GLAXOSMITHKLINE PLC
Form 6-K
July 27, 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 27 July 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

27 July 2018, London, UK - LSE Announcement

CHMP recommend Nucala (mepolizumab) for the treatment of severe eosinophilic asthma paediatric patients in Europe

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending Nucala (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in paediatric patients aged six up to 17 years. If approved it would be the first targeted biologic therapy for the treatment of severe eosinophilic asthma in paediatric patients in Europe.

Dr Hal Barron, Chief Scientific Officer and President, R&D GSK said: "Ensuring our medicines have the broadest possible label is very important, as it allows us to help the greatest number of patients who may benefit. If approved Nucala could provide an additional option for younger patients in Europe who still struggle to control their asthma despite taking inhaled steroids and other controller medications. These are patients who are at high risk of asthma attacks, which can be a very frightening experience for anyone, especially young children."

Asthma is the commonest chronic disease in childhood and severe asthma that is poorly responsive to current standard of care asthma treatments has been reported in approximately 4.5% of children with asthma.1

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission.

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.

About Nucala (mepolizumab)
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 white blood cells called 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 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).

This paediatric licence application is supported by a partial extrapolation approach agreed with the EU Paediatric Committee of the European Medicines Agency which utilised the efficacy and safety data available in paediatric patients and its well-documented positive benefit to risk profile in adult patients. Existing data was used from adolescent participants in the mepolizumab severe asthma pivotal programme in addition to new data from children in the pharmacokinetic (PK)/ pharmacodynamic (PD) study 200363. Part A, completed in children 6-11 years old with severe eosinophilic asthma, collected uncontrolled safety and limited efficacy data and showed that subcutaneous PK data in children 6 to 11 years is consistent with adults after adjustment for bodyweight and bioavailability and that mepolizumab blood eosinophil count reduction in adults is predictive of the blood eosinophil count reduction in paediatric patients. The safety profile of mepolizumab in children and adolescents with severe asthma appears similar to that of adolescents and adults from the Phase III placebo controlled severe eosinophilic asthma studies. No new safety concerns were identified for paediatrics when compared with the overall adolescent and adult data from the Phase III placebo controlled severe eosinophilic asthma studies.

The adult application was supported with data from the mepolizumab phase II/III clinical development programme, which involved nine studies and a total of 915 patients with severe refractory eosinophilic asthma. Patients 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 European Marketing Authorisation Application for Nucala in patients over 18 was submitted to the EMA on 21 November 2014 and was approved on 2 December 2015.

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
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. 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. 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

1. ERS White Book. https://www.erswhitebook.org/files/public/Chapters/11_childhood_asthma.pdf (last accessed July 2018)

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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 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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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: July 27, 2018

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc