GLAXOSMITHKLINE PLC
Form 6-K
April 17, 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

--

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

--

Issued: Thursday 17 April 2014, London UK - LSE Announcement

GSK announces approval in Canada for Incruse™ Ellipta™ (umeclidinium) as a treatment for COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that Incruse™ Ellipta™ (umeclidinium, as umeclidinium bromide) has received market authorisation in Canada for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. This is the first market authorisation granted for this product anywhere in the world.

Incruse Ellipta is GSK's first long-acting muscarinic antagonist (LAMA) monotherapy, a type of bronchodilator also known as a long-acting anticholinergic. It contains
62.5 micrograms of umeclidinium delivered by GSK's Ellipta dry powder inhaler.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said: "COPD affects a significant and growing number of people globally. For over 40 years GSK has been at the forefront of research and development of new respiratory medicines, and our goal in COPD is to introduce a range of medicines so that physicians can choose the treatment option which best meets their individual patients' needs. We are delighted that our LAMA monotherapy has achieved its first approval, and are now looking forward to progressing the ongoing regulatory submissions elsewhere."

The clinical programme for Umeclidinium included seven phase III clinical trials which involved over 2,500 COPD patients treated with umeclidinium or placebo.

About COPD
Chronic obstructive pulmonary disease (COPD) is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterised by obstruction to airflow that interferes with normal breathing.

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.

About Incruse Ellipta
Incruse Ellipta is a new once-daily long-acting muscarinic antagonist (LAMA) approved in Canada for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. Incruse Ellipta is not indicated for the relief of acute deterioration of COPD, and should not be used in patients under 18 years of age. Incruse contains 62.5 micrograms umeclidinium delivered by the Ellipta inhaler.

Important Safety Information
The following important safety information is based on the Product Monograph for Incruse Ellipta. Please consult the full Product Monograph for all the labeled safety information for Incruse Ellipta.

Incruse Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins.

Incruse Ellipta is not indicated for the treatment of acute episodes of bronchospasm (i.e. as rescue therapy). Incruse Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. Patients should be instructed to discontinue regular use of short-acting bronchodilators and to use them only for acute respiratory symptoms.
Exacerbations may occur during treatment.

Incruse Ellipta should not be used more often or at higher doses than recommended.

Incruse Ellipta should not be used in conjunction with other medicines containing a LAMA.

There have been no studies investigating the effect of Incruse Ellipta on the ability to perform tasks that require judgement, motor or cognitive skills.

Incruse Ellipta should be used with caution in patients with narrow-angle glaucoma or urinary retention.

Incruse Ellipta should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias. In some cases, treatment may need to be discontinued.

Incruse Ellipta should be discontinued if paradoxical bronchospasm occurs and alternative therapy considered if necessary.

As with all medications, immediate hypersensitivity reactions may occur after administration of Incruse Ellipta.

Incruse Ellipta should not be used in patients under 18 years of age.

Use during pregnancy, labour and in breastfeeding women should only occur if the potential benefit justifies the potential risk.

Co-administration with other anticholinergics should be avoided.

Adverse events reported at a frequency of ≥1% and greater than placebo include: nasopharyngitis, upper respiratory tract infection, cough, arthralgia, abdominal pain upper, contusion, myalgia, pharyngitis, tachycardia, toothache and viral upper respiratory tract infection.

The recommended dose is one oral inhalation of Incruse Ellipta 62.5 mcg once daily. No dosage adjustment is required in patients over 65 years of age, in patients with renal impairment, or in patients with mild or moderate hepatic impairment. Incruse Ellipta has not been studied in patients with severe hepatic impairment.

V A Whyte
Company Secretary
17 April 2014

For More Information:

Please consult the Product Monograph that will be posted at www.gsk.ca/ for complete safety information. The Product Monograph is also available by calling 1-800-387-7374.

Other Umeclidinium Regulatory Activity:

Regulatory applications for umeclidinium have been submitted and are undergoing assessment in a number of countries including the US, the European Union and Australia.
Umeclidinium is not currently licensed anywhere outside Canada.

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

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)
	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)
Canadian Media enquiries:	Sarey Wulf	+1 905 819 3363	(Mississauga)
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.

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 17, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc