16 December 2021
EMA/34538/2022
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): selpercatinib

Procedure No. EMEA/H/C/PSUSA/00010917/202105

Period covered by the PSUR: 08/11/2020 To: 08/05/2021

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 selpercatinib, the scientific conclusions of CHMP are as follows:

In view of available data on tumour lysis syndrome (TLS), one reported positive rechallenge confounded by the advance state of the disease, TLS listed for several class products, and due to the severity of the event, the PRAC concluded that the product information selpercatinib 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 selpercatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing selpercatinib 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.