



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 June 2024  
EMA/CHMP/293400/2024  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Tepkinly epcoritamab

On 27 June 2024, 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 Tepkinly. The marketing authorisation holder for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

The CHMP adopted a new indication to include treatment of adults with relapsed or refractory follicular lymphoma. For information, the full indications for Tepkinly will be as follows:<sup>2</sup>

Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

**Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.**

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.

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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> New text in bold

