12 October 2023
EMA/CHMP/440550/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Brukinsa

zanubrutinib

On 12 October 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 Brukinsa. The marketing authorisation holder for this medicinal product is BeiGene Ireland Ltd.

The CHMP adopted a new indication for the treatment of refractory or relapsed follicular lymphoma (FL). For information, the full indications for Brukinsa will therefore be as follows:[2]

> Brukinsa as monotherapy is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.
>
> Brukinsa as monotherapy is indicated for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.
>
> Brukinsa as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL).
>
> **Brukinsa in combination with obinutuzumab is indicated for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.**

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

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