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

ViiV Healthcare announces superior efficacy of dolutegravir versus lopinavir/ritonavir in second-line HIV treatment in resource-limited settings

DAWNING study modified to allow patients the opportunity to receive dolutegravir-based regimens

London, UK. 25 July 2017 - ViiV Healthcare, the global specialist HIV company, majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced positive interim results from DAWNING. This is a non-inferiority study conducted to compare second-line treatment of the protease inhibitor-sparing regimen of dolutegravir and 2 nucleoside reverse transcriptase inhibitors (NRTIs), with a current WHO-recommended regimen of lopinavir/ritonavir and 2 NRTIs in HIV-1-infected adults. Results are being presented at the International AIDS Society congress in Paris.

The study's Independent Data Monitoring Committee (IDMC) noted significant and clinically-relevant differences between treatment arms in favour of dolutegravir and recommended that the boosted lopinavir treatment arm be discontinued. Participants receiving lopinavir/ritonavir were offered the opportunity to switch to a regimen with dolutegravir as the core agent, if considered appropriate by the investigator.

The primary endpoint was the proportion of patients with plasma HIV-1 RNA <50 copies per millilitre (c/mL) at week 48. The 24-week interim data showed an 82% response rate in the dolutegravir arm versus 69% for lopinavir/ritonavir ($p<0.001$). Key secondary endpoints include evaluation of the development of viral resistance and measurements of safety and tolerability. No subjects in the dolutegravir arm of the study failed treatment with either integrase or nucleoside resistance. The safety data for dolutegravir at week 24 was consistent with previous dolutegravir studies. Additional data from DAWNING will be presented at future medical meetings.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented "The initial results from DAWNING are important because they not only provide information that may help guide second-line treatment decisions in resource-limited settings, but also reaffirm the position of dolutegravir at the core of HIV care. We are working with investigators to ensure that dolutegravir can be provided to patients in the control arm and are looking forward to sharing the 48-week results, as soon as they will be available."

- 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 DAWNING study
DAWNING is a phase IIIb, non-inferiority study conducted to compare a protease inhibitor-sparing regimen of DTG and 2 NRTIs with a current WHO-recommended regimen of LPV/RTV + 2 NRTIs in HIV-1 infected patients failing first-line therapy of a NNRTI + 2 NRTIs (ClinicalTrials.gov: NCT02227238). The IDMC performed periodic reviews of data to protect the ethical and safety interests of patients.

Adult patients failing first-line therapy, with HIV-1 RNA ≥400 copies(c)/mL, were randomised (1:1, stratified by baseline plasma HIV-1 RNA and number of fully active background NRTIs) to 52 weeks of open-label treatment with DTG or LPV/RTV combined with an investigator-selected dual NRTI background, including at least one fully active NRTI.

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.

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