9 November 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): lorlatinib

Procedure No. EMEA/H/C/PSUSA/00010760/202303

Period covered by the PSUR: 21/09/2022 To: 20/03/2023

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Scientific conclusions

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

In view of available data on proteinuria from clinical trials, the literature, spontaneous reports, including in majority of cases a close temporal relationship, a positive de-challenge in 2 cases and re-challenge in 3 cases, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between lorlatinib and proteinuria is at least a reasonable possibility. The PRAC concluded that the product information of products containing lorlatinib 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 lorlatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lorlatinib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation