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# GSK's Nucala wins positive opinion from EMA for treatment of children with severe asthma

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GlaxoSmithKline has 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.

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.