14 September 2023
EMA/CHMP/405889/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pepaxti

melphalan flufenamide

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Pepaxti. The marketing authorisation holder for this medicinal product is Oncopeptides AB.

The CHMP adopted a change to the existing indication for the treatment of adult patients with multiple myeloma. For information, the full indication for Pepaxti will be as follows:[2]

> Pepaxti is indicated, in combination with dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least ~~three~~ **two** prior lines of therapies, whose disease is refractory to ~~at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody~~ **lenalidomide** and ~~who have demonstrated disease progression on or after~~ the last **line of** therapy.
>
> For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation (see section 4.4).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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] New text in bold, removed text as strikethrough

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