13 October 2022
EMA/942004/2022
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): ribociclib

Procedure No. EMEA/H/C/PSUSA/00010633/202203

Period covered by the PSUR: from 13/03/2021 to 12/03/2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ribociclib, the scientific conclusions of CHMP are as follows:

In view of available data on interstitial lung disease (ILD)/pneumonitis from clinical trial(s), the literature, spontaneous reports including in one case a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between ribociclib and ILD/pneumonitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing ribociclib 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

On the basis of the scientific conclusions for ribociclib the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing ribociclib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.