GLAXOSMITHKLINE PLC
Form 6-K
September 23, 2015

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 September 2015

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:

New Phase IIIb/IV data show switching to once-daily Triumeq® maintains HIV viral suppression

London, UK, 23 September 2015 - ViiV Healthcare today announced 24-week data from the Phase IIIb/IV STRIIVING study, an open-label study evaluating the efficacy, safety and tolerability of switching from an antiretroviral therapy (ART) to the once-daily, fixed-dose dolutegravir-based regimen, Triumeq® (abacavir/dolutegravir/lamivudine) in virologically suppressed adults with HIV-1 (n=274).[1] The study included (n=277) adults who remained on their existing ART to 24 weeks. STRIIVING met its primary endpoint, demonstrating that viral suppression was non-inferior for patients switching to abacavir/dolutegravir/lamivudine (HIV RNA <50 copies/mL in intention to treat efficacy (ITTe, primary endpoint; n=551): 85% (abacavir/dolutegravir/lamivudine) vs. 88% (existing ART) [adjusted difference -3.4%; 95% CI: -9.1, 2.3], per protocol (PP; n=435): 93% vs. 93% [adjusted difference -0.3%; 95% CI:
-4.9, 4.4]).1 No patients had protocol defined virologic failure (confirmed plasma HIV-1 RNA ≥400 copies/mL) and therefore no patients were evaluated for treatment-emergent resistance in either arm (ITTe).1

Furthermore, statistically, the treatment satisfaction score improved significantly more for those patients switching to once-daily abacavir/dolutegravir/lamivudine from their established regimen, as assessed by the HIV Treatment Satisfaction Questionnaire (adjusted difference 2.4, 95% CI: 1.3, 3.5; p<0.001).1

"For clinicians, choosing among antiretroviral therapies now involves balancing efficacy with factors such as tolerability, dosing, ability to use with other medications, and resistance profile. These data support the use of once-daily abacavir/dolutegravir/lamivudine as a treatment option in the switch setting for appropriate patients," said John Pottage, MD, Chief Scientific and Medical Officer, ViiV Healthcare.

The STRIIVING study recruited patients switching from a broad range of protease inhibitor (PI; n=234), integrase strand transfer inhibitor (INSTI; n=146) and non-nucleoside reverse transcriptase inhibitor (NNRTI; n=171)-based regimens, with the aim of reflecting a common clinical situation.1

Patients switching to abacavir/dolutegravir/lamivudine reported more adverse events (AEs) leading to withdrawal compared with those who continued on their established regimen (ITTe: 4% vs. 0%).1 The majority of these AEs were Grade I & 2.1 The most common AEs (≥ 5%) reported in patients switched to the abacavir/dolutegravir/lamivudine arm included cough (5%), diarrhoea (7%), fatigue (7%), headache (5%), nausea (10%) and upper respiratory tract infection (7%).1 The AE profile observed with abacavir/dolutegravir/lamivudine in the study is in line with previous studies with dolutegravir-based regimens.[2],[3],[4],[5],[6]

STRIIVING study design
STRIIVING is a Phase IIIb/IV randomised, open-label, multicentre, North American study to evaluate the efficacy, safety and tolerability of switching from an ART regimen to once-daily, fixed-dose abacavir/dolutegravir/lamivudine in virologically-suppressed (HIV-1 RNA <50 copies/mL) adults with HIV-1. Participants were randomised 1:1 to switch to abacavir/dolutegravir/lamivudine (n=274) or continue on their current ART (n=277) for 24 weeks. The total number of patients in the study was 551.1

Important Safety Information (ISI) for Triumeq® (abacavir, dolutegravir and lamivudine) tablets

The following ISI is based on the Highlights section of the Prescribing Information for Triumeq. Please consult the full Prescribing Information for all the labelled safety information for Triumeq.

BOXED WARNING: RISK OF HYPERSENSITIVITY REACTIONS, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, AND EXACERBATIONS OF HEPATITIS B
See full Prescribing Information for complete boxed warning.

- Serious and sometimes fatal hypersensitivity reactions have been associated with abacavir-containing products.
- Hypersensitivity to abacavir is a multi-organ clinical syndrome.
- Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir.
- Discontinue Triumeq as soon as a hypersensitivity reaction is suspected. Regardless of HLA-B*5701 status, permanently discontinue Triumeq if hypersensitivity cannot be ruled out, even when other diagnoses are possible.
- Following a hypersensitivity reaction to abacavir, NEVER restart Triumeq or any other abacavir-containing product.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.
- Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV-1) and have discontinued lamivudine, a component of Triumeq. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.

CONTRAINDICATIONS
- Presence of HLA-B*5701 allele.
- Previous hypersensitivity reaction to abacavir, dolutegravir or lamivudine.
- Co-administration with dofetilide.
- Moderate or severe hepatic impairment.

WARNINGS AND PRECAUTIONS
Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of Triumeq. Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during therapy with Triumeq is recommended in patients with underlying hepatic disease such as hepatitis B or C.
- Hepatic decompensation, some fatal, has occurred in HIV-1/Hepatitis C Virus (HCV) co-infected patients receiving combination antiretroviral therapy and interferon alfa with or without ribavirin. Discontinue Triumeq as medically appropriate and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both.
- Immune reconstitution syndrome and redistribution/accumulation of body fat have been reported in patients treated with combination antiretroviral therapy.
- Administration of Triumeq is not recommended in patients receiving other products containing abacavir or lamivudine.

ADVERSE REACTIONS
The most commonly reported (≥2%) adverse reactions of at least moderate intensity in treatment-naïve adult subjects receiving Triumeq were insomnia (3%), headache (2%), and fatigue (2%).

DRUG INTERACTIONS
Co-administration of Triumeq with other drugs can alter the concentration of other drugs and other drugs may alter the concentrations of Triumeq. The potential drug-drug interactions must be considered prior to and during therapy.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Triumeq should be used during pregnancy only if the potential benefit justifies the potential risk.
- Nursing mothers: Breastfeeding is not recommended due to the potential for HIV transmission.
- Triumeq is not recommended in patients with creatinine clearance less than 50 mL per min.
- If a dose reduction of abacavir, a component of Triumeq, is required for patients with mild hepatic impairment, then the individual components should be used.

About Triumeq®
Triumeq is a once-daily dolutegravir-based regimen, containing the integrase strand transfer inhibitor (INSTI) dolutegravir and the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir and lamivudine.

Two essential steps in the HIV life cycle are replication - when the virus turns its RNA copy into DNA - and integration - the moment when viral DNA becomes part of the host cell's DNA. These processes require two enzymes called reverse transcriptase and integrase. NRTIs and INSTIs interfere with the action of the two enzymes to prevent the virus from replicating. This decrease in replication will lead to less virus being available to cause subsequent infection of uninfected cells.

Please refer to the full US Prescribing Information for contraindications, special warnings and precautions for use.[7]

Triumeq is a registered trademark of the ViiV Healthcare group of companies.

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 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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References

[1]Trottier B, Lake J, Logue K et al. Switching to Abacavir/Dolutegravir/Lamivudine combination (ABC/DTG/3TC FDC) from a PI, INI or NNRTI based regimen maintains HIV suppression. Presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), 17-21 September 2015, San Diego, California
[2] Raffi F, Jaeger H, Quiros-Roldan E, Albrecht H, Belonosova E, Gatell JM, Baril J-G, Domingo P, Brennan C, Almond S, Min S, for the SPRING-2 Study Group. Once-daily dolutegravir versus twice-daily raltegravir in antiretroviral-naive adults with HIV-1 infection (SPRING-2 study): 96 week results from a randomised, double-blind, non-inferiority trial. Lancet Infect Dis. 2013;13(11):927-935.
[3] Pappa K, Baumgarten A, Felizarta F, et al. Dolutegravir (DTG) + abacavir/lamivudine once daily superior to tenofovir/emtricitabine/efavirenz in treatment naïve HIV subjects: 144-week results from SINGLE (ING114467). Abstract presented at: 54th Interscience Conference on Antimicrobial Agents and Chemotherapy; September 5-9, 2014; Washington, DC, USA.
[4] Castagna S, et al. Dolutegravir in antiretroviral-experienced patients with raltegravir- and/or elvitegravir-resistant HIV-1: 24-week results of the Phase III VIKING-3 study. J Infect Dis 2014;210:354-62
[5] Vavro C, Huang J, Avatapally C, Min S, Ait-Khaled M. Durable efficacy and limited integrase resistance in subjects receiving dolutegravir after failing a prior regimen: week 48 results from VIKING-3. Rev Antiviral Ther Infect Dis. 2014;2:Abstract O-10.
[6] Molina J, et al. Once-daily dolutegravir versus darunavir plus ritonavir for treatment-naive adults with HIV-1 infection (FLAMINGO): 96 week results from a randomised, open-label, phase 3b study. Lancet HIV 2015. Published online March 2015 http://dx.doi.org/10.1016/S2352-3018(15)00027-2 (Last Accessed March 2015)
[7] Triumeq US label

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 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

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: September 23, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc