GLAXOSMITHKLINE PLC
Form 6-K
September 24, 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 September 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: 24th September 2015, London UK - LSE Announcement

GSK receives positive CHMP opinion in Europe for novel anti-IL5 biological Nucala (mepolizumab) for the treatment of patients with severe refractory eosinophilic asthma

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending marketing authorisation for mepolizumab, which will be commercialised under the brand name Nucala, as an add-on treatment for severe refractory eosinophilic asthma in adult patients.

This decision is based on the results from the clinical study programme, which identified the patients that may be suitable for treatment with mepolizumab. Severe refractory eosinophilic asthma patients who participated in the Phase III trials were evaluated by eosinophil level and either a history of recurrent exacerbations or dependency on systemic corticosteroids. All patients were on high-dose inhaled corticosteroids plus another maintenance treatment.

Dave Allen, Head, Respiratory Therapy Area Unit, R&D, said, "For these difficult-to-treat patients there are very limited treatment options. Many struggle to control their asthma even when taking high doses of inhaled therapies and are often reliant on daily oral corticosteroids, which can cause serious long-term side effects. This positive opinion brings us a step closer to adding a targeted biologic therapy, specifically developed for patients with severe eosinophilic asthma, to our respiratory portfolio."

Mepolizumab is an anti-IL 5 monoclonal antibody that is delivered in a 100mg dose via subcutaneous injection every four weeks. The Phase III clinical development programme for mepolizumab investigated the efficacy and safety of mepolizumab in 915 patients with severe asthma who received mepolizumab in addition to standard of care.All patients in studies MEA115588 and MEA115575 had peripheral blood eosinophil levels greater than or equal to 150 cells/μL at initiation of treatment or greater than or equal to 300 cells/μL within the past 12 months.

The Marketing Authorisation Application for mepolizumab was submitted to the EMA in November 2014. The CHMP positive opinion is a formal recommendation to grant marketing authorisation for mepolizumab. If approved, mepolizumab would be the first anti-IL5 biological treatment approved for use in this difficult-to-treat population. The final decision will be made by the European Commission and is anticipated before the end of 2015.

Mepolizumab is not currently approved for use anywhere in the world. Regulatory applications in a number of other countries, including the USA and Japan, have been submitted and are under review. Further submissions are planned during the course of 2015 and 2016.

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 reactions during treatment were headache (very common - may affect one or more in ten people), injection site reactions and back pain.

Other commonly reported adverse events, which may affect one or more in 100 people (but less than one in ten), were lower respiratory tract infections, urinary tract infections, sore throat (pharyngitis), nasal congestion, upper area of abdominal pain, eczema, fever (pyrexia), systemic non-allergic administration-related reactions (including rash, flushing and myalgia) and hypersensitivity reactions (e.g. urticaria, angioedema, rash, bronchospasm, hypotension).

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.

About asthma

Current estimates indicate that as many as 242 million people live with asthma worldwide. For many of these patients, existing therapies can provide adequate control of their symptoms if used appropriately. Approximately 5-10% of patients are estimated to have severe asthma. Studies suggest that approximately 60% of patients with severe asthma have eosinophilic airway inflammation; this group represents up to 3% of the total number of people with asthma.

About severe asthma and eosinophil inflammation

Severe asthma is defined as "asthma that 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.

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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 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: September 24, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc