21 July 2022
EMA/CHMP/644929/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tecvayli

teclistamab

On 21 July 2022, 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 Tecvayli[3], intended for treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies.

Tecvayli was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is Janssen-Cilag International N.V.

Tecvayli will be available as 10 mg/ml and 90 mg/ml solutions for injection. The active substance of Tecvayli is teclistamab, a bispecific antibody that targets the CD3 receptor expressed on the surface of T cells and B cell maturation antigen (BCMA), which is expressed on the surface of malignant multiple myeloma B-lineage cells.

The benefit of Tecvayli is its ability to bring about a response in patients with relapsed and refractory multiple myeloma. The most common side effects are hypogammaglobulinaemia, cytokine release syndrome and neutropenia.

The full indication is:

> Tecvayli is is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Tecvayli should be initiated and supervised by physicians experienced in the treatment of multiple myeloma.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.