23 February 2023
EMEA/CHMP/72305/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Bekemv

eculizumab

On 23 February 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 Bekemv, intended for the treatment of adults and children in paroxysmal nocturnal haemoglobinuria (PNH).

The applicant for this medicinal product is Amgen Technology (Ireland) Unlimited Company.

Bekemv will be available as a 300 mg concentrate for solution for infusion. The active substance of Bekemv is eculizumab, a selective immunosuppressant (ATC code: L04AA25). Bekemv is a recombinant humanised monoclonal IgG2/4k antibody that binds to the human C5 complement protein and thereby inhibits the activation of terminal complement.

Bekemv is a biosimilar medicinal product. It is highly similar to the reference product Soliris (eculizumab), which was authorised in the EU on 20 June 2007. Data show that Bekemv has comparable quality, safety and efficacy to Soliris. More information on biosimilar medicines can be found here.

The full indication is:

> BEKEMV is indicated in adults and children for the treatment of paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history (see section 5.1).

Bekemv must be administered by a healthcare professional and under the supervision of a physician experienced in the management of patients with haematological disorders. Unlike the reference product, Bekemv contains sorbitol. It is therefore contraindicated in patients with hereditary fructose intolerance (HFI), in whom sorbitol exposure may cause serious metabolic harms. It is also contraindicated in children under 2 years of age who may not yet be diagnosed with HFI.

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.