23 July 2020
EMA/383350/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Blenrep

belantamab mafodotin

On 23 July 2020, 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 Blenrep[3], intended for the treatment of relapsed and refractory multiple myeloma. Blenrep was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is GlaxoSmithKline (Ireland) Limited.

Blenrep will be available as a 100 mg powder for concentrate for solution for infusion. The active substance of Blenrep is belantamab mafodotin, a humanised IgG1κ monoclonal antibody against the B-cell maturation antigen (BCMA) conjugated with a cytotoxic agent, maleimidocaproyl monomethyl auristatin F (mcMMAF) (ATC code: L01XC39). The antibody-drug conjugate binds to BCMA on myeloma cell surfaces causing cell cycle arrest and inducing antibody-dependent cellular cytotoxicity.

The benefit with Blenrep is its ability to provide durable responses in patients with relapsed and refractory multiple myeloma. The most significant frequently reported side effects (in ≥30% of patients) are keratopathy and thrombocytopenia.

The full indication is:

> "Blenrep is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy."

Blenrep should be prescribed 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

[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.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.