GLAXOSMITHKLINE PLC
Form 6-K
March 26, 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 March 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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Issued: Wednesday 26 March 2014, London UK

Regulatory update: combined use of Mekinist™ (trametinib) and Tafinlar® (dabrafenib) in Europe

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that it has withdrawn its Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for the use of Mekinist (trametinib) in combination with the previously approved BRAF inhibitor Tafinlar (dabrafenib) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. The application for the use of Mekinist as a single agent in the same patient population, submitted simultaneously with the MAA for the combination, is still undergoing review by the EMA.

The Committee for Medicinal Products for Human Use (CHMP) of the EMA has indicated that the data provided to date by GSK did not allow the Committee to conclude on a positive benefit-risk balance of the combination. GSK intends to re-submit the MAA for the combined use of Tafinlar and Mekinist when additional data from the ongoing Phase III programme become available.

The regulatory submission for the combination was based on the results from an open-label randomised three-arm phase II study, provided to EMA in 2012. The study aimed to assess the safety and efficacy of dabrafenib in combination with two different doses of trametinib compared to dabrafenib monotherapy in patients with unresectable or metastatic BRAF V600 E or K mutation-positive melanoma.

Additional data from the randomised, double-blind Phase III study (COMBI-d) comparing the combination of dabrafenib and trametinib to dabrafenib and placebo as first-line therapy in the same patient population were also provided to EMA earlier this year.

Dr Rafael Amado, Head of Oncology R&D at GSK, said "Although we have withdrawn our application, we remain committed to providing further data from our ongoing Phase III development programme to support a subsequent re-submission in Europe.

"While significant progress has been made in treating metastatic melanoma over the last few years, we believe more treatment options are needed, and we will work with the European regulators towards making the combination available for patients."

Other Regulatory Activity
Mekinist is approved as a single agent and in combination with Tafinlar in the US and Australia. Mekinist is also approved as monotherapy in Canada. Detailed prescribing information, which may differ between the countries, can be accessed on:

Australia
http://www.gsk.com.au/resources.ashx/prescriptionmedicinesproductschilddataproinfo/1990/FileName/A5A6DF2E45A98313A

Canada
http://www.gsk.ca/english/docs-pdf/product-monographs/mekinist.pdf

US
http://us.gsk.com/products/assets/us_mekinist.pdf

Mekinist was in-licensed by GSK in 2006. GSK holds the worldwide exclusive rights to develop, manufacture and commercialise Mekinist, while Japan Tobacco retains co-promotion rights in Japan.

V A Whyte
Company Secretary
26 March 2014

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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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 20-F for 2013.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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: March 26, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc