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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): loncastuximab tesirine

Procedure No. PSUSA/00011027/202504

Period covered by the PSUR:
6 months to 22 April 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for loncastuximab tesirine, the scientific conclusions of PRAC are as follows:

In view of available data on Cutaneous collagenous vasculopathy from clinical trials and the literature including in some cases a compatible temporal relationship, and in view of a plausible mechanism of action and similar adverse reactions caused by other antibody-drug conjugates, the PRAC considers a causal relationship between loncastuximab tesirine and Cutaneous collagenous vasculopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing loncastuximab tesirine should be amended accordingly.

In view of available data on Capillary leak syndrome from toxicology studies and clinical trials, literature and spontaneous reporting including in some cases a compatible temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a warning on possible Capillary leak syndrome should be included in loncastuximab tesirine product information in order to raise awareness of treating physicians and patients of this condition. The PRAC concluded that the product information of products containing loncastuximab tesirine 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(s)

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

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