25 July 2024
EMA/329501/2024
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): roxadustat

Procedure No. EMEA/H/C/PSUSA/00010955/202312

Period covered by the PSUR: 17/06/2023 To: 16/12/2023

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

**Scientific conclusions**

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

In view of available data on Cerebrovascular accidents from clinical trials, the spontaneous reports including in some cases a temporal relationship, the PRAC considers a causal relationship between roxadustat and Cerebrovascular accidents is at least a reasonable possibility. Furthermore, in view of available data on Blood copper increased, from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between roxadustat and Blood copper increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing roxadustat 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 roxadustat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing roxadustat 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.