

GLAXOSMITHKLINE PLC

Form 6-K

April 26, 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  Form 40-F

--

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

--

Issued: Friday 26 April 2013, London UK

GSK announces regulatory submission for umeclidinium monotherapy in European Union

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

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

A Marketing Authorisation Application (MAA) for UMEC monotherapy (55 mcg delivered dose) has been submitted to the European Medicines Agency (EMA), for a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

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

V A Whyte  
Company Secretary  
26 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](http://www.gsk.com)

GlaxoSmithKline

Enquiries:

UK Media enquiries: David Mawdsley +44 (0) 20 8047 5502 (London)

Edgar Filing: GLAXOSMITHKLINE PLC - Form 6-K

David Daley +44 (0) 20 8047 (London)  
5502

Catherine +44 (0) 20 8047 (London)  
Hartley 5502

US Media enquiries: Stephen Rea +1 215 751 4394 (Philadelphia)  
Kevin Colgan +1 919 483 2933 (North  
Carolina)  
Melinda +1 919 483 2510 (North  
Stubbee Carolina)  
Mary Anne +1 919 483 0492 (North  
Rhyne Carolina)  
Sarah Alspach +1 202 715 1048 (Washington,  
DC)  
Jennifer +1 215 751 5664 (Philadelphia)  
Armstrong

Analyst/Investor enquiries: Ziba Shamsi + 44 (0) 20 8047 (London)  
3289  
Lucy Budd +44 (0) 20 8047 (London)  
2248  
Tom Curry + 1 215 751 5419 (Philadelphia)  
Gary Davies + 44 (0) 20 8047 (London)  
5503  
James Dodwell + 44 (0) 20 8047 (London)  
2406  
Jeff + 1 215 751 7002 (Philadelphia)  
McLaughlin

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 26, 2013

By: VICTORIA WHYTE  
-----

Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc