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 30 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: Tuesday 30 October 2018, London UK - LSE Announcement

ViiV Healthcare reports positive 48-week results for second phase III study for novel, long-acting, injectable HIV-treatment regimen

FLAIR study meets primary endpoint, showing similar efficacy of a once-a-month, investigational, injectable two-drug regimen of cabotegravir and rilpivirine compared to a daily, oral three-drug, integrase-based regimen in virally-suppressed adults

London, 30 October 2018 - ViiV Healthcare today announced positive headline results from its global, Phase III FLAIR(First Long-Acting Injectable Regimen) study of a long-acting, injectable two-drug regimen (2DR) for the treatment of HIV. FLAIR was designed to study if adults infected with human immunodeficiency virus type-1 (HIV-1), whose virus is suppressed after 20 weeks on the daily, oral medicine Triumeq (abacavir/dolutegravir/lamivudine-ABC/DTG/3TC), remain suppressed at a similar rate to continuing Triumeq after switching to a monthly two-drug intramuscular long-acting injectable regimen of cabotegravir and rilpivirine.

The study showed long-acting cabotegravir and rilpivirine, injected once a month, had similar efficacy to Triumeq at Week 48 based on the proportion of participants with plasma HIV-1 RNA ≥50 copies per millilitre [c/mL] using the FDA Snapshot algorithm. Overall safety, virologic response and drug resistance results for the injectable regimen were consistent with results from the phase II LATTE and LATTE-2 studies.[1],[2]

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer of ViiV Healthcare, said: "The FLAIR data provide further evidence that a long-acting, injectable 2DR of cabotegravir and rilpivirine may offer an alternative to daily, oral therapy for people who have previously achieved viral suppression. This innovative dosing regimen could transform HIV therapy by reducing the number of days a person receives treatment from 365 to 12. Work on new methods of HIV treatment, including long-acting injectable therapies, supports our goal of making HIV a smaller part of the lives of people living with HIV."

Detailed results from the study will be presented at an upcoming scientific meeting.

FLAIR is ViiV Healthcare's second, phase III clinical trial to examine the safety and efficacy of monthly dosing of injectable formulations of cabotegravir and rilpivirine. The ATLAS (Antiretroviral Therapy as Long Acting Suppression) study, for which positive headline data was reported in August, compares a long-acting, injectable regimen against the continuation of current daily oral antiretroviral therapy in virologically suppressed, treatment-experienced patients.[3] ViiV Healthcare plans to use pooled data from the FLAIR and ATLAS studies for future regulatory submissions.

This investigational, long-acting, injectable regimen is being co-developed as part of a collaboration with Janssen Sciences Ireland UC and is not approved by regulatory authorities anywhere in the world.

Notes to editors
About FLAIR (NCT02938520)
FLAIR is phase III, randomised, open-label, multicentre, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of intramuscular, long-acting, injectable cabotegravir and rilpivirine in virologically suppressed adults living with HIV, following 20 weeks of induction therapy with Triumeq. The primary endpoint for FLAIR is the proportion of participants with a 'virologic failure' endpoint as per the FDA Snapshot algorithm at Week 48 compared to those continuing Triumeq (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population).

For further information please see https://clinicaltrials.gov/ct2/show/NCT02938520.

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 short-term use and oral bridging, 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 Triumeq® (abacavir, dolutegravir, and lamivudine) tablets
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
TRIUMEQ is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and in pediatric patients weighing at least 40 kg.

Limitations of Use:
TRIUMEQ alone is not recommended in patients with resistance-associated integrase substitutions or clinically suspected INSTI resistance because the dose of dolutegravir in TRIUMEQ is insufficient in these subpopulations. See full prescribing information for TIVICAY.

Important Safety Information

BOXED WARNING: HYPERSENSITIVITY REACTIONS AND EXACERBATIONS OF HEPATITIS B VIRUS (HBV) Hypersensitivity Reactions:
Serious and sometimes fatal hypersensitivity reactions have occurred with abacavir-containing products
Hypersensitivity to abacavir is a multi-organ clinical syndrome
Patients who carry the HLA-B*5701 allele are at a higher risk of experiencing a hypersensitivity reaction to abacavir, although hypersensitivity reactions have occurred in patients who do not carry the HLA-B*5701 allele
TRIUMEQ is contraindicated in patients with a prior hypersensitivity reaction to abacavir and in HLA-B*5701-positive patients. All patients should be screened for the HLA-B*5701 allele prior to initiating therapy or reinitiation of therapy with TRIUMEQ unless patients have a previously documented HLA-B*5701 allele assessment
Discontinue TRIUMEQ as soon as hypersensitivity reaction is suspected. Regardless of HLA-B*5701 status, permanently discontinue TRIUMEQ if hypersensitivity cannot be ruled out, even when other diagnoses are possible
Following a hypersensitivity reaction to TRIUMEQ, NEVER restart TRIUMEQ or any other abacavir-containing produc

