GLAXOSMITHKLINE PLC
Form 6-K
November 22, 2013

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 November 2013

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

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GlaxoSmithKline plc (LSE:GSK) today announced that ViiV Healthcare Ltd (a global specialist HIV company with GlaxoSmithKline, Pfizer, Inc. and Shionogi Limited as shareholders) is issuing the following statement today:

Tivicay® (dolutegravir) receives positive CHMP opinion in Europe for the treatment of HIV

London, UK, 22 November 2013 - ViiV Healthcare today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending marketing authorisation for Tivicay® (dolutegravir) for use in combination with other antiretroviral medicinal products for the treatment of HIV-infected adults and adolescents above 12 years of age.

"We welcome the CHMP's positive opinion on dolutegravir - it puts us a step closer to offering this new treatment option to people across Europe who are living with HIV," said Dr John Pottage, Chief Medical Officer, ViiV Healthcare. "We are committed to research that seeks to make advances in treatment options for people living with HIV. To make progress, thousands of patients have supported us through their participation in clinical development work and we recognise their commitment today with great gratitude."

The CHMP opinion is based on safety and efficacy data for dolutegravir from four pivotal Phase III studies1-4. These involved people living with HIV who were new to treatment and also those with prior experience of treatment, and included comparators representing antiretroviral treatments commonly used today in the battle against HIV. More than 2,500 people were treated across these studies, and the regulatory submission also included data in children aged 12 years and older.

A CHMP positive opinion is one of the final steps in the regulatory process leading to the marketing authorisation decision of the European Commission, which is expected early in 2014.

About Tivicay® (dolutegravir)
Tivicay® was approved by the U.S. FDA in August 2013 and by Health Canada in October 2013 - please refer to local labelling for more information. It is a human immunodeficiency virus type 1 (HIV-1) integrase inhibitor. 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.

Regulatory applications are being evaluated in other countries worldwide. Regulatory applications for ViiV Healthcare's developmental single-tablet regimen (STR) combining Tivicay with Kivexa®/Epzicom® (abacavir/lamivudine) were submitted to regulatory authorities in Europe, Canada and the U.S. in October 2013.

Important Safety Information for Tivicay® (dolutegravir) 50 mg Tablets:

Dolutegravir is not approved for any indication in the European Union. The following information is based on the Highlights section of the U.S. Prescribing Information for Tivicay. Please refer to the full Prescribing Information for more details.

Indication and Usage: Tivicay is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40 kg.

The following should be considered prior to initiating treatment with Tivicay: poor virologic response was observed in subjects treated with Tivicay 50 mg twice daily with an integrase strand transfer inhibitor (INSTI)-resistance Q148 substitution plus 2 or more additional INSTI-resistance substitutions, including L74I/M, E138A/D/K/T, G140A/S, Y143H/R, E157Q, G163E/K/Q/R/S, or G193E/R.

Contraindication: Co-administration of TIVICAY with dofetilide (anti-arrhythmic) is contraindicated due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events.

Hypersensitivity Reactions:Hypersensitivity reactions have been reported and were characterised by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. The events were reported in 1% or fewer subjects receiving TIVICAY in Phase 3 clinical trials. Immediately discontinue TIVICAY and other suspect agents if signs or symptoms of hypersensitivity reaction develop, (including but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters or peeling of the skin, oral blisters or lesions, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing.) Monitor clinical status, including liver aminotransferases, and initiate appropriate therapy. Delay in stopping treatment with TIVICAY or other suspect agents after the onset of hypersensitivity may result in a life-threatening reaction. TIVICAY should not be used in patients who have experienced a hypersensitivity reaction to TIVICAY.

Effects on Serum Liver Biochemistries in Patients with Hepatitis B or C Coinfection: 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:Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy.

Immune Reconstitution Syndrome: During the initial phase of treatment, immune reconstitution syndrome can occur, which may necessitate further evaluation and treatment. Autoimmune disorders have been reported to occur in the setting of immune reconstitution; the time to onset is more variable and can occur many months after initiation of treatment.

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%) and headache (2%).

Drug Interactions: Co-administration of TIVICAY with drugs that are strong inducers of UGT1A1 and/or CYP3A4 may result in reduced plasma concentrations of dolutegravir and require dose adjustments of TIVICAY.

- TIVICAY should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral iron supplements, oral calcium supplements, or buffered medications.

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

Pregnancy: Pregnancy category B. TIVICAY should be used during pregnancy only if the potential benefit justifies the potential risk. An Antiretroviral Pregnancy Registry has been established.

Breastfeeding: Breastfeeding is NOT recommended due to the potential for HIV transmission and the potential for adverse reactions in nursing infants.

Paediatric Patients: Safety and efficacy of TIVICAY has not been established in children younger than 12 years old, or weighing <40 kg, or in INSTI-experienced paediatricpatients with documented or clinically suspected INSTI resistance.

References

1 SINGLE (Study ING114467). A Trial Comparing GSK1349572 (dolutegravir) 50mg Plus Abacavir/Lamivudine Once Daily to Atripla. National Institutes of Health Study Identifier NCT01263015.
More information available at: http://www.clinicaltrials.gov/show/NCT01263015
2 SPRING-2 (Study ING113086). A Trial Comparing GSK1349572 (dolutegravir) 50mg Once Daily to Raltegravir 400mg Twice Daily. National Institutes of Health Study Identifier NCT01227824.
More information available at: http://clinicaltrials.gov/show/NCT01227824
3 VIKING-3 (Study ING112574). A Study to Assess Dolutegravir in HIV-infected Subjects With Treatment Failure on an Integrase Inhibitor Containing Regimen. National Institutes of Health Study Identifier NCT01328041.
More information available at: http://clinicaltrials.gov/show/NCT01328041
4 SAILING (Study ING111762). A Study of GSK1349572 (dolutegravir) Versus Raltegravir (RAL) With Investigator Selected Background Regimen in Antiretroviral-Experienced, Integrase Inhibitor-Naive Adults. National Institutes
of Health Study Identifier NCT01231516.
More information available at: http://clinicaltrials.gov/show/NCT01231516

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. Shionogi joined as a 10% 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 new HIV medicines, 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.

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GlaxoSmithKline 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. Factors that may affect GSK' s operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

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: November 22, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc