GLAXOSMITHKLINE PLC
Form 6-K
July 25, 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 25 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

Switching to a dolutegravir regimen from a boosted protease inhibitor regimen maintained viral suppression and improved lipid fractions in patients with HIV and high cardiovascular risk

Data presented at the International AIDS Society meeting in Paris

London, UK. 25 July 2017- ViiV Healthcare and NEAT-ID announced results from the NEAT 022 study of more than 400 patients with HIV and high cardiovascular risk. The study was conducted by the NEAT-ID group with support from ViiV Healthcare and St Stephen's AIDS Trust (SSAT), and showed that switching virologically suppressed patients at high risk of cardiovascular disease (CVD) from a boosted protease inhibitor regimen (PI/r) to a dolutegravir-based regimen maintained viral suppression while decreasing blood lipids. The study results were presented at the annual conference of the International AIDS Society (IAS) in Paris, France.

CVD is a leading cause of morbidity and mortality across the world1 and certain antiretroviral agents are associated with adverse changes in blood lipids, an established factor contributing to risk for CVD. The NEAT study sought to evaluate the safety and efficacy of switching to dolutegravir in patients with HIV and high cardiovascular risk.

Overall, 415 patients from six European countries were randomised to switch from a boosted PI to dolutegravir or to remain on a boosted PI for 48 weeks. Of these, 89% were men, 87% were older than 50 years and 74% had a Framingham CVD risk score of greater than 10% over the next 10 years.

The study demonstrated that switching to a dolutegravir-based regimen in virologically suppressed HIV-infected patients with high CVD risk was non-inferior compared with continuing a boosted PI-based regimen, with no emergent resistance mutations in any of the groups. Total cholesterol and other lipid fractions (except high-density lipoprotein cholesterol) improved significantly ($p<0.001$) in the dolutegravir group. There was no significant difference in severe, grade 3 or 4 or treatment-modifying adverse events.

Michael Aboud, Vice President and Global Medical Lead for dolutegravir, said: "Simply having HIV is a risk factor for premature CVD, so it is important for people with HIV and other CVD risk factors to have effective treatment options that avoid adding to that risk. We were pleased to collaborate with the NEAT-ID group on this study that showed switching to a dolutegravir-based regimen not only maintained viral suppression in a population with HIV and high risk for CVD, but also improved their overall lipid profile."

Jose M Gatell, Senior Consultant at Hospital Clìnic/IDIBAPS, Professor of Medicine at the University of Barcelona and chief investigator of the NEAT 022 study, said: "This is the first switching study targeting a population with high cardiovascular risk. To minimise this risk the interventions should be in this order: maintaining the virological suppression, switching to antiretroviral agents with a neutral lipid profile and, if still necessary, adding lipid-lowering agents. In the NEAT 022 study we have demonstrated that switching from a ritonavir-boosted PI regimen to dolutegravir was able to maintain virological suppression and significantly improved the plasma lipid profile."

- Ends -

Notes to editors
Tivicay is a registered trademark of the ViiV Healthcare group of companies. For more information on the trials please visit: www.clinicaltrials.gov

About the NEAT-ID study group
The NEAT-ID Foundation is a not for profit private foundation to promote research and education projects in HIV, hepatitis and global infectious diseases.

About SSAT

SSAT through its wholly owned subsidiary St Stephen's Clinical Research sponsors, manages and conducts single and multicenter clinical trials throughout Europe and in Africa.

About the NEAT 022 study
NEAT022-NCT02098837 is a European, open label, randomized, non-inferiority trial. HIV-infected adults ≥ 50 years or with a Framingham score ≥10% were eligible if HIV RNA < 50 copies/mL for at least 24 weeks while on a PI/r regimen. Patients were randomized (1:1) to switch to DTG or to remain on PI/r. Primary end-points were: proportion of patients with HIV RNA < 50 copies/ml at week 48 and a non-inferiority margin of -10% and percentage change of total plasma cholesterol. Secondary end-points included changes in other plasma lipid fractions, and adverse events. The NEAT022/SSAT060 trial was also supported by St Stephens AIDS Trust (SSAT) and ViiV Healthcare.

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

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 and paediatric patients weighing at least 30 kg

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 III 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 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 WHO. Cardiovascular diseases (CVDs) Fact sheet. May 2017. Available at: http://www.who.int/mediacentre/factsheets/fs317/en/Last accessed July 2017

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 25, 2017

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc