GLAXOSMITHKLINE PLC
Form 6-K
June 14, 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 14 June 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: Thursday 14 June 2018, London UK - LSE Announcement

ViiV Healthcare reports landmark phase III studies for dolutegravir and lamivudine, demonstrating the ability to control HIV with a two-drug regimen in treatment naïve patients

- GEMINI 1&2 studies meet primary endpoint, demonstrating similar efficacy of two-drug regimen compared to standard three-drug regimen
- Full results from the studies will be presented at an upcoming scientific meeting

London, 14 June 2018
ViiV Healthcare today announced positive headline results from its phase III GEMINI study programme. The studies (GEMINI-1 and GEMINI-2) are designed to evaluate the safety and efficacy of a two-drug regimen (2DR) of dolutegravir and lamivudine compared to a three-drug regimen of dolutegravir and two nucleoside reverse transcriptase inhibitors, tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in treatment naïve HIV-1 infected adults with baseline viral loads less than 500,000 copies per ml.

The studies met their primary endpoint for non-inferiority based on plasma HIV-1 RNA <50 copies per millilitre (c/mL), a standard measure of HIV control, at Week 48. The safety results for the 2DR of dolutegravir and lamivudine were consistent with the product labelling for the medicines. No patient who experienced virologic failure in either treatment arm developed treatment-emergent resistance.
Full results from the studies will be presented at an upcoming scientific meeting.

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer of ViiV Healthcare, said: "People with HIV are living longer and more productive lives. However, under current standard of care, many patients still take three or more medicines every day. The GEMINI studies demonstrate the potency, safety and tolerability of the dolutegravir plus lamivudine combination. They affirm our two-drug regimen strategy, and reinforce our belief that many patients can control their disease with two drugs instead of three or more. Importantly, the studies show that this two-drug regimen could be an option for treatment naïve patients and can support a broad range of patients living with HIV around the world."

The GEMINI studies are part of ViiV Healthcare's innovative clinical trial programme for two-drug regimens that seeks to address long-term toxicity concerns of people living with HIV by reducing the number of medicines used in their treatment. The studies together include approximately 1,400 men and women living with HIV and are being conducted at research centres in Europe, Central and South America, North America, South Africa and Asia Pacific.

ViiV Healthcare will now plan for regulatory submissions for the two-drug regimen of dolutegravir and lamivudine later this year.

Notes to editors
GEMINI 1 & 2 study design
GEMINI 1 (204861) and GEMINI 2 (205543) are duplicate, phase III, randomised, double-blind, multicentre, parallel group, non-inferiority studies. These studies evaluate a two-drug regimen of dolutegravir and lamivudine compared with a standard three-drug, first-line regimen in HIV-1 infected, antiretroviral therapy (ART)-naïve adult participants with baseline viral loads less than 500,000 copies per ml. The studies are designed to demonstrate the non-inferior efficacy, safety, and tolerability of once-daily dolutegravir and lamivudine compared to once-daily dolutegravir and the fixed-dose combination of TDF/FDC at 48 weeks in HIV-1-infected, ART-naïve participants.

For more information please search for NCT02831673 (GEMINI 1) or NCT02831764 (GEMINI 2) on www.clinicaltrials.gov.

About dolutegravir and lamivudine

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.

Lamivudine is a nucleoside analogue used in combination with other antiretroviral agents for the treatment of HIV infection. Lamivudine is available in branded (Epivir) and generic forms. Trademarks are owned by or licensed to 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 and for people who are at risk of becoming infected with HIV. Shionogi joined as a 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 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.

Cautionary statement regarding forward-looking statements

ViiV Healthcare Limited, the global specialist HIV company, is majority owned by GlaxoSmithKline plc, with Pfizer Inc. and Shionogi Limited. 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 2017.

About GSK

GSK - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

Inside Information

The information contained in this announcement is inside information.

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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: June 14, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc