GLAXOSMITHKLINE PLC
Form 6-K
April 29, 2019

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 29 April 2019

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

Issued: 29 April 2019, London UK - LSE Announcement

ViiV Healthcare submits New Drug Application to US FDA for the first monthly, injectable, two-drug regimen of cabotegravir and rilpivirine for treatment of HIV

If approved, cabotegravir and rilpivirine would be the first-ever long-acting, injectable treatment regimen for adults living with HIV

London, 29 April 2019 - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) seeking approval for the investigational, monthly, injectable, two-drug regimen of ViiV Healthcare's cabotegravir and Janssen's rilpivirine to treat HIV-1 infection in adults whose viral load is suppressed and who are not resistant to cabotegravir or rilpivirine.

The submission is based on the global ATLAS (Antiretroviral Therapy as Long-Acting Suppression) and FLAIR (First Long-Acting Injectable Regimen) pivotal phase III studies that included more than 1,100 patients from 16 countries and demonstrated the combination of cabotegravir and rilpivirine, injected monthly, was as effective as a standard of care, daily, oral, three-drug regimen in maintaining viral suppression throughout the 48-week study period. These results were presented in March at the 2019 Conference on Retroviruses and Opportunistic Infections.

Deborah Waterhouse, CEO of ViiV Healthcare, said: "The long-acting, once-monthly, injectable regimen of cabotegravir and rilpivirine has the potential to give people living with HIV one month between doses with similar safety and efficacy as today's standard of care - an oral three-drug regimen that has to be taken every day. ViiV Healthcare is proud to be at the forefront of this innovation in HIV treatment and we look forward to working with the FDA to provide people living with HIV in the US this novel option."

John C. Pottage, Jr., M.D., Chief Scientific and Medical Officer of ViiV Healthcare, commented: "Our focus on developing innovative new HIV treatments, including long-acting injectable therapies, supports our goal of giving people living with HIV more options for managing the virus. The ATLAS and FLAIR data support the efficacy and safety of this investigational two-drug regimen, and the fact that more than 85 percent of study participants said they preferred it to their prior, daily oral therapy suggests we are delivering a welcome option. If approved, people receiving the monthly injectable regimen of cabotegravir and rilpivirine will reduce the number of days they have to take treatment from 365 to 12 per year."

ViiV Healthcare and Janssen plan to submit regulatory applications for the two-drug regimen of cabotegravir and rilpivirine to the European Medicines Agency, Health Canada and other global agencies in the coming months.

As part of the regulatory submission package to the FDA, ViiV Healthcare submitted a second NDA for an oral tablet formulation of cabotegravir that would be taken as an oral lead-in with an already-approved, once-daily, oral tablet formulation of rilpivirine (marketed by Janssen as EDURANT®).

The ATLAS and FLAIR studies are part of ViiV Healthcare's innovative clinical trial programme for two-drug regimens.

Notes to editors: About ATLAS and FLAIR
ATLAS (NCT02951052) 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.

FLAIR (NCT02938520) is a 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 (abacavir, dolutegravir, and lamivudine tablets). The primary endpoint for FLAIR 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).

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. It is 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 patients 12 years of age and older and weighing at least 35-kg with a viral load ≤ 100,000 HIV RNA copies/mL. Long-acting injectable 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 EDURANT® (Rilpivirine)

Note: this is taken from the US label and local variations apply. Please refer to applicable local labelling.

About EDURANT® (Rilpivirine)

EDURANT® (rilpivirine) is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older and who weigh at least 77 lbs (35 kg):

- Have never taken HIV medicines before, and
- Have an amount of HIV in their blood (called "viral load") that is no more than 100,000 copies/mL

EDURANT® is not recommended for patients less than 12 years of age or who weigh less than 77 lbs (35 kg)

IMPORTANT SAFETY INFORMATION

Who should not take EDURANT®?

Do not take EDURANT® if you also take:

anti-seizure medicines:

o carbamazepine
o oxcarbazepine
o phenobarbital

o phenytoin
anti-tuberculosis (anti-TB) medicines:
o rifampin
o rifapentine
proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems:
o esomeprazole
o lansoprazole
o omeprazole
o pantoprazole sodium
o rabeprazole
more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
St. John's wort (Hypericum perforatum)

What should I tell my healthcare provider before taking EDURANT®?
Before taking EDURANT®, tell your healthcare provider about all your medical conditions, including if you:
have or had liver problems, including hepatitis B or C virus infection
have kidney problems
have ever had a mental health problem
are pregnant or plan to become pregnant. It is not known if EDURANT® will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with EDURANT®.
are breastfeeding or plan to breastfeed. Do not breastfeed if you take EDURANT®.
o You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
o It is not known if EDURANT® passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby during EDURANT® treatment.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take EDURANT® with other medicines.

How should I take EDURANT®?
Take EDURANT® every day exactly as your healthcare provider tells you to.
Take EDURANT® 1 time each day with a meal. A protein drink alone does not replace a meal.
Do not change your dose or stop taking EDURANT® without first talking with your healthcare provider. Stay under the care of your healthcare provider during treatment with EDURANT®.
Do not miss a dose of EDURANT®.
If you take an H2-receptor antagonist (famotidine, cimetidine, nizatidine, or ranitidine), you should take these medicines at least 12 hours before or at least 4 hours after you take EDURANT®.
If you take antacids, or other products that contain aluminum, calcium carbonate, or magnesium hydroxide, you should take these medicines at least 2 hours before or at least 4 hours after you take EDURANT®.
If you miss a dose of EDURANT® within 12 hours of the time you usually take it, take your dose of EDURANT® with a meal as soon as possible. Then, take your next dose of EDURANT® at the regularly scheduled time. If you miss a dose of EDURANT® by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT® at the regularly scheduled time.
Do not take more than your prescribed dose to make up for a missed dose.
If you take too much EDURANT®, call your healthcare provider or go to the nearest hospital emergency room right away.

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

Severe skin rash and allergic reactions. Skin rash is a common side effect of EDURANT®. Skin rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital.

If you get a rash with any of the following symptoms, stop taking EDURANT® and get medical help right away:

- o fever
- o skin blisters
- o mouth sores
- o redness or swelling of the eyes (conjunctivitis)
- o swelling of the face, lips, mouth, tongue, or throat
- o trouble breathing or swallowing
- o pain on the right side of the stomach (abdominal) area
- o dark-colored urine "tea colored"

Change in liver enzymes. 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 with EDURANT®. Liver problems have also happened during treatment with EDURANT® in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with EDURANT®.

Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:

- o feeling sad or hopeless
- o feeling anxious or restless
- o have thoughts of hurting yourself (suicide) or have tried to hurt yourself

Changes in body fat can happen in people who take HIV medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most 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 provider right away. Do not stop taking EDURANT® or any other medications without first talking to your healthcare provider.

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.
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 visit www.viivhealthcare.com.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.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 2018.

ViiV Healthcare Media enquiries:	Melinda Stubbee	+1 919 491 0831 (US)
	Audrey Abernathy	+1 919 605 4521 (US)
GSK Global Media enquiries:	Simon Steel	+44 (0) 20 8047 5502 (UK)
	Kristen Neese	+1 804 217 8147 (US)
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 20 8047 5194 (UK)
	Danielle Smith	+44 (0) 20 8047 0932 (UK)
	James Dodwell	+44 (0) 20 8047 2406 (UK)
	Jeff McLaughlin	+1 215 751 7002 (US)

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: April 29, 2019

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc