GLAXOSMITHKLINE PLC
Form 6-K
November 03, 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 November 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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PRESS RELEASE

ViiV Healthcare announces positive headline results from a study of two drug injectable regimen for HIV maintenance therapy

London, UK, 3 November 2015 - ViiV Healthcare, a global specialist HIV company with GSK, Pfizer Inc. and Shionogi Limited as shareholders, today announced that the Phase IIb study LATTE 2 (NCT02120352) met its primary endpoint at 32 weeks. These results show that the investigational, long acting, injectable formulations of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen) were comparable in maintaining viral suppression rates to a three drug oral regimen of investigational cabotegravir and two nucleoside reverse transcriptase inhibitors (NRTIs). The 32 week results of LATTE 2 will be presented at a forthcoming scientific conference. ViiV Healthcare and Janssen Sciences Ireland UC (Janssen) are collaborating to conduct LATTE 2.

Viral suppression rates (plasma HIV-1 RNA <50 c/ml by FDA snapshot analysis) for patients at 32 weeks receiving two drug maintenance therapy with investigational long acting cabotegravir (CAB LA) and long acting rilpivirine (RPV LA) dosed every 8 weeks (Q8W, 95%) or every 4 weeks (Q4W, 94%) were comparable to the rate observed in patients continuing with a three drug oral regimen of investigational CAB + NRTIs (91%).

Patients switching to CAB LA and RPV LA administered Q4W reported more adverse events (AEs) leading to withdrawal (5%; n=6) compared with those receiving an injection Q8W (2%; n=2) or who continued on oral CAB + NRTIs (2%, n=1). The most common adverse event (AE) reported by patients was injection site pain (93% of injection recipients). Two patients in the Q8W arm (none in the Q4W arm) withdrew for injection intolerance. Two patients met protocol defined virologic failure criteria, Q8W (n=1), oral (n=1); neither patient had evidence of resistance at failure.

"ViiV Healthcare is committed to identifying new therapeutic options for physicians and people living with HIV. These initial phase IIb data investigating long-acting cabotegravir and rilpivirine are promising and build on the results we have seen to date. We look forward to seeing further results as we move into phase III," said John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare.

Following the results of the proof of concept two-drug oral dose-ranging study LATTE1, LATTE 2 was initiated as a phase IIb, multicentre, open label 96 week study investigating CAB LA with RPV LA as a two-drug antiretroviral (ART) regimen for suppressive maintenance therapy in ART-naïve, HIV infected adults. LATTE 2 included adults (n=309) who, after reaching virologic suppression on oral therapy with once-daily investigational oral cabotegravir 30mg + 2 NRTIs (n=286, 93%), were subsequently randomised to one of three study arms to receive either CAB LA + RPV LA injections every 4 weeks (n=115, Q4W), 8 weeks (n=115 Q8W) or continued on oral CAB + NRTIs (n=56).

About cabotegravir

Cabotegravir is an investigational integrase strand transfer inhibitor (INSTI) and analogue of dolutegravir (Tivicay®). Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV and is currently being evaluated as a once-daily oral tablet formulation and as a LA nanosuspension formulation for intramuscular (IM) injection.

About Edurant® (rilpivirine)

Rilpivirine is a once daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used for the treatment of human immunodeficiency virus (HIV 1) infection in combination with other antiretroviral agents in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV RNA copies/mL.

Rilpivirine was developed by Janssen. Rilpivirine is approved in US and EU as EDURANT® as a single agent tablet dosed at 25mg taken once a day. The overall safety profile of rilpivirine is based on Phase III clinical studies. Rilpivirine is also available in the United States (US) and the European Union as part of a once daily fixed dose antiretroviral combination with Gilead Sciences Inc's tenofovir and emtricitabine. This combination, known as COMPLERA® (US) or EVIPLERA®.

Rilpivirine is currently being developed as a long-acting nanosuspension formulation for intramuscular (IM) injection.

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. Margolis DA et al., Cabotegravir plus rilpivirine, once a day, after induction with cabotegravir plus nucleoside reverse transcriptase inhibitors in antiretroviral-naive adults with HIV-1 infection (LATTE): a randomised phase 2b dose-ranging trial. Lancet Inf Dis 2015:15(10):1145-55

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 03, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc