



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2017
EMA/727638/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Fasenra benralizumab

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fasenra, intended for the treatment of severe eosinophilic asthma. The applicant for this medicinal product is AstraZeneca AB.

Fasenra will be available as 30-mg solution for injection in pre-filled syringes. The active substance of Fasenra is benralizumab, an anti-eosinophil, humanised monoclonal antibody (ATC code: R03DX10). Benralizumab binds to the human interleukin-5 receptor expressed on the surface of eosinophils and basophils. This leads to apoptosis of eosinophils and basophils through enhanced antibody-dependent cell-mediated cytotoxicity, and therefore, reduces eosinophilic inflammation.

The benefits with Fasenra are its ability to induce depletion of eosinophils in the blood and lung. This leads to significant reductions in annual exacerbation rates compared with placebo, especially in patients with more than 300 eosinophils/microlitre of blood pre-treatment. The most frequent side effects are headache (8%) and pharyngitis (3%).

The full indication is: "Fasenra is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β -agonists."

It is proposed that Fasenra be prescribed by physicians experienced in the diagnosis and treatment of severe 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

