q8W) and 10% (12/115; Q4W) of patients had AEs leading to withdrawal or discontinuation and only 3/274 patients had ISRs leading to discontinuation through Week 160.

The long-acting regimen of cabotegravir and rilpivirine is being investigated in three phase III studies: FLAIR,[3] ATLAS[4] and ATLAS-2M.[5] The ATLAS studies are evaluating the safety and efficacy of the four-week and eight-week dosing regimen in people living with HIV who are suppressed on any three-drug oral regimen with two NRTIs, while FLAIR is looking at people living with HIV who are suppressed on TRIUMEQ (DTG/ABC/3TC).

Patients in LATTE-2 were first put on an oral, three-drug regimen for 20 weeks, then were randomised to receive either the long-acting injectable (LAI) regimen every four or every eight weeks; or to continue the three-drug, oral regimen. After 96 weeks, patients on the LAI regimen were extended through to 160 weeks and patients on the oral regimen were given the option of transitioning to the LAI regimen either every four or eight weeks.

Notes to editors

About LATTE-2
LATTE-2[6] is a phase IIb, multicentre, parallel-group, open-label study in ART-naïve HIV-infected adults designed to test the antiviral activity, tolerability, and safety of two intramuscular dosing regimens of a long-acting, two-drug regimen of cabotegravir and rilpivirine. After a 20-week induction period on oral cabotegravir and abacavir/lamivudine, suppressed patients were randomized 2:2:1 to receive the long-acting injectable cabotegravir and rilpivirine every eight weeks, every four weeks or to continue the oral cabotegravir and abacavir/lamivudine. After 96

weeks patients on the oral cabotegravir and abacavir/lamivudine regimen chose an injectable regimen of every eight or four weeks in the extension phase.2

About cabotegravir

Cabotegravir is an investigational integrase inhibitor (INI) 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 and also as a once-daily oral tablet for use as a lead-in to establish the tolerability of cabotegravir prior to long-acting injection.

About rilpivirine

Edurant® (rilpivirine) is a once daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used for the treatment of human immunodeficiency virus (HIV-1) infection in combination with other antiretroviral agents in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV RNA copies/mL. Long-acting rilpivirine is not approved by regulatory authorities anywhere in the world.

Rilpivirine was developed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Rilpivirine is approved in the U.S. and E.U. as Edurant® as a 25mg tablet taken once-a-day and is always taken with a meal. The most common side effects of Edurant include: depression, headache, trouble sleeping (insomnia) and rash.

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

INDICATIONS AND USAGE

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 12 years of age and older and weighing at least 35 kg 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

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

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 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
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
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
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-Barre 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: In a clinical trial, total rilpivirine exposures were generally lower during pregnancy compared to the postpartum period
Lactation: Women infected with HIV should be instructed not to breastfeed due to the potential for HIV transmission

This list of uses in specific populations is not complete.

Please refer to the EDURANT® Prescribing Information for additional information.

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%)

This is not a complete list of all adverse drug reactions reported with the use of EDURANT®.

Please refer to the full Prescribing Information for a complete list of adverse drug reactions.

Click here for full US prescribing information.

Click here for the EU Summary of Product Characteristics.

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.

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 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.

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[1] Margolis D A et al. Safety, Efficacy and Durability of Long-acting CAB and RPV as Two Drug IM Maintenance Therapy for HIV-1 Infection: LATTE-2 Week 160 Results. Presented at HIV Glasgow, 28-31 October, 2018.
[2] Margolis, D. et al. Long-acting intramuscular cabotegravir and rilpivirine in adults with HIV-1 infection (LATTE-2):96-week results of a randomised, open-label, phase 2b, non-inferiority trial. The Lancet. July 2017. Published online: http://dx.doi.org/10.1016/S0140-6736(17)31917-7 Last accessed October 2018
[3] FLAIR: 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. https://clinicaltrials.gov/ct2/show/NCT02938520?term=FLAIR&cond=HIV&rank=2. Last accessed October 2018.
[4] ATLAS: Study 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 https://clinicaltrials.gov/ct2/show/NCT02951052?term=ATLAS&cond=HIV&rank=3. Last accessed October 2018.
[5] ATLAS-2M: Efficacy, Safety and Tolerability Study of Long-acting Cabotegravir Plus Long-acting Rilpivirine (CAB LA + RPV LA) in Human-immunodeficiency Virus-1 (HIV-1) Infected Adults https://clinicaltrials.gov/ct2/show/NCT03299049?term=ATLAS-2M&rank=1. Last accessed October 2018.
[6] LATTE-2: A Phase IIb Study to Evaluate a Long-Acting Intramuscular Regimen for Maintenance of Virologic Suppression (Following Induction With an Oral Regimen of GSK1265744 and Abacavir/Lamivudine) in Human Immunodeficiency Virus Type 1 (HIV-1) Infected, Antiretroviral Therapy-Naive Adult Subjects. https://clinicaltrials.gov/ct2/show/NCT02120352. Last accessed October 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: October 29, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc