GLAXOSMITHKLINE PLC
Form 6-K
July 09, 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 July 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: 9 July 2013, London UK

Regulatory Update - GSK announces US submission for dabrafenib/trametinib combination in metastatic melanoma

GlaxoSmithKline plc (LSE:GSK) today announced submission of supplemental New Drug Applications (NDAs) to the US Food and Drug Administration for use of dabrafenib, a BRAF inhibitor, in combination with trametinib, a MEK inhibitor. Supplemental applications were submitted to each of the currently approved NDAs for the use of each drug in combination with the other, for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 E or K mutation.

The applications are based on data from a randomised Phase I/II study comparing dabrafenib monotherapy to combination therapy with dabrafenib and trametinib in patients with BRAF V600E and V600K mutation positive metastatic melanoma.

Use of dabrafenib and trametinib in combination is investigational and not approved anywhere in the world. European review of the MAA submission for trametinib, both as monotherapy and in combination with dabrafenib, is ongoing. CHMP has reverted from the accelerated assessment review process to standard timelines to allow sufficient time for review of the submission.

For full US Prescribing Information and Medication Guide, which includes information on the approved use of Tafinlar® (dabrafenib) and for the full US Prescribing Information and Patient Information leaflet, which includes information on the approved use of Mekinist® (trametinib) please visit http://us.gsk.com/html/medicines/index.html

V A Whyte
Company Secretary
9 July 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

GlaxoSmithKline
Enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Stephen Rea	+1 215 751 4394	(Philadelphia)
	Kevin Colgan	+1 919 483 2933	

			(North Carolina)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+ 44 (0) 20 8047 3289	(London)
	Lucy Budd	+44 (0) 20 8047 2248	(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)

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. Factors that may affect GSK' s operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

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: July 09, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc