25 April 2025
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. EMEA/H/C/PSUSA/00000107/202409

Period covered by the PSUR:
22/03/2024 To: 21/09/2024

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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 HLH; at least three of the cases identified, reported compatible TTO and diagnostic confirmation of HLH (in 2 of these cases, epcoritamab was withdrawn as a consequence of the ADR) and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between Epcoritamab and HLH cannot be excluded or confirmed. The PRAC Rapporteur 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 authorisation

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

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