15 September 2022
EMA/CHMP/760015/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Yescarta

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On 15 September 2022, 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 Yescarta. As Yescarta is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies (CAT). The marketing authorisation holder for this medicinal product is Kite Pharma EU B.V.

The CHMP adopted an extension to the existing indication for the treatment of diffuse large cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL).

For information, the full indications for Yescarta will be as follows[2]:

> **Yescarta is indicated for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.**
>
> Yescarta is indicated for the treatment of adult patients with relapsed or refractory (r/r) DLBCL and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy.
>
> Yescarta is indicated for the treatment of adult patients with r/r follicular lymphoma (FL) after three 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.

[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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