GLAXOSMITHKLINE PLC
Form 6-K
February 07, 2013

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 2013

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: Thursday 7 February 2013, London UK - LSE Announcement

Regulatory Update - GSK announces European submission for MEK monotherapy and BRAF/MEK combination therapy in metastatic melanoma

GlaxoSmithKline plc (LSE:GSK) today announced submission of a Marketing Authorisation Application to the European Medicines Agency (EMA) for trametinib (MEK) as monotherapy and in combination with dabrafenib (BRAF) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. The EMA's Committee for Medicinal Products for Human Use (CHMP) has granted GSK's request for accelerated assessment of this application.

The application includes data from a randomised, Phase III study of trametinib monotherapy compared to dacarbazine monotherapy in patients with BRAF V600 mutation positive metastatic melanoma, as well as data from a randomised Phase I/II study comparing dabrafenib monotherapy to combination therapy with dabrafenib and trametinib in patients with BRAF V600 mutation positive metastatic melanoma.

"We initiated a randomised study very early in the development programme to test whether the novel-novel combination could circumvent resistance to single agent anti-BRAF therapy and are encouraged by the results from this Phase I/II trial." said Dr Rafael Amado, Head of Oncology R&D. "We are planning further regulatory submissions based on these data, in the US and other countries in the coming months."

An application that has been granted accelerated assessment will have a maximum review time of 150 days. However, at any time during the assessment CHMP may decide to continue the assessment under the standard centralised procedure assessment timelines of 210 days or GSK may submit a request for a change to a standard assessment procedure.

The ongoing Phase III development programme for the combination in BRAF V600 mutation positive melanoma comprises three randomised trials: two trials in the metastatic setting (NCT01584648 and NCT01597908) and one trial in the adjuvant setting (NCT01682083). In August 2012, GSK announced regulatory submissions for dabrafenib monotherapy as a treatment for BRAF V600 metastatic melanoma in the EU and US as well as a US submission for trametinib monotherapy as a treatment for BRAF V600 metastatic melanoma. Trametinib and dabrafenib are investigational medicines and their use as monotherapy or combination therapy is not approved anywhere in the world.

V A Whyte
Company Secretary
7 February 2013

GlaxoSmithKline - 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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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: February 07, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc