GLAXOSMITHKLINE PLC
Form 6-K
June 27, 2014

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 June 2014

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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GlaxoSmithKline plc (LSE:GSK) today announced that ViiV Healthcare Ltd (a global specialist HIV company with GlaxoSmithKline, Pfizer, Inc. and Shionogi Limited as shareholders) is issuing the following statement today:

Triumeq® (dolutegravir/abacavir/lamivudine) single-tablet regimen receives positive CHMP opinion in Europe for the treatment of HIV

ViiV Healthcare's first investigational once-daily single-tablet regimen, combining the integrase inhibitor dolutegravir and nucleoside analogues abacavir/lamivudine

London, UK, 27 June 2014 - ViiV Healthcare today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending marketing authorisation for Triumeq®(dolutegravir/abacavir/lamivudine) for the treatment of HIV infection in adults and adolescents aged 12 years and older and weighing at least 40kg.

"Today's positive opinion takes us a step closer to bringing physicians and people living with HIV a dolutegravir based regimen that can be taken once-daily as a single-tablet," said Dr John Pottage, Chief Scientific and Medical Officer, ViiV Healthcare. "This opinion supports the potential of dolutegravir based regimens, as well as the importance of our ongoing research into additional single-tablet treatment options."

The CHMP positive opinion is based upon data from two pivotal studies:

· the Phase III study of dolutegravir (SINGLE), conducted with dolutegravir and abacavir/lamivudine as separate pills1
· a separate bioequivalence study of the fixed-dose combination of dolutegravir/abacavir/lamivudine when taken as a single tablet compared to the administration of dolutegravir and abacavir/lamivudine as separate pills.2

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission (EC), but does not always result in marketing authorisation. A final decision by the EC is anticipated during the third quarter of 2014.

About Triumeq
Triumeq (dolutegravir/abacavir/lamivudine) is not currently approved in any country and is an investigational once-daily single tablet dolutegravir based regimen, containing the integrase inhibitor dolutegravir which was approved by the EMA in January 2014 under the brand name Tivicay®.

A New Drug Application (NDA) for abacavir/dolutegravir/lamivudine was submitted to the U.S. Food and Drug Administration (FDA) in October 2013, and is currently under review. The regulatory submission and review processes have also been initiated in Canada, Australia, Brazil and Japan. Important Safety Information for Tivicay(dolutegravir) and Kivexa (abacavir/lamivudine) in the European Union: Please refer to the full European Summary of Product Characteristics for full prescribing information for dolutegravirand abacavir/lamivudine.

Kivexa®, Tivicay and Triumeq are registered trademarks of the ViiV Healthcare group of companies. The use of the brand name TRIUMEQ is not approved by any regulatory authorities.

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 as a 10% 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 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.

References

1. Walmsley SL, Antela A, Clumeck N et al; for the SINGLE Investigators. Dolutegravir plus abacavir-lamivudine for the treatment of HIV-1 infection. N Engl J Med. 2013;369(19):1807-1818.

2. Weller S, Chen S, Borland J et al. Bioequivalence of a Dolutegravir, Abacavir and Lamivudine Fixed-Dose Combination Tablet and the Effect of Food. JAIDS. 2014 May doi: 10.1097/QAI.0000000000000193. http://journals.lww.com/jaids/Abstract/publishahead/Bioequivalence_of_a_Dolutegravir,_A

ViiV UK/U.S. Media enquiries:	Sébastien Desprez	+44 7920 567 707
	Marc Meachem	+1 919 483 8756
GSK Global Media enquiries:	David Daley	+44 (0) 20 8047 5502
	Melinda Stubbee	+1 919 483 2510
GSK Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543
	Kirsty Collins (SRI & CG)	+44 (0) 20 8047 5534
	Tom Curry	+ 1 215 751 5419
	Gary Davies	+44 (0) 20 8047 5503
	James Dodwell	+44 (0) 20 8047 2406
	Jeff McLaughlin	+1 215 751 7002
	Lucy Singah	44 (0) 20 8047 2248

GlaxoSmithKline 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 'Risk factors' in the company's Annual Report on Form

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 27, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc