GLAXOSMITHKLINE PLC
Form 6-K
February 14, 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 14 February 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

PRESS RELEASE
ViiV Healthcare announces detailed positive phase III results for investigational two-drug regimen of dolutegravir and rilpivirine for HIV treatment

In the SWORD studies, the two-drug regimen showed comparable efficacy to three- or four-drug regimens in virologically suppressed patients

London, UK 13 February 2017 - ViiV Healthcare, the global specialist HIV company majority-owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced detailed study results from its phase III programme evaluating the safety and efficacy of switching virologically suppressed patients from a three- or four-drug antiretroviral regimen to a two-drug regimen of dolutegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC). Headline results were announced in December 2016 and detailed study results are being presented at the annual Conference on Retroviruses and Opportunistic Infections in Seattle.

Use of dolutegravir and rilpivirine as a two-drug regimen for HIV-1 maintenance therapy is investigational and not approved anywhere in the world.

The dolutegravir and rilpivirine regimen achieved non-inferior viral suppression (HIV-1 RNA <50 copies/millilitre) at 48 weeks compared with a three- or four-drug regimen in both pooled and individual analyses of the SWORD 1 and SWORD 2 studies (current antiretroviral therapy (CAR) 485/511 (95%), dolutegravir + rilpivirine 486/513 (95%) [adjusted difference -0.2% (95% CI: 3.0%, 2.5%%], pooled analysis]). Virologic suppression rates were similar between treatment arms. The median duration of antiretroviral treatment was just over four years at the time of entry into the studies. The most commonly reported (>5%) adverse events in the dolutegravir and rilpivirine arm were nasopharyngitis, headache, diarrhoea and upper respiratory tract infection. For the CAR arm, the most commonly reported adverse events were nasopharyngitis, upper respiratory tract infection, back pain, headache and diarrhoea. The studies are ongoing for 148 weeks.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "The results from these studies may change our understanding of how HIV can be managed. For more than 20 years we thought that three or more drugs were required to maintain virologic suppression, but the SWORD studies provide compelling data that suppression may be maintained with a two drug regimen of dolutegravir and rilpivirine. These data mark an exciting first step towards making two drug regimens a reality in HIV treatment. We are planning regulatory submissions for this two-drug regimen as a single tablet in 2017."

The programme comprises two studies with over 1000 patients who previously achieved viral suppression on a three- or four-drug (integrase strand transfer inhibitor [INSTI]-, non-nucleoside reverse transcriptase inhibitor [NNRTI]-, or protease inhibitor [PI]-based) antiretroviral regimen. These patients were randomised to either stay on their three- or four-drug regimen or switch to a dolutegravir and rilpivirine regimen.

Virologic failure rates were <1% in the dolutegravir and rilpivirine arm and 1% in the three- or four-antiretroviral-drug arm. No INSTI resistance-associated mutations were reported.

The overall rate of serious adverse events was comparable between treatment groups (dolutegravir + rilpivirine: 27, CAR: 21). As would be expected when switching from a stable regimen to a new regimen, more adverse events were reported and led to withdrawal from the study in the dolutegravir and rilpivirine arm compared to the CAR arm (dolutegravir + rilpivirine: 21, CAR: 3).

The safety profiles for dolutegravir and rilpivirine in these studies were consistent with the product labelling for each medicine.

Conference call for investors and analysts
ViiV Healthcare will host a conference call for investors and analysts at 15:00 GMT (10:00 EST) on the 15th February 2017.

UK Freefone: 080 8234 7616
UK direct: +44 207 365 4163
US Toll free: 1 888 419 5570
International direct: +1 617 896 9871

For a complete list of dial-in numbers available by country, please visit:
http://www.btconferencing.com/globalaccess/?bid=54_attended

Once connected, follow the instructions provided over the phone. When prompted, give the following information:
1. Participant passcode: 188 060 38
2. Name, Company Name

Notes to editors
In June 2014, ViiV Healthcare and Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson announced a partnership to investigate the potential of combining dolutegravir and rilpivirine in a single tablet in order to expand the treatment options available to people living with HIV.

About the SWORD phase III programme for dolutegravir (Tivicay®) and rilpivirine (Edurant®)
The phase III programme evaluates the efficacy, safety, and tolerability of switching to dolutegravir and rilpivirine from current integrase inhibitor-, non-nucleoside reverse transcriptase inhibitor-, or boosted protease inhibitor-based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed with a three or four-drug regimen. In the clinical trials, dolutegravir and rilpivirine are provided as individual tablets. SWORD-1 (NCT02429791) and SWORD-2 (NCT02422797) are replicate 148-week, randomised, open-label, non-inferiority studies to assess the antiviral activity and safety of a two-drug, daily oral regimen of dolutegravir plus rilpivirine compared with current antiretroviral therapy.

The primary endpoint is the proportion of patients with plasma HIV-1 RNA <50 copies per milliliter (c/mL) at Week 48. Key secondary endpoints include evaluation of the development of viral resistance, measurements of safety and tolerability, and changes in renal, bone and cardiovascular biomarkers. The studies also include exploratory measures to assess change in health-related quality of life, willingness to switch and adherence to treatment regimens.

Tivicay® is a registered trademark of the ViiV Healthcare group of companies
Edurant® is a registered trademark of Janssen Sciences Ireland UC
For more information on the trials please visit: www.clinicaltrials.gov

TIVICAY® (dolutegravir) tablets
Professional Indication(s) and Important Safety Information

U.S. Indications and Usage
TIVICAY is a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults

Limitations of use:

Use of TIVICAY in INSTI-experienced patients should be guided by the number and type of baseline INSTI substitutions. The efficacy of TIVICAY 50 mg twice daily is reduced in patients with an INSTI-resistance Q148 substitution plus 2 or more additional INSTI-resistance substitutions including T66A, L74I/M, E138A/K/T, G140S/A/C, Y143R/C/H, E157Q, G163S/E/K/Q, or G193E/R

Important Safety Information

Contraindications:
TIVICAY is contraindicated in patients:

With previous hypersensitivity reaction to dolutegravir
Receiving dofetilide (antiarrhythmic)

Hypersensitivity Reactions:

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

Discontinue TIVICAY and other suspect agents immediately if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Monitor clinical status, including liver aminotransferases, and initiate appropriate therapy if hypersensitivity reaction is suspected

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 TIVICAY. 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 TIVICAY are recommended in patients with underlying hepatic disease such as hepatitis B or C

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

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported.

Adverse Reactions: The most commonly reported (≥2%) adverse reactions of moderate to severe intensity in treatment-naïve adult subjects in any one trial receiving TIVICAY in a combination regimen were insomnia (3%), fatigue (2%), and headache (2%).

Drug Interactions:

Coadministration of TIVICAY with certain inducers of UGT1A and/or CYP3A may reduce plasma concentrations of dolutegravir and require dose adjustments of TIVICAY

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

Consult the full Prescribing Information for TIVICAY for more information on potentially significant drug interactions, including clinical comments

Pregnancy: TIVICAY 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.

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.

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.

Please see 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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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: February 14, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc