GLAXOSMITHKLINE PLC
Form 6-K
August 30, 2018

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 30 August 2018

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

30 August 2018, London, UK - LSE Announcement

European Commission approves Nucala (mepolizumab) for the treatment of children with severe asthma

First anti-IL-5 biologic treatment for paediatric patients with severe eosinophilic asthma in Europe

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 paediatric patients aged six up to 17 years. As a result of this licence extension Nucala is now approved for use for severe refractory eosinophilic asthma in both adult and paediatric patients in the 31 European countries covered by the European Medicines Agency (EMA).

Dr Hal Barron, Chief Scientific Officer and President, Pharmaceuticals R&D, GlaxoSmithKline, said: "Asthma is the most common chronic disease in children. The availability of Nucala as the first targeted treatment available for young children with severe asthma, will help provide asthma control for these children and reassurance to their parents."

Nucala is the first and only approved biologic therapy for paediatric patients with severe asthma that targets interleukin-5 (IL-5), which plays an important role in regulating the function of eosinophils.
There is a high unmet need in this population as the severity of disease is greater among children and adolescents than adults, and they are at greater risk of fatal or near-fatal events. Children are also in need of new treatment options as they currently have very limited options for severe asthma. In addition, long-term use of the current standard of care, oral corticosteroids, is associated with many of the adverse events observed in adults, with the additional burden of impaired growth in children.

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. 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 (mepolizumab)

First approved in 2015 for severe eosinophilic asthma, mepolizumab is the first-in-class monoclonal antibody that targets IL-5. It is believed to work by preventing IL-5 from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this way reduces blood eosinophils.

Mepolizumab has been developed for the treatment of diseases that are driven by inflammation caused by eosinophils. It has been studied in over 3,000 patients in 16 clinical trials across a number of eosinophilic indications and has been approved (under the brand name Nucala) in the US, Europe and in over 20 other markets, as an add-on maintenance treatment for patients with severe eosinophilic asthma and is the leading biologic in this indication. In the US, Japan and Canada, it is approved as add-on maintenance treatment for patients with eosinophilic granulomatosis with polyangiitis (EGPA). Mepolizumab is currently being investigated for severe hypereosinophilic syndrome, nasal polyposis and COPD.

This marketing authorisation is based on a partial data extrapolation approach which was agreed with the paediatrics committee (PDCO) of the EMA. With this approach, efficacy and safety data from the Phase III studies included in the mepolizumab severe asthma development programme for patients 12 and over were extrapolated to children. This approach was supported by the adolescent data included in the Phase III severe asthma studies and a PK/PD study in children 6-11 years old with severe eosinophilic asthma. The agreement of this approach is based on an overlap in the clinical presentation of both adult and paediatric severe eosinophilic asthma, consistency in therapeutic approach, consistency of mepolizumab mechanism of action, and relevance of the clinical endpoints for both efficacy and safety. Additional PK, PD and safety data in children under 18 years old in other indications were also included in the data package, and the safety profile in paediatric patients aged six up to 12 years is similar to the safety profile in patients aged 12 years and older.

GSK's commitment to respiratory disease
GSK has led the way in developing innovative medicines to advance the management of asthma and COPD for nearly 50 years. Over the last five years we have launched six innovative medicines responding to continued unmet patient need, despite existing therapies. This is an industry leading portfolio in breadth, depth and innovation, developed to reach the right patients, with the right treatment.

Important Safety Information for Nucala (mepolizumab)
The following Important Safety Information is based on a summary of the European Summary of Product Characteristics and Prescribing Information for Nucala in patients 18 and over. For the full EU Summary of Product Characteristics for Nucala, please
visit: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003860/human_med_001933.jsp&mid

Prior to the label for paediatric use 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.

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. anaphylaxis, 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.

Herpes zoster has occurred in subjects receiving Nucala in controlled clinical trials. Consider vaccination if medically appropriate.

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 - a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com

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Cautionary statement regarding forward-looking statementsGSK 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 Principal risks and uncertainties in the company's Annual Report on Form 20-F for 2017.

Registered in England & Wales:
No. 3888792

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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: August 30, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc