GLAXOSMITHKLINE PLC
Form 6-K
June 11, 2015

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 June 2015

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 11 June 2015, London UK

GSK announces outcome of US FDA Advisory Committee recommending approval of mepolizumab for the treatment of adults with severe asthma

GlaxoSmithKline plc (LSE: GSK) today announced the outcome of the meeting of the Pulmonary Allergy Drugs Advisory Committee of the United States (US) Food and Drug Administration (FDA) regarding the Biologics Licence Application (BLA) for mepolizumab as an add-on maintenance treatment for severe asthma with eosinophilic inflammation.

The FDA Advisory Committee voted unanimously (14 yes, 0 no) that the efficacy and safety data for mepolizumab, an anti IL-5 monoclonal antibody delivered as a 100mg fixed dose via a subcutaneous injection every four weeks, supported approval in adults 18 years of age and older with severe asthma. The Committee also voted that the efficacy data provided substantial evidence of a clinically meaningful benefit in this population (14 yes, 0 no) and safety in adults with severe asthma had been adequately demonstrated (13 yes, 1 no).

The Committee voted against approval of mepolizumab for use in adolescents 12-17 years of age with severe asthma (4 yes, 10 no). The Committee voted that the efficacy (5 yes, 9 no) and safety (2 yes, 12 no) of mepolizumab had not been adequately demonstrated primarily due to the limited number of patients in the 12-17 age group in the overall database. It recommended that further data are needed in this sub-population where there is a high unmet need.

Patrick Vallance, President, Pharmaceuticals R&D, said: "Our clinical development programme has demonstrated the potential of mepolizumab as a targeted treatment for difficult to treat adults with severe asthma, many of whom have been struggling to live with their condition for many years. These are patients who currently have very few treatment options and our belief in this medicine as a new treatment option has today been reinforced by the Advisory Committee's decision. GSK will continue to work closely with the FDA to complete the review of the BLA for mepolizumab."

The BLA for mepolizumab was submitted to the FDA in November 2014 for approval as an add-on maintenance treatment for patients with severe asthma with eosinophilic inflammation, identified by a blood eosinophil count of at least 150 cells per microlitre at the start of treatment or 300 cells per microlitre in the past 12 months.

FDA Advisory Committees provide non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for mepolizumab is 4 November 2015.

Mepolizumab is not currently approved for use anywhere in the world. Regulatory filings in a number of other countries, including the EU and Japan, are underway. Further submissions are planned during the course of 2015.

Safety Information
In the pivotal studies of mepolizumab, the overall adverse event profile was similar between those patients receiving mepolizumab and patients receiving standard of care. The most commonly reported adverse events were headache, nasopharyngitis, bronchitis, sinusitis, fatigue and asthma. Local injection site reactions were higher in patients receiving mepolizumab subcutaneously, but were normally transient and not considered as severe. No events of anaphylaxis were attributed to mepolizumab.

The mepolizumab Phases II-III clinical development programme involved over 1,500 patients and comprised 9 studies.

About asthma
Currently the World Health Organization estimates that as many as 235 million people live with asthma worldwide. For many of these patients existing therapies can provide adequate control of their symptoms if used appropriately. However approximately 5% of patients with severe asthma cannot achieve symptom control with existing therapies.

About severe asthma and eosinophil inflammation
Severe asthma is defined as "asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy. Severe asthma patients are also often categorised by long-term use of oral corticosteroids (OCS). In a sub set of severe asthma patients, the over-production of eosinophils (a type of white blood cell) is known to cause inflammation in the lungs that can affect the airways, limiting breathing and increasing the frequency of exacerbations. Interleukin-5 (IL-5) is the main promoter of eosinophil growth, activation and survival and provides an essential signal for the movement of eosinophils from the bone marrow into the lung.

About mepolizumab
Mepolizumab is an investigational monoclonal antibody, which stops IL-5 from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this way reduces blood, tissue and sputum eosinophil levels.

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)
	Claire Brough	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Jenni Ligday	+1 202 715 1049	(Washington, DC)
	Karen Hagens	+1 919 483 2863	(North Carolina)

	Gwynne Oosterbaan	+1 215 751 7468	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(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)

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 2014.

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: June 11, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc