GLAXOSMITHKLINE PLC
Form 6-K
October 31, 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 31 October 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

--

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: 31 October 2018, London UK - LSE Announcement

ViiV Healthcare announces positive phase 3 results from the BRIGHTE study of fostemsavir in heavily treatment-experienced patients with HIV

BRIGHTE study highlights ViiV Healthcare's commitment to developing innovative medicines for all people living with HIV, including those heavily-treated and failing on current antiretroviral regimens

London, UK 31 October 2018 - ViiV Healthcare today announced 48-week results from the phase III BRIGHTE study of investigational fostemsavir in heavily treatment-experienced (HTE) patients with HIV-1 infection.

Fostemsavir, in combination with optimised background treatment (OBT), maintained virologic suppression from Week 24 to Week 48 in this difficult-to-treat population. Results show 54% of patients in the randomised cohort (n = 146/272) achieved virologic suppression (<40 copies/mL) at 48 weeks of treatment with fostemsavir plus optimised background therapy. Additionally, patients in the randomised cohort showed immunologic improvement through week 48 as demonstrated by an increase in CD4+ T-cell counts (mean change from baseline of +139 cells/μL). These data at 48 weeks build on the primary endpoint data (day 8) announced last year.

Most patients who received fostemsavir experienced at least one adverse event (AE) by week 48. The most commonly reported drug-related AEs were diarrhoea, nausea and headache. Thirty-five percent of participants had one or more serious adverse events (SAE), most commonly related to infections, and these occurred in the most immunocompromised patients. Three percent (3%) of SAEs related to the study medication, and seven percent (7%) of participants discontinued due to an AE.

John C. Pottage, Jr., MD, Chief Scientific and Medical Officer of ViiV Healthcare, said: "We are excited by the results of the BRIGHTE study which evaluated fostemsavir, a first-in-class attachment inhibitor, specifically developed for heavily treatment-experienced patients. People living with HIV who participated in this study were failing on their current antiretroviral regimens and had few treatment options left available to them; we were encouraged to see that treatment with fostemsavir resulted in both meaningful reductions in viral load and improvements in the health of their immune systems. At ViiV Healthcare we remain dedicated to developing innovative medicines for all people living with HIV and expect to seek regulatory approval for fostemsavir in 2019."

Searching for new ways to prevent the HIV virus from replicating is important, especially for those who develop resistance to their treatment regimens. Fostemsavir is a prodrug that is metabolised to the active compound, temsavir, a first-in-class attachment inhibitor that binds to glycoprotein 120 (gp120) on the envelope of the HIV, locking gp120 in a conformational state that inhibits initial interaction between the virus and host immune cells, preventing viral attachment and entry into the host CD4+ T-cell. Because of its mechanism of action there is no in-vitro cross-resistance to other classes of ARVs, which may help patients who have become resistant to most other medicines.

In addition to the primary efficacy results, a pre-specified subgroup analysis was also conducted and showed numerically higher rates of virologic response in patients >50 years, females, or in patients who self-reported their race as "black" or "African-American" compared to their respective counterparts through Week 48. Not unique to the BRIGHTE study was the fact that subgroups with high baseline HIV-1 RNA (>=100,000 c/mL) and low baseline CD4+ cell counts (<20 cells/mm3) had lower rates of virologic response through Week 48. There were comparable increases in CD4+ T-cell counts across subgroups of: age, gender, race, and geographic region. Notably, subjects with the lowest baseline CD4 counts (<20 cells/lL), had comparable improvement in mean change in baseline CD4 count to those with the highest baseline CD4 values (>200 cells/lL); +145 and +150 cells/lL, respectively.

Notes to editors

About the BRIGHTE study
BRIGHTE (NCT02362503) is a two-cohort (Randomised and Non-Randomised), phase 3 clinical trial evaluating the safety and efficacy of the HIV-1 attachment inhibitor fostemsavir in heavily treatment-experienced adults with HIV-1 infection. Three hundred seventy-one patients enrolled. All had documented resistance, intolerability, and/or contraindication to all ARV agents in at least four of the six available ARV classes. Patients in the Randomised Cohort had to have one but no more than two fully active ARV classes remaining at baseline and were unable to form a viable antiretroviral regimen out of their remaining agents. These patients were randomised 3:1 to add blinded fostemsavir or blinded placebo (n=272) to their current failing regimen for eight days of functional monotherapy. Patients without any remaining fully active approved ARVs (n=99) were assigned to the Non-Randomised Cohort and received open-label fostemsavir plus optimised background therapy on Day 1. The primary endpoint of the study was mean change in log10 HIV-1 RNA between Day 1 and Day 8 for the Randomised Cohort. Beyond the eight-day blinded period, all patients in the Randomised Cohort received open-label fostemsavir plus optimised background therapy. Key secondary endpoints include durability of response at Weeks 24, 48 and 96, as well as safety changes from baseline CD4+ cell counts, and emergence of viral resistance.

About the patient population
Antiretroviral medicines have significantly decreased mortality over the past 30 years; however, treatment failure and antiviral resistance remain a concern for HTE patients and their providers. Failure of HIV medicines to control the virus can result in selected mutations resistant to one or more ARV medicines. Patient co-morbidities, tolerability, and safety issues may further decrease the number of ARV therapies available to design effective treatment regimens for these HTE patients. As a result, treatment options that address the complex needs of HTE people living with HIV remain a significant unmet need.

About fostemsavir
Fostemsavir is an investigational prodrug of temsavir, a human immunodeficiency virus type 1 (HIV-1) attachment inhibitor class and is not approved by regulatory authorities anywhere in the world. Fostemsavir is being developed by ViiV Healthcare for treatment of HIV-1-infected heavily treatment-experienced patients in combination with other antiretroviral agents.

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
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.

ViiV Healthcare Media enquiries:	Melinda Stubbee	+1 919 491 0831
	Audrey Abernathy	+1 919 605 4521
GSK Global Media enquiries:	Simon Steel	+44 (0) 20 8047 5502
	Sarah Spencer	+1 215 751 3335
Analyst/Investor enquiries:	Sarah Elton-Farr	+44 (0) 20 8047 5194
	Mel Foster-Hawes	+44 (0) 20 8047 0674
	Danielle Smith	+44 (0) 20 8047 7562
	James Dodwell	+44 (0) 20 8047 2406
	Jeff McLaughlin	+1 215 751 7002

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: October 31, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc