15 December 2022
EMA/140012/2023
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): zanubrutinib

Procedure No. EMEA/H/C/PSUSA/00010960/202205

Period covered by the PSUR: 12 November 2021 to: 12 May 2022

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Scientific conclusions

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

In view of available data on dermatitis exfoliative generalised from spontaneous reporting including one case with a close temporal relationship, a positive de-challenge and re-challenge, the PRAC considers a causal relationship between zanubrutinib and dermatitis exfoliative generalised is at least a reasonable possibility. The PRAC concluded that the product information of products containing zanubrutinib should be amended accordingly.

In view of available data on febrile neutropenia from clinical trials, the PRAC considers a causal relationship between zanubrutinib and febrile neutropenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing zanubrutinib 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 zanubrutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing zanubrutinib 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.