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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): siponimod

Procedure No. EMEA/H/C/PSUSA/00010818/202109

Period covered by the PSUR: 26 March 2021 To: 25 September 2021

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Scientific conclusions

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

In view of available data on squamous cell carcinoma, varicella zoster virus infection reactivation and cryptococcal meningitis from clinical trials and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between siponimod and squamous cell carcinoma, varicella zoster virus meningitis or meningoencephalitis and cryptococcal meningitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing siponimod 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 siponimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing siponimod 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.