GLAXOSMITHKLINE PLC
Form 6-K
February 23, 2016

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 February 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

--

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 announces phase II study results for first two drug, long-acting injectable regimen for HIV-1 treatment

32 week maintenance data presented at CROI showed comparable viral suppression rates between injectable regimen and three drug oral regimen

London, UK, 23 February 2016 - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today presented positive results from the LATTE-2 study at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. Headline results were announced in November 2015.

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 HIV viral suppression with a three drug oral regimen of cabotegravir plus two nucleoside reverse transcriptase inhibitors (NRTIs). The primary endpoint evaluated antiviral activity and safety through 32 weeks of maintenance treatment.

Following 32 weeks of maintenance treatment, viral suppression rates (%) for the two drug regimen dosed every eight weeks (95%) or every four weeks (94%) were comparable to the rate observed in patients continuing with a three drug oral regimen (91%). One patient 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. The most common drug-related adverse event reported by patients receiving injectable study medication was injection site pain (92%), most of which were mild (82%) or moderate (17%) in severity.

John C Pottage, Jr., MD, Chief Scientific and Medical Officer, ViiV Healthcare commented "There continues to be a need for new HIV medicines, including those that could offer more flexible dosing regimens for people living with HIV. The LATTE-2 study results provide the first evidence that a long-acting two-drug injectable regimen may offer an alternative to daily, oral three-drug therapy for people who have achieved viral suppression. We are aiming to commence Phase III studies this year."

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 (one 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.

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.

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 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

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:

- 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 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.

ViiV Healthcare Contact:
Sébastien Desprez (UK) +44 7920 567 707
Global Communications
ViiV Healthcare

Marc Meachem (US) +1 919 483 8756
US Communications
ViiV Healthcare

GSK enquiries:

UK Media enquiries:	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Kathleen Cuca	+1 215 859 1922	(Philadelphia)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

[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: 23 February, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc