15 December 2022
EMA/242978/2023
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): ripretinib

Procedure No. EMEA/H/C/PSUSA/00010962/202205

Period covered by the PSUR: 15/05/2021 To: 14/05/2022

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 ripretinib, the scientific conclusions of the CHMP are as follows:

In view of available data on risk from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ripretinib and malignant melanoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing ripretinib should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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

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