EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2024
EMA/20913/2024
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): binimetinib

Procedure No. EMEA/H/C/PSUSA/00010717/202306

Period covered by the PSUR: 26 June 2022 To: 26 June 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 binimetinib, the scientific conclusions of PRAC are as follows:

In view of available data on Tumour lysis syndrome from both clinical trial cases and spontaneous reports including in 3 cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between binimetinib and Tumour lysis syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing binimetinib 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 binimetinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing binimetinib 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.