GLAXOSMITHKLINE PLC
Form 6-K
March 05, 2018

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 05 March 2018

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

Issued: 5 March 2018, London UK - LSE Announcement

ViiV Healthcare announces positive new dolutegravir data for the treatment of people living with HIV co-infected with tuberculosis

INSPIRING study results contribute to the extensive body of evidence for dolutegravir, the leading integrase strand transfer inhibitor, in diverse and hard to treat patient populations
London, UK 5 March 2018 - ViiV Healthcare, the global specialist HIV company, majority owned by GlaxoSmithKline, with Pfizer Inc. and Shionogi Limited as shareholders, today announced interim (Week 24) study results from INSPIRING, a phase IIIb study evaluating the safety and efficacy of dolutegravir in antiretroviral treatment-naive (ART-naïve) adults with HIV, co-infected with tuberculosis (TB). Results presented today at the annual Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, show that dolutegravir when administered at 50mg twice-daily with dual nucleoside reverse transcriptase inhibitors (NRTI), was effective and well-tolerated in HIV/TB co-infected adults receiving rifampin-based TB therapy.[1]

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, said, "Tuberculosis remains the leading cause of death among people living with HIV, accounting for around one in three AIDS-related deaths. Concurrent treatment of TB and HIV remains a challenge as it is compounded by drug interactions, overlapping toxicities and immune reconstitution inflammatory syndrome. This is why the INSPIRING study is so important, as we look to provide this underserved population with as many effective treatment options as possible. The INSPIRING results add to the breadth and depth of data available for dolutegravir and support its use in the treatment of people living with HIV co-infected with TB."

INSPIRING is a phase IIIb, non-comparative, active control, randomised, open-label study in HIV-1 infected ART-naive adults with drug-sensitive TB. Of the 113 enrolled participants on a rifampin-based TB treatment for up to 8 weeks, 69 were randomised to receive dolutegravir (50mg twice-daily during and for two weeks after TB therapy followed by 50mg once-daily) with two NRTIs and 44 to receive efavirenz (600mg once-daily) with two NRTIs. The primary endpoint of the study is the proportion of dolutegravir patients with HIV-1 RNA <50 copies per mL at week 48.1 The study, being conducted in Argentina, Brazil, Mexico, Peru, Russia, South Africa and Thailand, was not powered to show a difference between study arms and no formal statistical hypothesis was tested.

An interim analysis conducted at 24 weeks showed that the proportion of patients who maintained viral suppression (HIV-1 RNA less than 50 copies per ml) in the dolutegravir arm was 56/69 (81%) (95% confidence interval CI: 72%, 90%).1 In the efavirenz arm, 39/44 patients (89%) (95% CI: 79%, 98%) maintained viral suppression. No patients in the dolutegravir arm and two patients in the efavirenz arm discontinued due to adverse events, while five participants (7%) in the dolutegravir arm and none in the efavirenz arm discontinued due to non-treatment related reasons (loss to follow-up/protocol deviations).1 There were no reports of treatment emergent resistance in the dolutegravir arm and there was one report in the efavirenz arm.1 TB-associated immune reconstitution inflammatory syndrome (IRIS) rates were low in both arms (dolutegravir, n=4; efavirenz n=4) with no patients discontinuing due to IRIS or liver events.1 The INSPIRING study is ongoing and 48-week data will be presented at a future scientific meeting.

In 2016, there were an estimated 10.4 million cases of TB globally, including 1.2 million (11%) among people living with HIV (PLHIV).[2] Although TB-related deaths among PLHIV have been steadily declining (33% decrease between 2005 and 2015), almost 60% of TB cases among PLHIV were not diagnosed or treated, resulting in 390,000 tuberculosis-related deaths among PLHIV in 2015.2

Notes to editors

About HIV

HIV stands for the Human Immunodeficiency Virus. Unlike some other viruses, the human body cannot get rid of HIV, so once someone has HIV they have it for life. There is no cure for HIV, but effective treatment can control the virus so that people with HIV can enjoy healthy and productive lives.

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, but more can be done for the estimated 36.7 million people living with HIV and 1.8 million individuals newly infected each year worldwide.[3]

About INSPIRING
INSPIRING is a phase IIIb, randomised, open-label, multicentre, parallel-group study to assess the antiviral activity of dolutegravir or efavirenz-containing regimens in HIV/TB co-infected patients undergoing rifampin-based TB therapy. The study includes a screening period, a randomised phase (Day 1 to 48 weeks plus a 4-week extension) and a dolutegravir open-label extension. During the dolutegravir open-label extension, patients were provided with dolutegravir until it is locally approved and commercially available, the patient no longer derives clinical benefit, or the patient meets a protocol-defined reason for discontinuation, whichever comes first.

The primary endpoint is the proportion of dolutegravir patients with plasma HIV-1 RNA <50 copies per millilitre (c/mL) at Week 48. Key secondary endpoints include the proportion of efavirenz patients with plasma HIV-1 RNA <50 c/mL at Week 48 and evaluation of both study arms at Week 24. Additional secondary endpoints include evaluation of the development of viral resistance, measurements of safety, tolerability and changes from baseline CD4+ counts.

About Tivicay (dolutegravir)
Dolutegravir (Tivicay) is an integrase strand transfer inhibitor (INSTI) for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. Tivicay is approved in over 100 countries across North America, Europe, Asia, Australia, Africa and Latin America.

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 pediatric patients weighing at least 30 kg
- rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies per mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent (US Only)

Important Safety Information

CONTRAINDICATIONS:
TIVICAY is contraindicated in patients:
with previous hypersensitivity reaction to dolutegravir
receiving dofetilide (antiarrhythmic)

WARNINGS AND PRECAUTIONS:

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

Hepatotoxicity:

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

Cases of hepatic toxicity, including elevated serum liver biochemistries, hepatitis, and acute liver failure, have also been reported in patients receiving a dolutegravir-containing regimen who had no pre-existing hepatic disease or other identifiable risk factors. Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ (abacavir, dolutegravir, and lamivudine)

Monitoring for hepatotoxicity is recommended

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

The concomitant use of TIVICAY and other drugs may result in known or potentially significant drug interactions (see Contraindications or Drug Interactions).

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

USE IN SPECIFIC POPULATIONS:

Pregnancy:

There are insufficient human data on the use of TIVICAY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.

Lactation:

Breastfeeding is not recommended due to the potential for HIV transmission and developing viral resistance in HIV-positive infants.

Paediatric Use:
Safety and efficacy of TIVICAY have not been established in paediatric patients weighing less than 30 kg or in any paediatric patients who are INSTI-experienced.

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.

GSK - 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

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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.

References

[1] Dooley KE, et al. Safety and efficacy of dolutegravir-based ART in TB/HIV co-infected adults at week 24. Presented at the Conference on Retroviruses and Opportunistic Infections, 2018. Boston, MA
[2] World Health Organization. Global Tuberculosis Report. 2017
[3] World Health Organization. HIV/AIDS Fact Sheet. Available at: http://www.who.int/mediacentre/factsheets/fs360/en/. Last accessed November 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: March 05, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc