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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. EMEA/H/C/PSUSA/00011027/202410

Period covered by the PSUR:
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Scientific conclusions

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

In view of available data on sepsis from clinical trials, spontaneous reports including in some cases a close temporal relationship, and in view of myelosuppression as the plausible mechanism of action, the PRAC considers a causal relationship between loncastuximab tesirine and sepsis is at least a reasonable possibility. 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

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 containing loncastuximab tesirine is unchanged subject to the proposed changes to the product information

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