EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
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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): midostaurin

Procedure No. EMEA/H/C/PSUSA/00010638/202010

Period covered by the PSUR: 28 October 2019 – 27 October 2020

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Scientific conclusions

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

In view of available data on Interstitial lung disease and Pneumonitis from clinical trials, the literature, and spontaneous reports, including in some cases with a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between midostaurin and Interstitial lung disease and Pneumonitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing midostaurin should be amended accordingly.

In view of available data on electrocardiogram QT prolonged from non-clinical data, clinical trials, spontaneous reports, including in 5 cases a close temporal relationship, a positive de-challenge and in some a positive re-challenge, the PRAC considers a causal relationship between midostaurin and electrocardiogram QT prolonged is at least a reasonable possibility. The PRAC concluded that the product information of products containing midostaurin 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 midostaurin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing midostaurin is unchanged subject to the proposed changes to the product information