28 January 2021
EMA/CHMP/17719/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kesimpta

ofatumumab

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kesimpta, intended for the treatment of adult patients with active relapsing forms of multiple sclerosis. The applicant for this medicinal product is Novartis Ireland Limited.

Kesimpta will be available as a 20 mg solution for injection for subcutaneous administration. The active substance of Kesimpta is ofatumumab, a fully human monoclonal antibody that targets a receptor called CD20 expressed on the B-cells.

The benefits with Kesimpta are its ability to prevent relapses and slowing disease progression. The most common side effects are upper respiratory tract infections and injection-related reactions.

The full indication is:

> Kesimpta 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).

Kesimpta treatment should be initiated by physicians experienced in the management of neurological conditions.

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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