19 September 2024
EMA/560220/2024
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): besilesomab

Procedure No. EMEA/H/C/PSUSA/00000385/202401

Period covered by the PSUR:
10/01/2019 To: 10/01/2024

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
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 besilesomab, the scientific conclusions of PRAC are as follows:

In view of available cumulative data reviewed on the risks of human anti-mouse antibody (HAMA) generation, hypersensitivity reactions and acute hypotension, the PRAC considers that the additional risk minimisation measures consisting of a DHPC and Patient Alert Card to minimise these risks are no longer warranted at this stage. The PRAC recommended to remove these additional risk minimisation measures from the Annex IID of the product information. The PRAC concluded that the product information of products containing besilesomab 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 besilesomab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing besilesomab 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.