GLAXOSMITHKLINE PLC
Form 6-K
August 15, 2018

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 15 August 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

PRESS RELEASE

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

ATLAS study meets primary endpoint, showing similar efficacy of a once-a-month, investigational, injectable two-drug regimen of cabotegravir and rilpivirine compared to a standard of care, daily, oral three-drug regimen

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

London, 15 August 2018 - ViiV Healthcare today announced positive headline results from its global, phase III ATLAS study of a long-acting, injectable two-drug regimen (2DR) for the treatment of HIV. ATLAS (Antiretroviral Therapy as Long-Acting Suppression) was designed to establish if HIV-1-infected adult participants who had maintained viral suppression for at least six months, on a daily oral regimen comprised of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a third agent, maintained similar rates of viral suppression upon switching to the investigational, two-drug, long-acting, injectable regimen of cabotegravir and rilpivirine, compared with continuing the three-drug oral regimen.

The study showed long-acting cabotegravir and rilpivirine, injected once a month, had similar efficacy to a standard of care, daily, oral three-drug regimen at Week 48. The injectable treatment regimen met the primary endpoint for non-inferiority (the proportion of participants with plasma HIV-1 RNA ≥50 copies per milliliter [c/mL] using the FDA Snapshot algorithm at Week 48). 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: "This novel approach is another step towards potentially reducing the treatment burden for people living with HIV. The data from ATLAS suggest a long-acting, injectable 2DR of cabotegravir and rilpivirine may offer an alternative to daily, oral three-drug therapy for people who have previously achieved viral suppression. If approved, this regimen would give people living with HIV one month between each dose of antiretroviral therapy, changing HIV treatment from 365 dosing days per year, to just 12."

Detailed results from the study will be presented at an upcoming scientific meeting. Headline results from FLAIR, a second pivotal trial designed to evaluate a long-acting, injectable regimen of cabotegravir and rilpivirine in treatment-naïve individuals, are expected later this year.[3]

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 ATLAS (NCT02951052)
The ATLAS study is part of ViiV Healthcare's innovative clinical trial programme for two-drug regimens. The study includes 618 men and women living with HIV and is being conducted at research centres in Argentina, Australia, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden, and the United States.

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 oral anti-retroviral therapy (ART) of two nucleoside reverse transcriptase inhibitors (NRTIs) plus an integrase strand transfer inhibitor (INI), non-nucleoside reverse transcriptase inhibitor (NNRTI), or protease inhibitor (PI) among virally-suppressed individuals. The primary endpoint for ATLAS is the proportion of participants with plasma HIV-1 RNA ≥50 c/mL per the FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population). Subjects were required to be virally-suppressed for six months or greater, on first or second regimen, with no prior failure.

For further information please see https://clinicaltrials.gov/ct2/show/NCT02951052.

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.

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

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 12 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:

o Anti-seizure medicines: carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®, Epitol®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
o 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®)
o More than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
o 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 side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

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 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

ViiV Healthcare Limited, the global specialist HIV company, is majority owned by GlaxoSmithKline plc, with Pfizer Inc. and Shionogi Limited. 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.

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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

[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 August 2018

[3] 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 August 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: August 15, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc