26 April 2023
EMA/CHMP/166656/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Columvi

glofitamab

On 26 April 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Columvi[3], intended for the treatment of diffuse large B-cell lymphoma (DLBCL). The applicant for this medicinal product is Roche Registration GmbH.

Columvi will be available as 2.5 mg and 10 mg concentrate for solution for infusion. The active substance of Columvi is glofitamab, a monoclonal bispecific antibody (ATC code: L01FX28). By simultaneously binding to CD20 on the B cell and CD3 on the T cell, glofitamab mediates the formation of an immunological synapse with subsequent T-cell activation and proliferation, secretion of cytokines and release of cytolytic proteins resulting in the lysis of CD20-expressing B cells.

The benefits of Columvi were evident in terms of a complete response (CR) rate and overall response rate (ORR) with a significant duration, as observed in an open-label multicenter trial evaluating Columvi in patients with relapsed or refractory B-cell non-Hodgkin's lymphoma. The most common side effects are cytokine release syndrome, infections, neutropenia, anaemia, thrombocytopenia, tumour flare, headache, constipation, diarrhoea, nausea, rash, pyrexia, hypophosphataemia, hypomagnesaemia, hypocalcaemia and hypokalaemia.

The full indication is:

> 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.

Columvi should be prescribed by physicians experienced in the diagnosis and treatment of cancer patients who have access to appropriate medical support to manage severe reactions associated with cytokine release syndrome (CRS).

[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] 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.
[3] 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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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.