1 April 2016
EMA/CHMP/174469/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Darzalex

daratumumab

On 1 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Darzalex, intended for the treatment of relapsed and refractory multiple myeloma. Darzalex was designated as an orphan medicinal product on 17 July 2013. The applicant for this medicinal product is Janssen-Cilag International N.V.

Darzalex will be available as a 20 mg/ml concentrate for solution for infusion. The active substance of Darzalex is daratumumab, an IgG1κ human monoclonal antibody (ATC code: L01XC24) that binds to the CD38 protein and potently inhibits the *in-vivo* growth of CD38-expressing tumour cells.

The benefit with Darzalex is its ability to achieve responses in patients with relapsed and refractory multiple myeloma. The most frequently reported adverse reactions were infusion-related reactions, which occurred in 48% of patients. Other frequently reported adverse reactions (in ≥20% of patients) were fatigue, pyrexia, cough, nausea, back pain, upper respiratory tract infection, anaemia, neutropenia and thrombocytopenia.

The full indication is:

"Darzalex as monotherapy is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy."

Darzalex should be administered by a healthcare professional, in an environment where resuscitation facilities are available.

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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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