



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/54323/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Columvi glofitamab

On 27 February 2025, 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 Columvi. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a new indication to include treatment of adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified who are ineligible for autologous stem cell transplant. The full indications for Columvi will therefore be as follows:²

Columvi in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT).

Columvi 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.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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

