GLAXOSMITHKLINE PLC
Form 6-K
December 20, 2016

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 20 December 2016

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

ViiV Healthcare announces start of phase III study evaluating long-acting cabotegravir for HIV prevention

First injectable to be studied for efficacy in pre-exposure prophylaxis

London, UK 20 December 2016 - ViiV Healthcare, the global specialist HIV company majority-owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today announced the start of a phase III study to evaluate long-acting injectable cabotegravir for the prevention of HIV infection. The study will evaluate injections of cabotegravir given every two months compared to daily oral Pre-Exposure Prophylaxis (PrEP) with Truvada® and is being conducted through a public-private collaboration of ViiV Healthcare, the HIV Prevention Trials Network (HPTN), the US National Institute of Allergy and Infectious Disease (NIAID) and Gilead Sciences.

The global phase III study called HPTN 083 will seek to enrol 4,500 men who have sex with men, and transgender women who have sex with men, at more than 40 sites in North and South America, Asia and Africa. Participants will be aged 18 years or older and at high risk for HIV infection. A second phase III study, to evaluate long-acting cabotegravir for the prevention of HIV infection in young women, is anticipated to start in 2017.

John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare, commented, "Twenty years ago we couldn't have imagined a future with so many effective medicines to treat HIV. However, there remains a need to provide more options for preventing HIV infection, such as long-acting regimens that don't require daily dosing. ViiV Healthcare is committed to studying new prevention options and through our public-private collaboration on this large phase III study, we will evaluate whether long-acting injectable cabotegravir could be an option in the pre-exposure prophylaxis setting."

In 2014, UNAIDS set forth ambitious goals[1] with the aim towards ending the AIDS epidemic by 2030. An important element of the strategy to end the epidemic is to reduce HIV transmission rates. Antiretroviral therapy has been shown to be effective in preventing HIV transmission,[2],[3],[4],[5],[6] however, adherence to daily oral therapy varies among different populations.[7],[8] Because adherence to prevention regimens has been correlated with efficacy in preventing HIV infection,[9] it is important to continue to evaluate options that may facilitate adherence, including regimens that do not require daily dosing.

ViiV Healthcare is collaborating on the clinical trial of injectable cabotegravir with NIAID, the NIH-funded HIV Prevention Trials Network (HPTN) and Gilead Sciences. NIAID is sponsoring the trial and HPTN is conducting the study. ViiV Healthcare and NIAID are providing financial support and ViiV Healthcare and Gilead Sciences are providing the study medications.

Truvada is a registered trademark of Gilead Sciences, Inc.

- Ends -

Notes to editors

About PrEP - Pre-exposure prophylaxis or PrEP specifically refers to use of anti-retroviral medication in uninfected people to prevent HIV infection.

About cabotegravir -- Cabotegravir is an investigational integrase strand transfer inhibitor (INSTI) being developed by ViiV Healthcare for the treatment and prevention of HIV and is not approved by regulatory authorities anywhere in the world. Cabotegravir is currently being evaluated as a long-acting, nanosuspension formulation for intramuscular injection and also as a once-daily oral tablet for induction prior to long-acting injection.

About HPTN 083 (NCT 02720094) - This is a non-inferiority, double blind, double dummy, safety and efficacy study of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (Truvada®), for pre-exposure prophylaxis in HIV-uninfected cisgender men and transgender women who have sex with men. The primary objectives are incidence of HIV infection in participants randomised to injectable cabotegravir compared to

participants randomised to daily oral tenofovir disoproxil fumarate/emtricitabine and safety of both regimens. Additional endpoints include HIV drug resistance, acceptability of and preference for each regimen and resource utilisation. Primary outcome data are anticipated for 2020.

Further information on the study may be found on www.hptn.org/research/studies/176.

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 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.

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.

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[1] UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic. Published 2014, Available at: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf
[2] Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. The New England Journal of Medicine 2012;367:399-410
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[4] Thigpen M. Daily oral antiretroviral use for the prevention of HIV infection in heterosexually active young adults in Botswana: results from the TDF2 study. Abstract WELBC01. 6th IAS 2011.
[5] Marrazzo JM, Ramjee G, Richardson BA, et al. Tenofovir-based preexposure prophylaxis for HIV infection among African women. The New England journal of medicine 2015;372:509- 18.
[6] Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. The New England journal of medicine 2012;367:411-22.
[7] Haberer JE, Kahane J, Kigozi I, et al. Real-time adherence monitoring for HIV antiretroviral therapy. AIDS and behavior 2010;14:1340-6.

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[9] Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. The Lancet Infectious diseases 2014;14:820-9.

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: December 20, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc