30 March 2023
EMA/CHMP/122125/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Briumvi

ublituximab

On 30 March 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Briumvi, intended for the treatment of multiple sclerosis. The applicant for this medicinal product is Propharma Group The Netherlands B.V.

Briumvi will be available as a 150 mg concentrate for solution for infusion. The active substance of Briumvi is ublituximab, a selective immunosuppressant (ATC code: L04AG14) that selectively targets CD20-expressing B-cells involved in the inflammatory changes in the central nervous system of patients with multiple sclerosis.

The benefits of Briumvi are a 49-59% reduction in the annual relapse rate and a ≥90% reduction in the number of acute inflammatory lesions (97% of Gd-enhancing T1 lesions and 90-92% T2 hyperintense lesions per MRI scan), compared with teriflunomide in two Phase 3, randomised, double-blind, active-controlled clinical trials in patients with relapsing multiple sclerosis. The most common side effects are infusion-related reactions and infections.

The full indication is:

> Briumvi 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).

Briumvi should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions and who have 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 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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