17 September 2020
EMA/635532/2020
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): baricitinib

Procedure No. EMEA/H/C/PSUSA/00010578/202002

Period covered by the PSUR: from 12 August 2019 to 12 February 2020

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**Scientific conclusions**

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

The MAH was asked to analyse the frequency of Adverse Events (AEs) and Serious Adverse Events (SAEs) in baricitinib CT depending on the dose ($\leqslant$2 mg/d or $\geqslant$ 4 mg/d) in shorter (up to 16 weeks) and longer (over 16 weeks) clinical trials in RA and jointly in clinical trials for various indications. In the Extended 2-mg vs 4-mg analysis set submitted, the Exposure Adjusted Incidence Rate (EAIR) for any hepatic Standardized MedDRA Query (SMQ) event was higher in the 4-mg group (5.1) than in the 2-mg group (3.1). Based on "Friedman LS: Approach to the patient with abnormal liver biochemical and function tests. Uptodate.com (19 August 2020)", and in light of the data submitted, the PRAC was of the opinion that the effect of baricitinib on blood ALT and AST activity appears to be dose related and recommended an update of section 4.4 of the SmPC to modify the wording on "Hepatic transaminase elevations" to indicate that this effect is dose-dependent and update of section 4.8 of the SmPC "Hepatic transaminase elevations" accordingly. The PRAC concluded that the product information of products containing baricitinib 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 baricitinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing baricitinib 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.