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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): nemolizumab

Procedure No. PSUSA/00011111/202503

Period covered by the PSUR: 28 September 2024 to 27 March 2025

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Scientific conclusions

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

In view of available data on Bullous Pemphigoid (BP) from the literature, spontaneous reports and clinical trial(s), including

- at least 12 possible cases of BP with close temporal relationship, confirmed BP diagnosis and recovery (with treatment) following withdrawal;
- and 2 probable literature cases with a close temporal relationship, confirmed BP diagnosis and recovery (with treatment) following withdrawal, without reoccurrence of BP after withdrawal, supportive anti-BP 180 data and excluding the influence of most confounding factors;
- although the potential mechanism of the AE remains to be elucidated;

the PRAC considers a causal relationship between nemolizumab and Bullous Pemphigoid is at least a reasonable possibility. The PRAC concluded that the product information of products containing nemolizumab 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 nemolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nemolizumab 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.