GLAXOSMITHKLINE PLC
Form 6-K
April 30, 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 April 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: Tuesday 30 April 2013, London UK - LSE Announcement

GSK announces regulatory submission for umeclidinium monotherapy in US

GlaxoSmithKline plc (LSE:GSK) today announced the submission of a regulatory application in the US for the investigational once-daily medicine, umeclidinium bromide (UMEC), for patients with chronic obstructive pulmonary disease (COPD). On 26th April, GSK announced the submission of a regulatory application in Europe for UMEC for patients with COPD.

UMEC is an investigational bronchodilator molecule (formerly known as GSK573719), a long-acting muscarinic antagonist (LAMA), administered using the ELLIPTA™ inhaler.

A New Drug Application (NDA) for UMEC monotherapy (62.5mcg) has been submitted to the US Food and Drug Administration (FDA), for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema.

The UMEC dose of 62.5mcg is specified as the pre-dispensed dose (contained inside the inhaler) which is equivalent to the 55mcg delivered dose (emitted from the inhaler) submitted for approval in Europe.

Regulatory filings for UMEC monotherapy are planned in other countries during the course of 2013.

V A Whyte
Company Secretary
30 April 2013

Other Respiratory Development Programmes:
UMEC monotherapy is one of several late-stage assets in the GSK respiratory development portfolio. The development portfolio includes umeclidinium /vilanterol (UMEC/VI, with proposed brand name ANORO™), fluticasone furoate/vilanterol (FF/VI, with proposed brand names RELVAR™ and BREO™), VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

ANORO™, RELVAR™, BREO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names is not approved by any regulatory authorities.

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
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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. 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: April 30, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc