



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2023
EMA/CHMP/436072/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Elrexio elranatamab

On 12 October 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional² marketing authorisation for the medicinal product Elrexio³, intended for the treatment of multiple myeloma. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Elrexio will be available as a 40 mg/ml solution for injection. The active substance of Elrexio is elranatamab, a bispecific monoclonal antibody that targets the CD3 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 Elrexio is its ability to bring about 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 are cytokine release syndrome, anaemia, neutropenia, fatigue, upper respiratory tract infection and injection site reactions.

The full indication is:

ELREXFIO 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.

Elrexio should be prescribed 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 in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

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



granted by the European Commission.