EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2024
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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): trametinib

Procedure No. EMEA/H/C/PSUSA/00010262/202305

Period covered by the PSUR: 30 May 2022 To: 29 May 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
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Scientific conclusions

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

In view of available data on AV block from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, positive de-challenge cases and that there are known cardiac ADRs listed in the SmPC for trametinib, the PRAC considers a causal relationship between trametinib and AV block is at least a reasonable possibility. The PRAC concluded that the product information of products containing trametinib 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 trametinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing trametinib 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.