12 October 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): teclistamab

Procedure No. EMEA/H/C/PSUSA/00011010/202302

Period covered by the PSUR:
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Scientific conclusions

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

In view of available data on Immune effector cell-associated neurotoxicity syndrome (ICANS) from clinical trials and spontaneous reports including new symptoms of ICANS and in 6 cases of Grade 3 and higher ICANS with a close temporal relationship, and in view of a fact that ICANS is already known adverse reaction of teclistamab, the PRAC Rapporteur considers a causal relationship between teclistamab and new symptoms of ICANS and Grade 3 and higher ICANS is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing teclistamab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conslusions and grounds for recommendation.

Grounds for the variation to the terms of the Marketing Authorisation(s)

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