14 November 2019
EMA/CHMP/596356/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mayzent

siponimod

On 14 November 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mayzent, intended for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease. The applicant for this medicinal product is Novartis Europharm Limited.

Mayzent will be available as 0.25 mg and 2 mg film-coated tablets. The active substance of Mayzent is siponimod, a selective immunosuppressant (ATC code: L04AA42) acting as a sphingosine 1-phosphate (S1P) receptor modulator. Siponimod binds selectively to two out of five receptors for S1P, namely S1P1 and S1P5. By acting as a functional antagonist on S1P1 receptors on lymphocytes, siponimod prevents the egression from lymph nodes, reducing the recirculation of T-cells into the central nervous system and limiting central inflammation.

The benefits with Mayzent are its ability to reduce disability progression in active SPMS patients. The most common side effects are headache, hypertension and increased liver enzyme levels.

The full indication is: “treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity (see section 5.1)”. It is proposed that Mayzent be prescribed by physicians experienced in the treatment of multiple sclerosis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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