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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): enfortumab vedotin

Procedure No. PSUSA/00010989/202412

Period covered by the PSUR: 1 year to 17 December 2024

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Scientific conclusions

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

In view of available data on pneumonia from clinical trials and from spontaneous reports including in some cases a close temporal relationship and a positive de-challenge the PRAC considers a causal relationship between enfortumab vedotin and pneumonia is at least a reasonable possibility. The PRAC concluded that the product information of products containing enfortumab vedotin should be amended accordingly.

In view of available data on thrombocytopenia from clinical trials and from spontaneous reports including in some cases a close temporal relationship and a positive de-challenge the PRAC considers a causal relationship between enfortumab vedotin and thrombocytopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing enfortumab vedotin 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 enfortumab vedotin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing enfortumab vedotin 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.