30 January 2025
EMA/110085/2025
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): entrectinib

Procedure No. EMEA/H/C/PSUSA/00010874/202406

Period covered by the PSUR:
18/12/2023 To: 17/06/2024

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 entrectinib, the scientific conclusions of PRAC are as follows:

In view of available data on myocarditis from clinical trial(s), the literature, spontaneous reports including in nine cases a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between entrectinib and myocarditis is at least a reasonable possibility. The PRAC concluded that the product information of products containing entrectinib 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 entrectinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing entrectinib 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.