GLAXOSMITHKLINE PLC
Form 6-K
February 21, 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 February 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: Thursday 20 February 2014, London UK

GSK receives positive CHMP opinion for Incruse® (umeclidinium) for the treatment of COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for umeclidinium under the proposed brand name Incruse® as a once-daily, maintenance treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Umeclidinium is an investigational long-acting muscarinic antagonist (LAMA). The proposed strength is 55mcg inhalation powder contained in the Ellipta® inhaler.

Patrick Vallance, GSK's President of Pharmaceuticals R&D, said, "GSK is committed to the development of a range of respiratory medicines that allow physicians to make treatment choices based on their individual patients' needs. The CHMP's decision brings us a step closer to offering physicians a further once-daily treatment choice for appropriate COPD patients. We look forward to a final decision from the European Commission in the next few months."

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission. A final decision by the European Commission is anticipated during the second quarter of 2014.

The EMA assessment of umeclidinium included a review of seven Phase 3 clinical trials which included over 2,500 COPD patients treated with umeclidinium or placebo. These trials included a number of studies from the clinical development programme designed to investigate umeclidinium used as monotherapy and also in combination with the investigational long-acting beta2 agonist, vilanterol.The investigational combination therapy is currently undergoing regulatory review under the proposed brand name Anoro® (umeclidinium/vilanterol).

Important Safety Information for Umeclidinium
Umeclidinium is contraindicated in patients with hypersensitivity to umeclidinium, or any of the excipients.

Umeclidinium should not be used in patients with asthma since it has not been studied in this patient population. Administration of umeclidinium may produce paradoxical bronchospasm that may be life-threatening. Umeclidinium should not be used for the treatment of acute episodes of bronchospasm. In the event of deterioration of COPD during treatment with umeclidinium, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists, including umeclidinium. In addition, patients with clinically significant uncontrolled cardiovascular disease were excluded from clinical studies. Therefore, umeclidinium should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias.

Consistent with its antimuscarinic activity, umeclidinium should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

Umeclidinium contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take umeclidinium.

The most frequently reported adverse reactions with umeclidinium were nasopharyngitis, upper respiratory tract infection and headache, which were reported as common (frequency of ≥1/100 to <1/10).

Other Umeclidinium Regulatory Activity:

In April 2013, a New Drug Application (NDA) for umeclidinium monotherapy (62.5mcg) was submitted to the US Food and Drug Administration (FDA), under the trade name Incruse and is currently under review. The umeclidinium 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.

Umeclidinium is an investigational medicine and is not currently approved anywhere in the world.

B Kelly-Bisla
Corporate Secretariat
20 February 2014

Other Respiratory Development Programmes:
The GSK respiratory development portfolio also includes investigational VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines fluticasone furoate monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

INCRUSE®, ANORO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies. The use of the brand name INCRUSE is not approved by any regulatory authorities.

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.

GSK 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)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Emily Beamer	+1 215 751 6622	(Philadelphia)
	Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:	Sally Jackson	+44 (0) 20 8047 5543	(London)
	Kirsty Collins (SRI & CG)	+44 (0) 20 8047 5534	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell		(London)

	+44 (0) 20 8047 2406	
Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
Ziba Shamsi	+44 (0) 20 8047 3289	(London)
Lucy Singah	+44 (0) 20 8047 2248	(London)

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: February 21, 2014

By: SIMON BICKNELL

Simon Bicknell

Authorised Signatory for and on
behalf of GlaxoSmithKline plc