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 18 November 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

PRESS RELEASE
ViiV Healthcare launches phase III programme to evaluate a long-acting, injectable HIV treatment regimen

Studies will investigate monthly dosing with injectable cabotegravir and rilpivirine

London, UK, 18 November 2016 - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced the start of two phase III studies designed to evaluate an investigational long-acting, injectable regimen of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC) for the treatment of HIV-1 infection. The two studies, FLAIR (First Long-Acting Injectable Regimen) and ATLAS (Antiretroviral Therapy as Long-Acting Suppression), will examine the safety and efficacy of monthly dosing with the two-drug, injectable regimen in both treatment-naïve and treatment-experienced patients.

This investigational, long-acting, injectable regimen is being co-developed as part of a collaboration with Janssen Sciences Ireland UC.

While fixed-dose oral combination therapies have advanced HIV treatment by providing streamlined dosing through reduced pill burden, adherence to therapy continues to be essential to achieving viral suppression, and reducing the emergence of resistance mutations.[1] Therefore, it is important that new HIV treatment modalities, such as long-acting, injectable therapies, are investigated, as they may improve adherence and patient outcomes.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "Currently the treatment of HIV involves life-long therapy with multiple antiretrovirals, so it is important that we continue to improve on the durability, safety, tolerability, and convenience of treatment regimens. This phase III programme with long-acting cabotegravir and rilpivirine as a potential HIV treatment regimen is part of ViiV Healthcare's broader development programme evaluating two-drug treatment regimens and we look forward to seeing results from the ATLAS and FLAIR studies in 2018."

In FLAIR, treatment-naïve patients will be given a 20-week daily oral dolutegravir/abacavir/lamivudine (Triumeq®) regimen, and will then be randomised to switch to a regimen of long-acting, injectable cabotegravir and rilpivirine, or remain on oral therapy.[2] In ATLAS, treatment-experienced patients with suppressed viral load will be randomised to switch from their existing antiretroviral therapy (ART) to long-acting, injectable formulations of cabotegravir and rilpivirine or remain on oral ART.[3] Participants will be enrolled from investigative sites across Africa, the Americas, Asia and Europe.

The development of long-acting treatments for HIV forms part of a wider strategy to meet UNAIDS' ambitious aim[4] of ending the AIDS epidemic by 2030. As adherence to daily oral therapy varies among different populations,1 it is important to continue to evaluate additional treatment options, including regimens that require less frequent dosing, which may support adherence, and potentially improve patient outcomes.[5]

- Ends -

Notes to editors
About FLAIR (NCT02938520)2
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 treatment-naïve adults living with HIV. The primary endpoint for FLAIR is the proportion of participants

with a 'virologic failure' endpoint as per FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population).

Approximately 600 treatment-naïve participants will be enrolled.

About ATLAS (NCT02951052)3
ATLAS is a phase III, open-label, active-controlled, multicentre, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of long-acting, injectable cabotegravir and rilpivirine dosed every four 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). The primary endpoint for ATLAS is the proportion of participants with a 'virologic failure' endpoint as per FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population).

Approximately 600 participants who are on a stable antiretroviral regimen will be enrolled.

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, nanosuspension formulation for intramuscular injection and also as a once-daily oral tablet for induction 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.

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 overall safety and efficacy profile of rilpivirine is based on phase III clinical studies. The most common side effects of Edurant include: depression, headache, trouble sleeping (insomnia) and rash.

About dolutegravir/abacavir/lamivudine
Triumeq® is a once-daily dolutegravir-based regimen, containing the un-boosted integrase strand transfer inhibitor (INSTI) dolutegravir and the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir and lamivudine.

Two essential steps in the HIV life cycle are transcription - when the virus turns its RNA copy into DNA - and integration - the moment when viral DNA becomes part of the host cell's DNA. These processes require two enzymes called reverse transcriptase and integrase. NRTIs and INSTIs interfere with the action of the two enzymes to prevent the virus from replicating. This decrease in replication leads to less virus being available to cause subsequent infection of uninfected cells.

