GLAXOSMITHKLINE PLC
Form 6-K
November 05, 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 November 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 5 November 2014, London UK - LSE Announcement

GSK announces regulatory submissions for mepolizumab in severe eosinophilic asthma

- Submissions filed in USA and Europe for anti-IL5 monoclonal antibody

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that it has filed regulatory submissions in the USA and Europe for mepolizumab for approval as a maintenance treatment for patients with severe eosinophilic asthma, 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. The submissions comprise:

· A Biologics Licence Application to the US Food and Drug Administration as an add-on maintenance treatment for severe eosinophilic asthma in patients aged 12 years and older with a history of exacerbations.

· A Marketing Authorisation Application to the European Medicines Agency as an add-on treatment for severe eosinophilic asthma in adult patients with a history of exacerbations and/or dependency on systemic corticosteroids.

Mepolizumab is a monoclonal antibody that is delivered in a 100mg dose via subcutaneous injection every four weeks. The regulatory submissions in the USA and Europe are based on studies of patients with severe asthma and include the phase III MENSA1 and SIRIUS2 studies published in the New England Journal of Medicine in September 2014 as well as the earlier phase IIb/III DREAM3 study published in the Lancet in 2012. Both the MENSA and SIRIUS studies evaluated patients with bloodeosinophils of either 150 or more cells per microlitre at initiation of treatment or 300 or more cells per microlitre in the previous 12 months.

Dave Allen, Head, Respiratory Therapy Area Unit, R&D, said, "Severe asthma can have serious health consequences and for patients with elevated eosinophil levels whose disease remains uncontrolled despite taking medication, there are few treatment options. With the regulatory filings announced today, we are taking a further step towards making mepolizumab available for this difficult-to-treat group."

Regulatory filings in other countries are planned during the course of 2014 and 2015. Mepolizumab is not currently approved for use anywhere in the world.

About asthma
Currently the World Health Organization estimates that as many as 235 million people live with asthma worldwide. For many of these patients use of inhaled therapies can provide adequate control of their symptoms however there are as many as 10 percent who live with severe asthma and cannot achieve control with inhaled therapies.

The role of eosinophils in asthma
Although asthma is a heterogeneous disease it is often characterised by an accumulation of eosinophils (white blood cells) in lung tissues and, in general, eosinophil levels correlate with severity and 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 humanised IgG1 monoclonal antibody specific for IL-5, which binds to IL-5, stopping it from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this way reduces blood, tissue and sputum eosinophil levels. Mepolizumab is also being investigated in eosinophilic COPD and Eosinophilic Granulomatosis with Polyangiitis (EGPA).

V A Whyte
Company Secretary
5 November 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

1 N Engl J Med 2014;371: 1198-1207, Ortega HG et al

2 N Engl J Med 2014; 371: 1189-1197 Bel EH et al

3 Lancet 2012; 380: 651-59, Pavord I et al

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: November 05, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc