



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 April 2022  
EMA/CHMP/158054/2022  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Lunsumio mosunetuzumab

On 22 April 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional<sup>2</sup> marketing authorisation for the medicinal product Lunsumio<sup>3</sup>, intended for the treatment of relapsed or refractory follicular lymphoma.

Lunsumio was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is Roche Registration GmbH.

Lunsumio will be available as 1 mg and 30 mg concentrate for solution for infusion. The active substance of Lunsumio is mosunetuzumab, a bispecific monoclonal antibody (ATC code: L01XC) which simultaneously binds to CD20 on B cells and CD3 on T cells, thereby inducing the death of malignant B cells.

The benefits of Lunsumio are the high proportion of patients with a complete response and the durability of the treatment response. The most common side effects are cytokine release syndrome, neutropenia, pyrexia, hypophosphataemia and headache.

The full indication is:

Lunsumio as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies.

Lunsumio should be prescribed by physicians experienced in the use of anticancer therapies.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> 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 expected to provide comprehensive clinical data at a later stage.

<sup>3</sup> 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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