EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/403687/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cinqaero

reslizumab

On 23 June 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cinqaero, intended as add-on treatment in adult patients with severe eosinophilic asthma. The applicant for this medicinal product is Teva Pharmaceuticals Limited.

Cinqaero will be available as a 10 mg/ml concentrate for solution for infusion. The active substance of Cinqaero is reslizumab, a humanised monoclonal antibody (IgG4, κ) against human interleukin-5 (IL 5) (ATC code: R03DX08). Reslizumab binds specifically to IL 5, a key cytokine responsible for the differentiation, maturation, recruitment and activation of human eosinophils. By binding to human IL 5, it blocks its biological function; consequently survival and activity of eosinophils are reduced.

The benefits with Cinqaero are its ability to reduce the exacerbation rate and improve lung function and asthma-related quality of life in patients with severe eosinophilic asthma (with blood eosinophil count ≥ 400 cells/µL) and with at least one previous asthma exacerbation in the preceding year. The most common side effects are increased blood creatine phosphokinase, myalgia and anaphylactic reactions. An imbalance in malignant neoplasms was observed during the clinical trials between placebo and treatment arms.

The full indication is: “Cinqaero is indicated as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment (see section 5.1)”. It is proposed that Cinqaero be prescribed by physicians experienced in the diagnosis and treatment of the above-mentioned indication.

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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