16 September 2021
EMA/CHMP/352390/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Brukinsa

zanubrutinib

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Brukinsa[2], intended for the treatment of Waldenström's macroglobulinaemia (WM).

The applicant for this medicinal product is BeiGene Ireland Ltd.

Brukinsa will be available as 80 mg hard capsules. The active substance of Brukinsa is zanubrutinib, a Bruton's tyrosine kinase (BTK) inhibitor (ATC code: L01EL03) which blocks the activity of BTK inactivating the pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion.

The benefits of Brukinsa are a clinically meaningful rate of very good partial response (VGPR) and/or complete response (CR). The most common side effects are neutropenia, thrombocytopenia, upper respiratory tract infection, haemorrhage/haematoma, rash, bruising, anaemia, musculoskeletal pain, diarrhoea, pneumonia and cough.

The full indication is:

> 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 should be prescribed by physicians experienced in the use of anticancer medicinal products.

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] This product was designated as an 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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