GLAXOSMITHKLINE PLC
Form 6-K
March 12, 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 March 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 12 March 2014, London UK - LSE Announcement

GSK announce positive results from phase III studies for mepolizumab in severe eosinophilic asthma

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that a pivotal phase III study of mepolizumab, an investigational IL-5 antagonist monoclonal antibody, met its primary endpoint of reduction in the frequency of exacerbations, in patients with severe eosinophilic asthma.

The study (MEA115588) evaluated the efficacy of two dose regimens of mepolizumab in the treatment of patients with severe eosinophilic asthma. Patients remained on their current asthma maintenance therapy throughout the study and were randomised to receive either mepolizumab 75mg intravenous (IV), 100mg subcutaneous (SC), or placebo every four weeks.

For the primary end point, both mepolizumab treatment arms showed statistically significant reductions in the frequency of clinically significant exacerbations of asthma compared to placebo (75mg IV, 47%, $p<0.001$; 100mg SC, 53%, $p<0.001$).

Adverse events reported in the study were similar across all treatment groups. The most common reported adverse events across all treatment groups were nasopharyngitis, headache, upper respiratory tract infection and asthma. The frequency of adverse events was 83% in the placebo group, 84% in the mepolizumab 75mg IV and 78% in the mepolizumab 100mg SC group. The frequency of serious adverse events was 14% in the placebo group, 7% in the mepolizumab 75mg IV and 8% in the mepolizumab 100mg SC group.

Dave Allen, Head, GSK Respiratory Therapy Area Unit, R&D, said:"We are really pleased to have generated further positive data on mepolizumab, consistent with the findings from our earlier exacerbation study. We now have two studies showing a reduction in exacerbations in a specific group of patients with a severe form of asthma who continue to exacerbate despite treatment with high doses of their current maintenance therapies. This is very positive news for patients. For GSK it is exciting that this is the first non-inhaled treatment for severe asthma and we will be progressing towards global filings at the end of the year."

In addition, a second phase III study (MEA115575) designed to evaluate the use of mepolizumab 100mg SC, every 4 weeks in comparison to placebo in reducing daily oral corticosteroid use while maintaining asthma control also met its primary endpoint. The study showed that patients on mepolizumab 100mg SC were able to achieve greater reductions in their maintenance oral corticosteroid dose during weeks 20-24 compared to patients on placebo ($p =0.008$), while maintaining asthma control.

In this study adverse events were similar across treatment groups. The most common reported adverse events in the two treatment groups were headache, nasopharyngitis, bronchitis, sinusitis, fatigue and asthma. The frequency of adverse events was 92% in the placebo and 84% in the mepolizumab treatment group. Frequency of serious adverse events was 18% in the placebo group and 1% in the mepolizumab group.

The full results of these studies will be posted onto the GSK clinical study register, clinicaltrials.gov and presented at a future scientific meeting.

V A Whyte
Company Secretary

12 March 2014

About the studies:
Study MEA115588 was a 32-week double-blind, double-dummy, placebo-controlled, parallel group multicentre study that randomised and treated 576 patients with severe asthma, who had experienced frequent exacerbations despite treatment with high dose inhaled corticosteroids (ICS) plus at least one other controller medication. All patients were also required to have a blood eosinophil count above a pre-specified threshold of ≥150 cells/µl at initiation of treatment or who have had blood eosinophils ≥300 cells/µl in the past 12 months to be eligible for the study.

Study MEA115575 was a 24-week double-blind, placebo-controlled, parallel group multicentre study that randomised and treated 135 patients. To be eligible for the study patients had severe asthma and were on regular treatment with oral corticosteroids, high dose ICS plus an additional controller medication. All patients were also required to have a blood eosinophil count above a pre-specified threshold of ≥150 cells/µl at initiation of treatment or who have had blood eosinophils ≥300 cells/µl in the past 12 months to be eligible for the study.

About severe eosinophilic asthma and mepolizumab
The presence of eosinophils may represent a subtype of severe 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, raised eosinophils 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.

Mepolizumab is an investigational fully 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 in development for severe eosinophilic asthma in patients who exacerbate despite high-dose oral or inhaled corticosteroids (ICS) and an additional controller such as long-acting beta-2 agonist. In addition, mepolizumab is being investigated in COPD and Eosinophilic Granulomatosis with Polyangiitis (EGPA).

Mepolizumab is not approved anywhere in the world.

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.

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: March 12, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc