25 July 2024
EMA/493647/2024
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): mosunetuzumab

Procedure No. EMEA/H/C/PSUSA/00010999/202312

Period covered by the PSUR:
02/06/2023 To: 02/12/2023

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on ICANS from clinical trials, including a close temporal relationship in provided cases, a positive de-challenge after discontinuation of treatment and initiation of appropriate therapy and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between mosunetuzumab and Immune effector cell-associated neurotoxicity syndrome is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing mosunetuzumab 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 mosunetuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mosunetuzumab 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.