28 January 2016
EMA/CHMP/15592/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Empliciti

elotuzumab

On 28 January 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 Empliciti, intended for the treatment of multiple myeloma. Empliciti was designated as an orphan medicinal product on 9 August 2012. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Empliciti will be available as 300 mg and 400 mg powder for concentrate for solution for infusion. The active substance of Empliciti is elotuzumab, an immunostimulatory humanised, IgG1 monoclonal antibody (ATC code: L01XC) that specifically targets the SLAMF7 (signalling lymphocyte activation molecule family member 7) protein, highly expressed on multiple myeloma cells.

The benefits with Empliciti are its ability to delay the progression of disease and to increase the proportion of patients who have a response. The most common adverse reactions (occurring in > 10% of patients) with elotuzumab treatment were infusion related reactions, diarrhoea, herpes zoster, nasopharyngitis, cough, pneumonia, upper respiratory tract infection, lymphopenia and weight decrease.

The full indication is: "Empliciti is indicated in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy". It is proposed that Empliciti therapy should be initiated and supervised by physicians experienced in the treatment of multiple myeloma.

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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