GLAXOSMITHKLINE PLC
Form 6-K
February 24, 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 February 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

--

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

--

PRESS RELEASE

ViiV Healthcare announces first phase II HIV prevention study results for investigational long-acting injectable cabotegravir

London, UK, 24 February 2016 - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, today presented positive results from the 41 week phase IIa ECLAIR study, which evaluated the safety, tolerability, dosing and satisfaction with the investigational, long-acting, injectable cabotegravir as monotherapy for pre-exposure prophylaxis (PrEP) in HIV-uninfected healthy adult males not at high risk of acquiring HIV.[1] Results were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

Data from the study support the advancement of cabotegravir, an integrase strand transfer inhibitor, to the next stage of development as a potential drug for HIV prevention.1 Adverse events (AEs) during the injection phase occurred in 98% and 90% of cabotegravir and placebo group participants, respectively.1 Injection site pain was the most frequently reported Grade 2-4 AE for those receiving cabotegravir (59%, compared to 5% for placebo).1

The ECLAIR study randomised 127 HIV-uninfected participants to cabotegravir or placebo (5:1) beginning with a safety assessment on oral cabotegravir (30mg) or matching placebo tablet for four weeks, followed by intramuscular injections of 800mg cabotegravir or placebo (sterile saline solution) dosed once every 12 weeks for three cycles.1

A majority of participants in the study reported satisfaction with cabotegravir injections.1 Following repeat injections, 67/91 (74%) of participants favoured cabotegravir long-acting injections compared to oral cabotegravir.1

"There are more than 36 million people worldwide living with HIV today and, despite considerable progress made in the fight against HIV, infections are still increasing in parts of the world. Preventative measures like PrEP could play an important role in reducing the number of new infections and help contribute to the goal of ending the global AIDS epidemic," said John C Pottage, Jr, MD, Chief Scientific and Medical Officer, ViiV Healthcare. "We are encouraged by these first results from the ECLAIR study and look forward to understanding the potential efficacy and broader safety profile of cabotegravir in the PrEP setting as we move into phase III development later this year."

The ECLAIR study also collected cabotegravir exposure data throughout each 12-week dosing interval. Results showed drug concentrations were lower than anticipated at the end of the dosing interval in approximately two-thirds of participants.1 As a result, an alternative dosing strategy of 600mg intramuscular injections every eight weeks is now under investigation as a means to optimise cabotegravir dosing prior to future safety and efficacy studies.

Adverse events in ECLAIR
Adverse events (AEs) leading to withdrawal during the oral phase (7/105) included three events of neutropenia, three events of increasing blood creatine phosphokinase (CPK) and one event of fatigue.1 For participants who entered the injection phase, a similar proportion (93% [87/94] for cabotegravir and 95% [20/21] for placebo) completed all three injection cycles.1 Self- reported injection intolerability led to withdrawal in 4% (4/94) of cabotegravir participants.1 One participant in the placebo group withdrew during the injection phase due to HIV seroconversion.1

The number of Grade 2-4 AEs on the cabotegravir arm was higher compared to placebo during the injection phase (80% [75/94] for cabotegravir vs 48% [10/21] for placebo).1 Grade 2 AEs in the injection phase not related to injection site pain included pyrexia (fever) (7% [7/94] for cabotegravir subjects and 0% for placebo subjects), injection site pruritus (itching) (6% [6/94] for cabotegravir subjects and 0% for placebo subjects) and injection site swelling (6% [6/94] for cabotegravir subjects and 0% for placebo subjects).1

Additional supporting data from the ECLAIR study on the satisfaction and acceptability of long-acting cabotegravir will be presented at CROI later today.[2]

About HIV and PrEP
HIV stands for the Human Immunodeficiency Virus. Unlike some other viruses, the human body cannot get rid of HIV, so once someone has HIV they have it for life. There is no cure for HIV, but effective treatment can control the virus so that people with HIV can enjoy healthy and productive lives.

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medicines by HIV-uninfected people before potential exposure to block the acquisition of HIV.[3] Clinical trials of daily oral PrEP for uninfected individuals have shown evidence of high levels of effectiveness in men who have sex with men (MSM) and mixed levels in women. Two regimens are currently approved for use: a daily fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC), and TDF alone.[4]

About cabotegravir
Cabotegravir is an investigational integrase strand transfer inhibitor (INSTI) and analogue of dolutegravir. 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 long-acting nanosuspension formulation for intramuscular (IM) injection.

About ECLAIR study
ECLAIR (Phase IIa Study to Evaluate the Safety, Tolerability and Acceptability of Long Acting Injections of the HIV Integrase Inhibitor [cabotegravir] in HIV Uninfected Men) is a double-blind, randomised, multi-centre US study in HIV-uninfected healthy adult males not at high risk of acquiring HIV. It evaluated cabotegravir long-acting injections as a candidate for HIV Pre-Exposure Prophylaxis (PrEP).

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 (TYO: 4507) 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

ViiV Healthcare contacts:
Sébastien Desprez (UK) +44 7920 567 707
Global Communications
ViiV Healthcare

Marc Meachem (US) +1 919 483 8756
US Communications
ViiV Healthcare

GSK enquiries:

UK Media enquiries:	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Kathleen Cuca	+1 215 859 1922	(Philadelphia)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Sarah Spencer	+1 215 751 3335	(Philadelphia)

Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

[1] Markowitz M et al. ECLAIR: Phase 2A Safety and PK Study of Cabotegravir LA in HIV Uninfected Men. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, 22-25 February, 2016. Abstract #106
[2] Murray Miranda et al. Tolerability and Acceptability of Cabotegravir LA Injection-results from ECLAIR Study. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, 22-25 February, 2016. Abstract #471
[3] World Health Organization (WHO). Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. September 2015. Last accessed December 2015 http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf?ua=1
[4] World Health Organization (WHO). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: What's new. November 2015. Last accessed December 2015 http://apps.who.int/iris/bitstream/10665/198064/1/9789241509893_eng.pdf?ua=1

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: 24 February, 2016

By: VICTORIA WHYTE

Victoria Whyte

Authorised Signatory for and on
behalf of GlaxoSmithKline plc