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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): retifanlimab

Procedure No. PSUSA/00011059/202503

Period covered by the PSUR:
6 months to 20 March 2025

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**Scientific conclusions**

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

In view of data on patients with pre-existing autoimmune disease, that suggest an increased risk of immune-mediated adverse reactions and flares of the underlying autoimmune disease following therapy from the literature, the PRAC concluded that the product information of products containing retifanlimab 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 retifanlimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing retifanlimab 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.