GLAXOSMITHKLINE PLC
Form 6-K
October 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 October 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:

ViiV Healthcare announces US regulatory submission for a single-tablet regimen combining dolutegravir with abacavir and lamivudine for people living with HIV

London, UK - 22 October 2013:ViiV Healthcare today announced the submission of a regulatory application in the United States for its investigational single-tablet regimen (STR) combining dolutegravir, abacavir and lamivudine for the treatment of people living with HIV-1. This New Drug Application (NDA) follows the approval of dolutegravir by the US Food and Drug Administration (FDA) in August 2013 under the brand name Tivicay®, approved for use in combination with other antiretroviral agents for the treatment of HIV-1 in adults and children aged 12 years and older weighing at least 40 kg (approx. 88 lbs).

"People living with HIV and their doctors seek to use appropriate treatment options for the individual, while also trying to minimise the number of pills required for effective and acceptable antiretroviral treatment," said Dr John Pottage, Chief Medical Officer, ViiV Healthcare. "This submission aims to make a complete Tivicay-based regimen available for the first time in a single once-daily pill."

In Europe, a Marketing Authorisation Application (MAA) for this single-tablet regimen will be submitted in the near future. The review of the MAA for dolutegravir (DTG), submitted in Europe in December 2012, is in progress with the European Medicines Agency (EMA). A combination tablet containing abacavir (ABC) and lamivudine (3TC) is approved and available in the US under the brand name Epzicom® (abacavir sulfate 600 mg + lamivudine 300 mg) and in the EU under the brand name Kivexa®.

The investigational single-tablet combination of DTG/ABC/3TC has sometimes been referred to as "Trii". The submission announced today is based on data from one pivotal Phase III study of DTG1, supported by three other Phase III/IIIb studies2-4, which evaluated the safety and efficacy of this regimen. It additionally includes pivotal data evaluating the bioequivalence of DTG/ABC/3TC when taken as a single-tablet regimen compared to the administration of DTG with ABC/3TC as separate components5. A further 48-week Phase IIIb/IV study of this single-tablet regimen in treatment-naive HIV-positive women (the ARIA study) is ongoing6.

Important Information About Tivicay® (dolutegravir)
Indication 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 children aged 12 years and older and weighing at least 40 kg. The following should be considered prior to initiating TIVICAY: poor virologic response was observed in subjects treated with TIVICAY 50 mg twice daily with an 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.

Important Safety Information:
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 III 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 reactivationparticularly 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.

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.

Important Information About EPZICOM® (ABC+3TC)

INDICATION AND USAGE

• EPZICOM, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection. EPZICOM is one of multiple products containing abacavir

• Before starting EPZICOM, review medical history for prior exposure to any abacavir-containing product in order to avoid reintroduction in a patient with a history of hypersensitivity to abacavir

• In one controlled study, more patients taking abacavir 600 mg once daily had severe hypersensitivity reactions compared to patients taking abacavir 300 mg twice daily

• As a part of a triple-drug regimen, EPZICOM is recommended for use with ART agents from different pharmacological classes and not with other NRTIs

IMPORTANT SAFETY INFORMATION FOR EPZICOM

Hypersensitivity Reactions

• EPZICOM contains abacavir sulfate, which has been associated with serious and sometimes fatal hypersensitivity reactions. Hypersensitivity to abacavir is a multi-organ clinical syndrome usually characterized by a sign or symptom in 2 or more of the following groups: (1) fever, (2) rash, (3) gastrointestinal (including nausea, vomiting, diarrhea, or abdominal pain), (4) constitutional (including generalized malaise, fatigue, or achiness), and (5) respiratory (including dyspnea, cough, or pharyngitis). Discontinue EPZICOM as soon as a hypersensitivity reaction is suspected

• Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir. Prior to initiating therapy with abacavir, screening for the HLA-B*5701 allele is recommended; this approach has been found to decrease the risk of hypersensitivity reaction

• Screening is also recommended prior to reinitiation of abacavir in patients of unknown HLA-B*5701 status who have previously tolerated abacavir

• HLA-B*5701-negative patients may develop a suspected hypersensitivity reaction to abacavir; however, this occurs significantly less frequently than in HLA-B*5701-positive patients

• Regardless of HLA-B*5701 status, permanently discontinue EPZICOM if hypersensitivity cannot be ruled out, even when other diagnoses are possible

• Following a hypersensitivity reaction to abacavir, NEVER restart EPZICOM or any other abacavir-containing product because more severe symptoms can occur within hours and may include life-threatening hypotension and death

• Reintroduction of EPZICOM or any other abacavir-containing product, even in patients who have no identified history or unrecognized symptoms of hypersensitivity to abacavir therapy, can result in serious or fatal hypersensitivity reactions. Such reactions can occur within hours

• Hypersensitivity to abacavir was reported in approximately 8% of 2,670 patients (n=206) in 9 clinical trials (range 2% to 9%) with enrollment from November 1999 to February 2002

Lactic Acidosis

• Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including abacavir, lamivudine, and other antiretrovirals

Coinfection with Hepatitis B or HCV

• Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with hepatitis B virus (HBV) and HIV and have discontinued lamivudine, which is one component of EPZICOM. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue EPZICOM and are coinfected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted

• Hepatic decompensation (some fatal) has occurred in HIV/HCV coinfected patients receiving combination antiretroviral therapy for HIV and interferon with or without ribavirin. Patients receiving interferon with or without ribavirin and EPZICOM should be closely monitored for treatment-associated toxicities, especially hepatic decompensation. Discontinuation of EPZICOM should be considered as medically appropriate

Impaired Hepatic Function
• EPZICOM Tablets are contraindicated in patients with hepatic impairment

Immune Reconstitution Syndrome
• Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including EPZICOM. During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections (such as Mycobacterium avium infection, cytomegalovirus, Pneumocystis jirovecii pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment

• Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment

Fat Redistribution
• Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy. The causal relationship, mechanism, and long-term consequences of these events are currently unknown

Cardiovascular
• An observational study showed an increase in MI with abacavir; a sponsor-conducted, pooled analysis did not show increased risk. In totality, the available data are inconclusive

• The underlying risk of coronary heart disease should be considered when prescribing antiretroviral therapies, including abacavir, and action taken to minimize all modifiable risk factors (eg, hypertension, hyperlipidemia, diabetes mellitus, and smoking)

Impaired Renal Function
• Since EPZICOM is a fixed-dose tablet and the lamivudine component cannot be dose-adjusted, EPZICOM is not recommended for patients with creatinine-clearance <50 mL/min

Use With Other Abacavir-, Lamivudine- and/or Emtricitabine-Containing Products
• Do not use EPZICOM with other abacavir-, lamivudine- and/or emtricitabine-containing products

Adverse Events
• In one study of therapy-naïve patients (CNA30021), the most common adverse events (grade 2-4) reported with abacavir and lamivudine dosed once daily were hypersensitivity (9%), insomnia (7%), depression (7%), headache/migraine (7%), fatigue (6%), dizziness (6%), nausea (5%), diarrhea (5%), rash (5%), pyrexia (5%), abdominal pain (4%), abnormal dreams (4%), and anxiety (3%)

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.

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 FLAMINGO (Study ING114915). Dolutegravir Compared to Darunavir/Ritonavir , Each in Combination With Dual Nucleoside Reverse Transcriptase Inhibitors (NRTIs) in ART-naive Subjects. National Institutes of Health Study Identifier NCT01449929.
More information available at: http://clinicaltrials.gov/show/NCT01449929

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

5 Study ING114580. Evaluation of the Bioequivalence of a Combined Formulated Tablet. National Institutes of Health Study Identifier NCT01622790.
More information available at: http://clinicaltrials.gov/show/NCT01622790

6 ARIA (Study ING117172). A Study to Determine Safety and Efficacy of Dolutegravir/Abacavir/Lamivudine (DTG/ABC/3TC) in Human Immunodeficiency Virus (HIV)-1 Infected Antiretroviral Therapy (ART) Naïve Women. National Institutes of Health Study Identifier NCT01910402.
More information available at: http://clinicaltrials.gov/show/NCT01910402

Prescribing information for TIVICAY is available online at:
https://www.viivhealthcare.com/media/58599/us_tivicay.pdf

Prescribing information for EPZICOM is available online at:
https://www.viivhealthcare.com/media/70430/us_epzicom.pdf

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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: October 22, 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on

behalf of GlaxoSmithKline plc