Triumeq® is a registered trademark of the ViiV Healthcare group of companies.
Edurant® is a registered trademark of Janssen Sciences Ireland UC.

TRIUMEQ® (abacavir, dolutegravir, and lamivudine) tablets

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.

Limitations of Use:
TRIUMEQ alone is not recommended in patients with:
o Current or past history of resistance to any components of TRIUMEQ
o 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 dolutegravir

Important Safety Information

BOXED WARNING: HYPERSENSITIVITY REACTIONS, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, 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 product

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

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
TRIUMEQ is contraindicated in patients:
who have the HLA-B*5701 allele
with prior hypersensitivity reaction to abacavir, dolutegravir, or lamivudine
receiving dofetilide (antiarrhythmic)
with moderate or severe hepatic impairment

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions to Dolutegravir:
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

Clinically, it is not possible to determine whether a hypersensitivity reaction with TRIUMEQ would be caused by abacavir or dolutegravir. Discontinue TRIUMEQ and other suspect agents immediately if signs or symptoms of hypersensitivity reaction develop

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 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

Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during therapy with TRIUMEQ are recommended in patients with underlying hepatic disease such as hepatitis B or C

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.

Fat Redistribution or accumulation has been observed in patients receiving antiretroviral therapy.

Myocardial Infarction (MI):

An observational study showed an increase in MI with abacavir; a sponsor-conducted, pooled analysis did not show increased risk. In totality, the available data are 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)

Use with Certain Antiretroviral Products: TRIUMEQ should not be administered concomitantly with other products containing abacavir or lamivudine.

ADVERSE REACTIONS: The most commonly reported (≥2%) adverse reactions of at least moderate intensity in treatment-naïve adults receiving TRIUMEQ were insomnia (3%), headache (2%), and fatigue (2%).

DRUG INTERACTIONS

Coadministration of TRIUMEQ with certain inducers of UGT1A and/or CYP3A may reduce plasma concentrations of dolutegravir. Consult the full Prescribing Information for TRIUMEQ for more information

Administer TRIUMEQ 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, TRIUMEQ and supplements containing calcium or iron can be taken with food

USE IN SPECIFIC POPULATIONS

Pregnancy Category C. TRIUMEQ 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

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, a component of TRIUMEQ, is required for patients with mild hepatic impairment, then the individual components should be used

EDURANT® Consumer Indication and Important Safety Information (ISI)
About EDURANT®

EDURANT® (rilpivirine) is a prescription HIV medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1)
in adults:

- Who have never taken HIV medicines before, and
- Who have an amount of HIV in their blood (called "viral load") that is no more than 100,000 copies/mL. Your healthcare professional will measure your viral load

EDURANT® should be taken in combination with other HIV medicines. Your healthcare professional will work with you to find the right combination of HIV medicines

It is important that you remain under the care of your healthcare professional during treatment with EDURANT

EDURANT® is not recommended for patients less than 18 years of age

EDURANT® does not cure HIV infection or AIDS. You should remain on your
HIV medications without stopping to ensure that you control your HIV infection and decrease the risk
of HIV-related illnesses. Ask your healthcare professional about how to prevent passing HIV to other people.

Please read Important Safety Information below, and talk to your healthcare professional to learn
if EDURANT® is right for you.

Important Safety Information

Can EDURANT® be taken with other medicines?
EDURANT® may affect the way other medicines work and other medicines may affect how EDURANT® works and may cause serious side effects. If you take certain medicines with EDURANT®, the amount of EDURANT® in your body may be too low and it may not work to help control your HIV infection, and the HIV virus in your body may become resistant to EDURANT® or other HIV medicines that are like it. To help get the right amount of medicine in your body, you should always take EDURANT® with a meal. A protein drink alone does not replace
a meal.

Do not take EDURANT® if:

Your HIV infection has been previously treated with HIV medicines

You are taking any of the following medicines:

- Anti-seizure medicines: carbamazepine (Carbatrol®, Equetro®, Tegretol®,
Tegretol-XR®, Teril®, Epitol®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin
(Dilantin®, Dilantin-125®, Phenytek®)
- Anti-tuberculosis (anti-TB) medicines: rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®), rifapentine
(Priftin®)
- Proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems:
esomeprazole (Nexium®, Vimovo®), lansoprazole (Prevacid®), omeprazole
(Prilosec®, Zegerid®), pantoprazole sodium (Protonix®), rabeprazole (Aciphex®)
- More than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (Hypericum perforatum)

Especially tell your doctor if you take:

Rifabutin (Mycobutin®), a medicine to treat some bacterial infections). Talk to your doctor or pharmacist about the right amount of EDURANT® you should take if you also take rifabutin

Medicines used to treat HIV

An antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take EDURANT®

Medicines to block acid in your stomach, including cimetidine (Tagamet®), famotidine (Pepcid®), nizatidine (Axid®), or ranitidine hydrochloride (Zantac®). Take these medicines at least 12 hours before or at least 4 hours after you take EDURANT®

Any of these medicines (if taken by mouth or injection): clarithromycin (Biaxin®), erythromycin (E-Mycin®, Eryc®, Ery-Tab®, PCE®, Pediazole®, Ilosone®), fluconazole (Diflucan®), itraconazole (Sporanox®), ketoconazole (Nizoral®), methadone (Dolophine®), posaconazole (Noxafil®), telithromycin (Ketek®), voriconazole (Vfend®)

This is not a complete list of medicines. Before starting EDURANT®, be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Before taking EDURANT®, also tell your healthcare professional if you have had or currently have liver problems (including hepatitis B or C), have ever had a mental health problem, are pregnant or planning to become pregnant, or breastfeeding. It is not known if EDURANT® will harm your unborn baby.
You and your healthcare professional will need to decide if taking EDURANT® is right for you.
- Do not breastfeed if you are taking EDURANT®. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby

What are the possible side effects of EDURANT®?
EDURANT® can cause serious side effects including:

Severe skin rash and allergic reactions. Call your doctor right away if you get a rash. Stop taking EDURANT® and seek medical help right away if you get a rash with any of the following symptoms: severe allergic reaction causing swelling of the face, eyes, lips, mouth, tongue, or throat (which may lead to difficulty swallowing or breathing); mouth sores or blisters on your body; inflamed eye (conjunctivitis); fever; dark urine; or pain on the right side of the stomach area (abdominal pain)

Depression or mood changes. Tell your doctor right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, have thoughts of hurting yourself (suicide), or have tried to hurt yourself

Liver problems. People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening liver problems during treatment. Liver problems were also reported during treatment in some people without a history of liver disease. Your healthcare professional may need to do tests to check liver function before and during treatment

Changes in body shape or body fat have been seen in some patients taking HIV medicines. The exact cause and long-term health effects of these conditions are not known

Changes in your immune system (immune reconstitution syndrome).
Your immune system may get stronger and begin to fight infections. Tell your healthcare professional right away if you start having any new symptoms of infection

Other common side effects of EDURANT® include depression, headache, trouble sleeping (insomnia), and rash.

This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare professional right away. Do not stop taking EDURANT® or any other medications without first talking to your healthcare professional.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 (TYO: 4507) 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.

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[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 2016.

[3] 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. Available at: https://clinicaltrials.gov/ct2/show/NCT02951052?term=ATLAS+cabotegravir&rank=1. Last accessed November 2016.

[4] UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic. Published 2014. Available at: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf.

[5] Cohen CJ, Meyers JL, Davis KL. Association between daily antiretroviral pill burden and treatment adherence, hospitalisation risk, and other healthcare utilisation and costs in a US medicaid population with HIV. BMJ Open 2013;3: e003028.

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 18, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc