GLAXOSMITHKLINE PLC
Form 6-K
November 05, 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 November 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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PRESS
RELEASE

Issued: Wednesday 4 November 2015, London UK - LSE Announcement

GSK's Nucala® (mepolizumab) receives approval from US FDA

- First anti-IL5 treatment for adults and adolescents with severe asthma with an eosinophilic phenotype

GlaxoSmithKline plc (LSE/NYSE: GSK) today received approval from the US Food and Drug Administration (FDA) for its Biologics License Application (BLA) for Nucala® (mepolizumab) as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

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. Patients will receive Nucala in addition to their normal medications for severe asthma, which include high-dose inhaled corticosteroids plus at least one additional asthma control medicine, and may include oral corticosteroids.

This is the first marketing authorisation granted for mepolizumab anywhere in the world.

Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise, said: "Following today's approval, GSK can now offer, as part of our overall respiratory portfolio, a first-in-class biologic treatment for severe asthma patients whose condition is driven by eosinophilic inflammation. Our research has allowed us to better understand the specific role eosinophils play in severe asthma. We are proud of our contribution to this emerging area of science that has led to the approval of the first anti-IL5 treatment. We aim to offer this medicine to patients as soon as possible."

Patients who were shown to benefit from treatment with mepolizumab in the Phase III clinical trials were those with blood eosinophil levels of 150 cells/mcL or greater just prior to treatment. Further information on eosinophil data is included within the approved prescribing information.

Professor Ian Pavord, University of Oxford, lead investigator of the first proof of concept trial for mepolizumab and an investigator for the Phase III MENSA study said: "Severe asthma is a debilitating condition in which patients are at high risk of frequent and serious asthma attacks. Half of all severe asthma patients have at least one urgent care visit per year. As a clinician, the prospect of a treatment that can specifically target the underlying cause of the disease for patients whose condition is driven by eosinophilic inflammation is exciting."

Full US Prescribing Information is available at US Prescribing Information Nucala. Prior to the Prescribing Information being posted online, a copy 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. It is estimated that in the US asthma affects 25.7 million individuals. For many of these patients, existing therapies can provide adequate control of their symptoms if used appropriately. However approximately 5% of patients with asthma 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 on the role of eosinophils in severe asthma please see GSK's infographic.

About Nucala

Nucala is a 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 eosinophil levels.

The mepolizumab Phase II/III clinical development programme involved nine studies and over 1,300 patients. Three key clinical trials - DREAM (MEA112997), MENSA (MEA115588) and SIRIUS (MEA115575) - have established the efficacy and safety profile of Nucala.

The Biologics License Application for Nucala was submitted to the FDA in November 2014 and was approved on 4 November 2015.

Other mepolizumab regulatory activity

Regulatory applications in a number of other countries, including the EU and Japan, have been submitted and are under review. Further submissions are planned during the course of 2016.

Important Safety Information (ISI) for Nucala

The following ISI is based on the Highlights section of the US Prescribing Information for Nucala.

Please consult the full Prescribing Information for all the labelled safety information for Nucala.

Nucala should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

Hypersensitivity reactions (e.g., angioedema, bronchospasm, hypotension, urticaria, rash) have occurred following administration of Nucala. These reactions generally occur within hours of administration, but in some instances can have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, Nucala should be discontinued.

Do not use Nucala to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with Nucala.

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.

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Nucala. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician.

Patients with known parasitic infections were excluded from participation in clinical trials. It is unknown if Nucala will influence a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with Nucala. If patients become infected while receiving treatment with Nucala and do not respond to anti-helminth treatment, discontinue treatment with Nucala until infection resolves.

The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of two clinical trials with Nucala (and placebo) were headache, 19% (18%); injection site reaction, 8% (3%); back pain, 5% (4%); fatigue, 5% (4%); influenza, 3% (2%); urinary tract infection 3% (2%); upper abdominal pain, 3% (2%); pruritis, 3% (2%); eczema, 3% (<1%); and muscle spasm, 3% (<1%).

In three Phase III trials, 10% of subjects in the Nucala group experienced systemic (allergic and non-allergic) reactions compared to 7% in the placebo group. Systemic allergic/hypersensitivity reactions were reported by 1% of subjects who received Nucala compared to 2% of subjects in the placebo group. Manifestations included rash, pruritus, headache, and myalgia. Systemic non-allergic reactions were reported by 2% of subjects in the Nucala group and 3% of subjects in the placebo group. Manifestations included rash, flushing, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

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.

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

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: November 04, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc