24 September 2015
EMA/CHMP/519805/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nucala

mepolizumab

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nucala, intended for the treatment of severe refractory eosinophilic asthma. The applicant for this medicinal product is GlaxoSmithKline Trading Services.

Nucala will be available as 100 mg powder for solution for injection. The active substance of Nucala is mepolizumab, a humanised monoclonal antibody which targets with high affinity and specificity human interleukin-5 (IL-5). IL-5 is a protein that plays a major role in the growth and survival of the eosinophils involved in eosinophilic asthma.

The benefits with Nucala are its ability to reduce the number of asthma exacerbations, in patients who either remain uncontrolled on their previous standard of care or are dependent on systemic corticosteroids. The most common side effects are headache, injection site reactions and back pain.

The full indication is: "Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adult patients (see section 5.1)". It is proposed that Nucala should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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