EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 March 2023
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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): belantamab mafodotin

Procedure No. EMEA/H/C/PSUSA/00010869/202208

Period covered by the PSUR: 5 February 2022 – 4 August 2022

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Scientific conclusions

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

In view of available data on changes in the subbasal nerve plexus of cornea and decreased sensitivity of cornea from the literature, spontaneous reports including evident temporal and dose relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between belantamab mafodotin and changes in the subbasal nerve plexus of cornea and decreased sensitivity of cornea is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing belantamab mafodotin should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for belantamab mafodotin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing belantamab mafodotin 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.