26 March 2020
EMA/CHMP/136468/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zeposia

ozanimod

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zeposia, intended for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease. The applicant for this medicinal product is Celgene Europe BV.

Zeposia will be available as 0.23 mg and 0.46 mg capsules for dose escalation and 0.92 mg capsules for maintenance. The active substance of Zeposia is ozanimod, a selective immunosuppressant (ATC code: L04AA38). Ozanimod is a sphingosine 1-phosphate receptor modulator, which binds selectively to sphingosine 1-phosphate receptor subtypes 1 and 5. Ozanimod causes lymphocyte retention in lymphoid tissues. The mechanism by which ozanimod exerts therapeutic effects in multiple sclerosis is unknown but may involve the reduction of lymphocyte migration into the central nervous system.

The benefits with Zeposia are its ability to reduce focal inflammatory activity as defined by clinical (relapses) or imaging features (new/enlarging T2 lesions or new gadolinium-enhancing lesions) in active RRMS patients. The most common side effects are nasopharyngitis and lymphopenia (related to the mechanism of action); less common side effects are hypertension and increased liver enzyme level.

The full indication is:

> The treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.

Zeposia should 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

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