20 July 2023
EMA/CHMP/324066/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tepkinly

epcoritamab

On 20 July 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 Tepkinly[3], intended for the treatment of diffuse large B-cell lymphoma (DLBCL). The applicant for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

Tepkinly will be available as a 4 mg/0.8 ml concentrate for solution for injection and a 48 mg solution for injection. The active substance of Tepkinly is epcoritamab, an antineoplastic agent (ATC code: not yet assigned). By simultaneously binding to CD20 on the B cell and CD3 on the T cell, epcoritamab 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 Tepkinly 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, multicentre trial evaluating Tepkinly in patients with relapsed or refractory large B-cell lymphoma (LBCL), including DLBCL, after two or more lines of systemic therapy. The most common side effects are cytokine release syndrome, infections, neutropenia, fatigue, musculoskeletal pain, headache, abdominal pain, diarrhoea, nausea, pyrexia, injection site reactions.

The full indication is:

> 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 must only be administered under the supervision of a healthcare professional qualified in the use of anti-cancer therapy.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.