27 February 2025
EMA/CHMP/48992/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lynozyfic

linvoseltamab

On 27 February 2025, 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 Lynozyfic, intended for the treatment of patients with relapsed and refractory multiple myeloma who have received at least three prior therapies.

The applicant for this medicinal product is Regeneron Ireland DAC.

Lynozyfic will be available as a 5 mg or 200 mg concentrate for solution for infusion. The active substance of Lynozyfic is linvoseltamab, a bispecific monoclonal antibody (ATC code: not yet assigned). Lynozyfic targets CD3, a receptor expressed on the surface of T cells, and BCMA, expressed on the surface of plasma cells, including malignant multiple myeloma cells.

The benefit of Lynozyfic is its ability to induce a partial or complete response in patients with relapsed or refractory multiple myeloma, as shown in a phase 2, open-label study. The most common side effects with Lynozyfic are musculoskeletal pain, cytokine release syndrome, neutropenia, cough, diarrhoea, anaemia, fatigue, pneumonia and upper respiratory tract infection.

The full indication is:

> LYNOZYFIC is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy.

Treatment with Lynozyfic should be initiated and supervised by physicians experienced in the treatment of multiple myeloma.

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

[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.

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languages after the marketing authorisation has been granted by the European Commission.