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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/00010818/202303

Period covered by the PSUR: 26 March 2022 To: 25 March 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 siponimod, the scientific conclusions of PRAC are as follows:

In view of new data available on Progressive Multifocal Leukoencephalopathy (PML) from clinical trial(s), the PRAC considers that the frequency of PML in section 4.8 of the SmPC should be updated accordingly to the frequency in clinical trials. Therefore, the frequency should be "rare" instead of the current frequency "unknown".

In view of available data on bradyarrhythmic events risk(s) (specially the cases with atrioventricular block) from clinical trial(s) and the supportive cases from spontaneous reports, the PRAC concluded that the product information of products containing siponimod 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 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.