GLAXOSMITHKLINE PLC
Form 6-K
December 02, 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 December 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: 2 December 2015, London UK - LSE Announcement

GSK receives European marketing authorisation for Nucala® (mepolizumab) in 31 countries

- First anti-IL-5 treatment for patients with severe refractory eosinophilic asthma in the EU

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Commission has granted marketing authorisation for Nucala® (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in adult patients. As a result Nucala is now approved for use in the 31 European countries covered by the European Medicines Agency (EMA).

Nucala is the first and only approved biologic therapy that targets interleukin-5 (IL-5), which plays an important role in regulating the function of eosinophils, an inflammatory cell known to be important in asthma. It is administered as a 100mg fixed dose subcutaneous injection every four weeks in addition to the patient's normal respiratory medication, which often comprises high-dose inhaled corticosteroids plus additional medicines including oral corticosteroids.

"The marketing authorisation of Nucala in the EU is a significant treatment advance for appropriate asthma patients and reinforces GSK's leadership in respiratory. We are proud that our work in this area, to better understand the specific role eosinophils play in severe asthma, has resulted in the licensing of mepolizumab as the first anti-IL-5 biological treatment. We aim to offer this medicine to patients as soon as possible." said Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise.

The lead investigator of the first proof of concept trial for mepolizumab and an investigator for the Phase III MENSA study,Professor Ian Pavord, University of Oxford, commented: "Patients with severe refractory eosinophilic asthma are not the typical 'asthma' patients many people are familiar with. Despite taking high doses of inhaled medications, they struggle to control their asthma. They have particular problems with frequent asthma attacks and can require hospitalisation. Many also take oral corticosteroids to control their symptoms, which we know can lead to side effects that patients often find very difficult to deal with. To be able to offer these patients a treatment that specifically targets the underlying cause of their disease will be an important option."

The Phase IIb/III clinical development programme for mepolizumab investigated the efficacy and safety of mepolizumab in patients with severe asthma. All patients in studies MEA115588 (MENSA) and MEA115575 (SIRIUS) had peripheral blood eosinophil levels greater than or equalto 150 cells/μL at initiation of treatment or greater than or equal to 300 cells/μL within the past 12 months.

For the EU Summary of Product Characteristics for Nucala, please visit http://ec.europa.eu/health/documents/community-register/index_en.htm. 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 Enquiries" section at the end of this document.

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. However, less than 5% of patients with asthma have severe refractory asthma and cannot achieve symptom control with existing therapies.

About severe asthma and eosinophilic 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 asthma attacks. 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. Studies suggest that approximately 60% of patients with severe asthma have eosinophilic airway inflammation.

For more information please see GSK's infographic about severe asthma and role of eosinophils.

About Nucala

Nucala is a monoclonal antibody that 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.

The mepolizumab phase II/III clinical development programme involved nine studies and a total of 915 subjects with severe refractory eosinophilic asthma who received either a subcutaneous or an intravenous dose of mepolizumab during clinical studies of 24 to 52 weeks duration. Three key clinical trials - DREAM (MEA112997), MENSA (MEA115588) and SIRIUS (MEA115575) - have established the efficacy and safety profile of Nucala for severe refractory eosinophilic asthma patients.

The Marketing Authorisation Application for Nucala was submitted to the EMA in November 2014 and was approved on 2 December 2015.

Other mepolizumab regulatory activity
Nucala was approved in the US on 4 November 2015 as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Full US Prescribing Information is available at US Prescribing Information Nucala. Regulatory applications in a number of other countries, including Japan, have been submitted and are under review. Further submissions are planned during the course of 2016.

Nucala® is a registered trade mark of the GSK group of companies.

Important Safety Information for Nucala

The following Important Safety Information is based on a summary of the European Summary of Product Characteristics and US Prescribing Information for Nucala. Please consult the full Summary of Product Characteristics and Prescribing Information for all the safety information for Nucala.

Nucala is contraindicated in patients with hypersensitivity to mepolizumab or to any of the excipients.

Nucala should not be used to treat acute asthma exacerbations.

Asthma-related adverse events or exacerbations may occur during treatment. Patients should be instructed to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment.

Abrupt discontinuation of corticosteroids after initiation of Nucala therapy is not recommended. Reduction in corticosteroid doses, if required, should be gradual and performed under the supervision of a physician.

Acute and delayed systemic reactions, including hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), have occurred following administration of Nucala. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., typically within several days). These reactions may occur for the first time after a long duration of treatment.

In controlled clinical trials, two serious adverse reactions of herpes zoster occurred in subjects treated with Nucala compared with none in placebo. Consider varicella vaccination if medically appropriate prior to starting therapy with Nucala.

Eosinophils may be involved in the immunological response to some helminth infections. Patients with pre-existing helminth infections should be treated for the helminth infection before starting therapy with Nucala. If patients become infected whilst receiving treatment with Nucala and do not respond to anti-helminth treatment, temporary discontinuation of therapy should be considered.

In clinical studies in subjects with severe refractory eosinophilic asthma, the most commonly reported adverse reactions during treatment were headache, injection site reactions and back pain. Headache was considered very common, occurring with a frequency of ≥1/10. Common adverse drug reactions (≥1/100 to <1/10) included: lower respiratory tract infection, urinary tract infection, pharyngitis, hypersensitivity reactions (systemic, allergic), nasal congestion, upper abdominal pain, eczema, back pain, administration-related reaction (systemic, non-allergic), local injection site reactions, and pyrexia.

Injection site reactions (e.g., pain, erythema, swelling, itching, and burning sensation) occurred at a rate of 8% in subjects treated with Nucala compared with 3% in subjects treated with placebo.

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

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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: December 02, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc