EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
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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): talquetamab

Procedure No. EMEA/H/C/PSUSA/00000099/202408

Period covered by the PSUR:
09/02/2024 To: 08/08/2024

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

In view of available data and sufficient level of evidence, the PRAC Rapporteur concluded that the product information for talquetamab should be amended to included palmar-plantar erythrodysesthesia syndrome an individual ADR of talquetamab (instead of being included in footnote under Skin disorders).

The PRAC Rapporteur also concluded that Oral pain should be moved from SOC 'Respiratory, thoracic and mediastinal disorders' to SOC 'Gastrointestinal disorders'.

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 talquetamab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing talquetamab 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.