

11 December 2025  
EMADOC-1700519818-2912670  
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. PSUSA/00010917/202505

Period covered by the PSUR: 6 months to 08 May 2025



## **Scientific conclusions**

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

In view of available data on Stevens-Johnson syndrome (SJS) from the literature, including a close temporal relationship in 1 case from literature, and a diagnosis based on clinical picture together with histopathological findings, the PRAC Rapporteur considers a causal relationship between selpercatinib and Stevens-Johnson syndrome is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing selpercatinib 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 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.