9 November 2017
EMA/CHMP/643958/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ocrevus

ocrelizumab

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ocrevus, intended for the treatment of relapsing forms of multiple sclerosis and primary progressive multiple sclerosis. The applicant for this medicinal product is Roche Registration Limited.

Ocrevus will be available as a 300-mg concentrate for solution for infusion. The active substance of Ocrevus is ocrelizumab, a recombinant humanised anti-CD20 monoclonal antibody that selectively targets CD20-expressing B cells (ATC code: L04AA36).

The benefits with Ocrevus are its ability to significantly suppress relapses, sub-clinical disease activity measured by MRI, and disease progression in relapsing forms of multiple sclerosis, as well as to significantly delay disease progression and reduce deterioration in walking speed in patients with early primary progressive multiple sclerosis. The most common side effects are infusion-related reactions and infections.

The full indication is:

> "Ocrevus is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features (see section 5.1).
>
> Ocrevus is indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity (see section 5.1)."

Ocrevus treatment should be initiated and supervised by an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion-related reactions.

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.