BEKEMV

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.2 Change(s) in the Summary of Product	02/05/2025		SmPC and PL	To update sections 4.4, 4.8, 5.1 and 5.2 of the

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000263414	Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - To update sections 4.4, 4.8, 5.1 and 5.2 of the SmPC and section 3 and 4 of the Package Leaflet following assessment of the same change for the reference product, in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). - In addition, the applicant took the opportunity to update Section 4.2 of the SmPC, where the clinical data referred to in this paragraph relates to PNH Soliris clinical trials, not the Bekemv biosimilar data. The MAH replaced BEKEMV with eculizumab. - Furthermore, the MAH took the opportunity to introduce information regarding polysorbate in line with the QRD template. - Also, the MAH took the opportunity to remove the local representative for the United Kingdom (Northern Ireland), and				SmPC and section 3 and 4 of the Package Leaflet following assessment of the same change for the reference product, in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). In addition, the applicant took the opportunity to update Section 4.2 of the SmPC, where the clinical data referred to in this paragraph relates to PNH Soliris clinical trials, not the Bekemv biosimilar data. The MAH replaced BEKEMV with eculizumab.

	made editorial changes to the contact information for the local representatives for Iceland, Lithuania and Portugal.				
Variation type IB / EMA/VR/0000264089	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted	02/05/2025	N/A		
Variation type II / EMA/VR/0000247434	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted	25/04/2025			B.II.b.1.a Secondary packaging site. B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes
