GLAXOSMITHKLINE PLC
Form 6-K
April 28, 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 April 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: Monday 28 April 2014, London UK - LSE Announcement

GSK receives EU marketing authorisation for Incruse® (umeclidinium) for the treatment of COPD

GlaxoSmithKline plc (LSE/NYSE:GSK) announced today that the European Commission has granted marketing authorisation for Incruse® (umeclidinium) as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Now licensed across all EU member states, Incruse is a once-daily long-acting muscarinic antagonist (LAMA), a type of bronchodilator also known as an anticholinergic. Incruse is a 55mcg strength inhalation powder delivered by the Ellipta® inhaler.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said, "COPD affects millions of people in Europe and for many years we have been committed to researching and improving understanding of it. We are delighted by today's marketing authorisation for Incruse Ellipta, our first LAMA, which will provide healthcare professionals with a further treatment option for appropriate COPD patients. This is in line with our goal to develop a range of respiratory medicines that allow physicians to make treatment choices based on their individual patients' needs."

It is expected that the first launches will have taken place in Europe by the end of 2014.

The EMA assessment of umeclidinium included a review of seven phase III clinical trials which included over 2,500 COPD patients treated with umeclidinium or placebo. Within this, 576 patients received the recommended dose of umeclidinium 55mcg once-daily.

For the EU Summary of Product Characteristics for Incruse, please visit http://ec.europa.eu/health/documents/community-register/index_en.htm. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

About COPD
COPD is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing. COPD is thought to affect 4-10% of the adult population in Europe.[i]

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.[ii]

Important Safety Information for Incruse
The following Important Safety Information is based on a summary of the Summary of Product Characteristics for Incruse. Please consult the full Summary of Product Characteristics for all the safety information for Incruse.

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.

This medicinal product 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 2014, umeclidinium was licensed in Canada under the brand name Incruse Ellipta for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema.

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

Regulatory applications for umeclidinium have been submitted and are undergoing assessment in a number of other countries. Umeclidinium is not licensed anywhere outside of the EU and Canada.

Incruse® and Ellipta® are trademarks of the GSK group of companies.

V A Whyte
Company Secretary
28 April 2014

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 (London)

		+44 (0) 20 8047 5502	
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
	Sarah Spencer	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Robin Gaitens	+1 919 483 2678	(North Carolina)
	Juan Carlos Molina	+1 919 483 0471	(North Carolina)
	Bradd Pavur	+1 919 483 0044	(North Carolina)
	Karen Collins	+1 919 483 2527	(North Carolina)
Analyst/Investor enquiries:	Ziba Shamsi	+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	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

References

[i] European COPD Coalition. COPD Key Facts. Accessed March 2014. Available at: http://www.copdcoalition.eu/about-copd/key-facts. March 2014

[ii] National Heart Lung and Blood Institute. Who is at risk for COPD? Accessed March 2014. Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/copd/atrisk.html

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 28, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc