25 May 2023
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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): asciminib

Procedure No. EMEA/H/C/PSUSA/00011008/202210

Period covered by the PSUR: 29 October 2021 - 28 October 2022

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 asciminib, the scientific conclusions of CHMP are as follows:

In view of available data on hypersensitivity from clinical trial(s) and managed access programs including in three cases a close temporal relationship, and in two cases double positive re-challenge and in view of hypersensitivity reactions being common for other tyrosine kinase inhibitors, the PRAC considers that a causal relationship between asciminib and hypersensitivity is a reasonable possibility. The PRAC concluded that the product information of products containing asciminib 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 asciminib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing asciminib 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.