GLAXOSMITHKLINE PLC
Form 6-K
March 29, 2016

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 2016

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: Tuesday 29th March 2016, London UK - LSE Announcement

GSK receives marketing authorisation for Nucala® (mepolizumab) in Japan

GlaxoSmithKline plc (LSE/NYSE:GSK) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted approval for Nucala® (mepolizumab) as a treatment for bronchial asthma in patients with refractory asthma whose symptoms are inadequately controlled with standard treatment. Nucala is licensed in Japan for adults and adolescents aged 12 years or older.

Nucala is the first medicine in a new class of anti-interleukin-5 (IL-5) biologic therapies. IL-5 plays an important role in regulating the function of eosinophils, inflammatory white blood cells known to be important in asthma. The medicine is administered as a 100 mg fixed dose subcutaneous injection once every four weeks. Patients will receive the treatment in addition to their existing respiratory medication, which comprises high-dose inhaled corticosteroids plus additional medicines, and may include maintenance oral corticosteroids.

Approval in Japan comes just four months after the approval of Nucala in the US - the first approval of an anti-IL-5 treatment anywhere in the world.

Philippe Fauchet, President, GSK Japan said: "As the market leader in respiratory medicine, GSK has been focused on gaining approval and launching its new respiratory medicines to meet the needs of patients in Japan. Approval of Nucala not only complements our respiratory portfolio but also gives us the opportunity to make a difference to the lives of more patients in Japan. It is our aim to make Nucala available in Japan as soon as possible to support the needs of a significant group of severe asthma patients whose condition is driven by eosinophilic inflammation, which is difficult to control."

The MHLW assessment of mepolizumab was based on data from the global clinical development programme, including the pivotal DREAM (MEA112997), MENSA (MEA115588) and SIRIUS (MEA115575) studies, which investigated the efficacy and safety of mepolizumab in patients with severe eosinophilic asthma. All patients in the phase III MENSA and SIRIUS studies 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.

Japanese Drug Information for Nucala will be available soon at https://www.healthgsk.jp/. Prior to the label being posted online, a copy may be requested from one of the GSK Media or Investor Relations contacts listed in the "GlaxoSmithKline 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 8% of the 127 million people in Japan have asthma, equating to approximately 10 million people. For many of these patients, existing therapies can provide adequate control of their symptoms if used appropriately. However, up to 5% of patients with asthma have difficulty in achieving symptom control with existing therapies.

About severe asthma and eosinophilic 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. In a sub-set of severe asthma patients, the over-production of eosinophils 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.

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 age 12 years or older 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 these severe eosinophilic asthma patients.

The New Drug Application for Nucala was submitted to the MHLW in May 2015 and was approved on Monday 28th March 2016.

In the US Nucala is licensed as an add-on maintenance treatment for 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. Full US Prescribing Information is available at US Prescribing Information Nucala.

In the EU Nucala is licensed as an add-on treatment for severe refractory eosinophilic asthma in adult patients. For the EU Summary of Product Characteristics for Nucala, please visit: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003860/WC500198037

Nucala has also been approved in Canada and Australia. Further regulatory applications have been submitted and are under review in other countries.

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 Japanese Drug Information, European Summary of Product Characteristics and US Prescribing Information for Nucala. Please consult the full Drug Information, 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 2015.

Registered in England & Wales:
No. 3888792

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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.

(Registrant)

Date: March 29, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc