



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): epcoritamab

Procedure No. PSUSA/00000107/202503

Period covered by the PSUR:
6 months to 20 March 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for epcoritamab, the scientific conclusions of PRAC are as follows:

In view of available data on haemophagocytic lymphohistiocytosis (HLH) from clinical trials, the literature, spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between epcoritamab and HLH is at least a reasonable possibility. The PRAC concluded that the product information of products containing epcoritamab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for epcoritamab the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing epcoritamab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.