EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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. PSUSA/00011010/202508

Period covered by the PSUR:
6 months to 22 August 2025

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Scientific conclusions

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

In view of available data on tumour flare from clinical trials and the literature including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between teclistamab, and Tumour Flare is at least a reasonable possible. 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 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 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.