Exacerbations of Hepatitis B:

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HBV and HIV-1 and have discontinued lamivudine, a component of TRIUMEQ. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment

CONTRAINDICATIONS

Do not use TRIUMEQ in patients who have the HLA-B*5701 allele
Do not use TRIUMEQ in patients with previous hypersensitivity reaction to abacavir, dolutegravir, or lamivudine
Do not use TRIUMEQ in patients receiving dofetilide
Do not use TRIUMEQ in patients with moderate or severe hepatic impairment

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
Clinically, it is not possible to determine whether a hypersensitivity reaction with TRIUMEQ would be caused by abacavir or dolutegra
Discontinue TRIUMEQ immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of TRIUMEQ. 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
Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ
Monitoring for hepatotoxicity is recommended

Lactic Acidosis and Severe Hepatomegaly with Steatosis:

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including abacavir and lamivudine. Female sex and obesity may be risk factors in patients treated with nucleoside analogues

Embryofetal Toxicity:

Avoid use of dolutegravir, a component of TRIUMEQ, at the time of conception through the first trimester due to the risk of neural tube defects
Perform pregnancy testing before use of dolutegravir and advise that consistent use of effective contraception is recommended while using dolutegravir in adolescents and adults of childbearing potential

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

The concomitant use of TRIUMEQ and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)
Use with Interferon- and Ribavirin-based Regimens:
Hepatic decompensation, some fatal, has occurred in HIV-1/hepatitis C virus (HCV) co-infected patients receiving combination antiretroviral therapy and interferon alfa with or without ribavirin. Patients receiving interferon alfa, with or without ribavirin, and TRIUMEQ should be closely monitored.

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

Myocardial Infarction (MI):
Several observational studies have reported an association with the use of abacavir and the risk of MI; meta-analyses of randomized controlled clinical trials did not show increased risk. To date, there is no established biological mechanism to explain a potential increase in risk. In totality, the available data show inconsistency; therefore, evidence for a causal relationship between abacavir and the risk of MI is inconclusive
The underlying risk of coronary heart disease should be considered when prescribing antiretroviral therapies, including abacavir, and action taken to minimize all modifiable risk factors (eg, hypertension, hyperlipidemia, diabetes mellitus, smoking)

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥2%, Grades 2-4) in treatment-naïve adults receiving TRIUMEQ were insomnia (3%), headache (2%), and fatigue (2%).

DRUG INTERACTIONS
Coadministration of TRIUMEQ with drugs that induce or inhibit UGT1A1 and/or CYP3A may affect plasma concentrations
Administer TRIUMEQ 2 hours before or 6 hours after taking antacids, polyvalent cation-containing products or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications Alternatively, TRIUMEQ and supplements containing calcium and iron can be taken with a meal
Consult the full Prescribing Information for TRIUMEQ 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 TRIUMEQ during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.
Avoid use of dolutegravir, a component of TRIUMEQ, at the time of conception through the first trimester of pregnancy. If planning a pregnancy or if pregnancy is confirmed while taking dolutegravir during the first trimester, if possible, switch to an alternative regimen
Lactation: Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
Females and Males of Reproductive Potential: Perform pregnancy testing before initiation of dolutegravir. Advise adolescents and adults of childbearing potential to consistently use effective contraception while taking dolutegravir
Patients with Impaired Renal Function: TRIUMEQ is not recommended in patients with creatinine clearance <50 mL/min
Patients with Impaired Hepatic Function: If a dose reduction of abacavir is required for patients with mild hepatic impairment, then the individual components of TRIUMEQ should be used

Full US Prescribing Information for TRIUMEQ is available at:https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Triumeq/pdf/TRIUMEQ

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.

Full US prescribing information including is available at:
http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/EDURANT-pi.pdf

For the EU Summary of Product Characteristics, please visit:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002264/WC500118874.pdf

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 visitwww.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 visitwww.gsk.com.

Inside Information

The information contained in this announcement is inside information.

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[1] Margolis D A et al. Cabotegravir plus rilpivirine, once a day, after induction with cabotegravir plus nucleoside reverse transcriptase inhibitors in antiretroviral-naive adults with HIV-1 infection (LATTE): a randomised phase 2b dose-ranging trial. The Lancet Infectious Diseases. Published online July 2015. Available at:http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(15)00152-8/abstract Last accessed September 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 September 2018
[3] https://clinicaltrials.gov/ct2/show/NCT03299049

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 30, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc