GLAXOSMITHKLINE PLC
Form 6-K
July 24, 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 24 July 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

Phase II study results showed comparable viral suppression rates at 96 weeks for a two-drug regimen of long-acting cabotegravir and rilpivirine and a three-drug regimen in patients with HIV

LATTE-2 study results published in The Lancet and presented at the International AIDS Society Meeting in Paris

London, UK. 24 July 2017 - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced 96-week data from the LATTE-2 study. LATTE-2 is a phase IIb, open-label study investigating the long-acting, injectable formulations of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC) as a two-drug treatment for patients with HIV-1 infection who had already achieved viral suppression with a three-drug oral regimen of cabotegravir plus two nucleoside reverse transcriptase inhibitors (NRTIs). The study results were published online in The Lancet and were presented at the annual conference of the International AIDS Society (IAS) in Paris, France.

Fixed-dose oral treatments containing three or more medicines have advanced HIV treatment by reducing pill burden and providing convenience for people living with HIV. As research into new medicines for HIV progresses, adherence to therapy continues to be essential to achieving viral suppression and reducing the emergence of resistance mutations. The LATTE-2 study sought to evaluate injectable cabotegravir and rilpivirine dosed once every four or eight weeks compared with daily oral dosing with cabotegravir + 2 NRTIs.

Following 96 weeks of maintenance treatment in the LATTE-2 study, viral suppression rates (%) for the two-drug regimen dosed every eight weeks (94%) or every four weeks (87%) were comparable to the rate observed in patients continuing with a three-drug oral regimen (84%). Two patients in the eight-week dosing group and one patient in the oral regimen group met protocol-defined virologic failure criteria; neither patient had evidence of resistance at failure. Injection site pain was the most commonly reported injection site reaction (ISR) reported by patients receiving injectable cabotegravir and rilpivirine, most ISRs were mild (84%) or moderate (15%) in severity, with a median symptom duration of three days.

John C Pottage Jr, Chief Scientific and Medical Officer for ViiV Healthcare, said "These study results are important because we now have data showing the durability and tolerability of long-acting viral suppression for a two-drug regimen out to 96 weeks. Administration of long-acting parenteral medication removes the daily dosing burden for patients and the LATTE-2 results showed that long-acting cabotegravir and rilpivirine maintained viral suppression, with no virologic failures in the four-week dosing group. We look forward to results from our phase III programme with long-acting cabotegravir and rilpivirine in 2018."

- Ends -

Notes to editors

LATTE-2 (NCT02120352) is an ongoing international multicentre, parallel group, open-label study that included 309 HIV infected adults who had not received prior anti-retroviral treatment. Enrolled patients were suppressed virologically (HIV-1 RNA <50 c/mL) during a 20-week induction period with daily oral cabotegravir (30mg) + 2 NRTIs and subsequently randomised to one of three study arms in the maintenance period: intramuscular cabotegravir long acting formulation (400mg) + rilpivirine long acting formulation (600 mg) every four weeks; intramuscular cabotegravir long acting formulation (600mg) + rilpivirine long acting formulation (900mg) every eight weeks; or oral cabotegravir (30mg) + 2 NRTIs. The primary endpoint evaluated antiviral activity and safety through 32 weeks of maintenance treatment and the study will continue up to 104 weeks of treatment.

Adverse Events in LATTE-2
During the maintenance period, the most commonly reported adverse events not related to injection site reactions for the injectable treatment groups were nasopharyngitis (20%), headache (14%) and diarrhoea (12%). For patients randomised to oral treatment, the most common adverse events during the maintenance period were nasopharyngitis (25%), headache (7%), and diarrhoea (5%). Serious adverse events occurred in 6% of patients receiving injectable treatment (none drug-related) and 5% of patients receiving oral cabotegravir (none drug-related). One patient in the eight week injectable treatment group died due to an event unrelated to study drug (seizure). Nine patients withdrew from the study due to adverse events. Lab abnormalities that emerged during the maintenance phase (≥ Grade 3 severity) occurred in 16% of injectable treatment patients and 14% of oral treatment patients through week 32.

About HIV
HIV has largely become a chronic treatable disease, with improved access to antiretroviral treatment leading to a 22% drop in global HIV mortality between 2009 and 2013[1] but more can be done for the estimated 37 million people living with HIV and 2 million individuals newly infected each year worldwide.[2]

About cabotegravir
Cabotegravir is an investigational integrase strand transfer inhibitor and analogue of dolutegravir. Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV and is currently being evaluated as a once-daily oral tablet formulation and as a long-acting nanosuspension formulation for intramuscular injection.

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 St. John's wort (Hypericum perforatum)

Especially tell your doctor if you take:

o 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

o Medicines used to treat HIV

o 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®

o 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®

o 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).

Please see accompanying full Product Information for more details.

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.

[1] http://apps.who.int/iris/bitstream/10665/128494/1/9789241507585_eng.pdf?ua=1

[2] http://www.who.int/mediacentre/factsheets/fs360/en/

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: July 24, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc