GLAXOSMITHKLINE PLC
Form 6-K
May 01, 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 May 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: Wednesday 30 April 2014, London UK - LSE announcement

GSK receives approval for Incruse™ Ellipta® (umeclidinium) in the US for the treatment of COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved Incruse™ Ellipta® (umeclidinium) as an anticholinergic indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Umeclidinium is GSK's first once-daily anticholinergic, a type of bronchodilator also known as a long-acting muscarinic antagonist (LAMA), and is contained in the Ellipta® inhaler. The FDA-approved strength is 62.5 mcg.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said: "We believe Incruse Ellipta, our first monotherapy in the anticholinergic class, will be an important once-daily treatment option for appropriate patients with COPD. GSK has a long-standing commitment to the development of respiratory medicines in order to offer physicians a choice of treatment options for their patients. We are delighted by this approval, and are looking forward to making Incruse Ellipta available for appropriate patients with COPD in the US."

Following this approval by the FDA, it is anticipated that launch activities in the US will commence during the fourth quarter of 2014.

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

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. The National Heart, Lung and Blood Institute (NHLBI) estimates that nearly 27 million people in the US alone are affected by COPD.[i]

According to the NHLBI, long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. In the United States, the most common irritant that causes COPD is cigarette smoke. Breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace also can contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.

About Incruse Ellipta
Incruse Ellipta is an anticholinergic approved in the US for the long-term once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Incruse contains 62.5 mcg umeclidinium delivered by the Ellipta inhaler.

Full US Prescribing Information including Patient Information Leaflet will be available soon at:us.gsk.com. 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 Inquiries" section at the end of this document.

Important Safety Information for Incruse Ellipta
The following Important Safety Information is based on the Highlights section of the Prescribing Information for Incruse Ellipta. Please consult the full Prescribing Information for all the labeled safety information for Incruse

Ellipta.

Incruse Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either umeclidinium, or any of the other ingredients.

Incruse Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm, which should be treated with an inhaled, short-acting beta2-agonist.

As with other inhaled medicines, Incruse Ellipta can produce paradoxical bronchospasm, which may be life-threatening.

Incruse Ellipta should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Incruse Ellipta should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

The most common adverse reactions (incidence ≥2% and more common than placebo) with Incruse Ellipta (and placebo) were nasopharyngitis, 8% (7%); upper respiratory tract infection, 5% (4%); cough, 3% (2%); and arthralgia, 2% (1%). Other adverse reactions with Incruse Ellipta observed with an incidence less than 1% but more common than placebo included atrial fibrillation.

Avoid co-administration of Incruse Ellipta with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as worsening of narrow-angle glaucoma, and worsening of urinary retention.

Other Umeclidinium Regulatory Activity:
In April 2014, Canada's regulatory authority Health Canada approved Incruse™ Ellipta™ in Canada for the treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema.

Also in April 2014, the European Commission granted marketing authorisation for Incruse® in Europe as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

Regulatory applications for umeclidinium have been submitted and are undergoing assessment in a number of other countries.

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

V A Whyte
Company Secretary
30 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.

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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. 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] National Heart, Lung, and Blood Institute. 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases. February 2012 http://www.nhlbi.nih.gov/resources/docs/2012_ChartBook_508.pdf

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
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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: May 01, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc