FABHALTA

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, you may need to 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 IA /	This was an application for a group of	19/12/2025		Annex II and	

[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/0000319878	variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted			PL	
Variation type II / EMA/VR/0000278268	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study KLC-NO24-05 as part of a post-authorisation	11/12/2025	N/A		

	measure (REC) recommended within initial marketing authorisation procedure. This is in vitro evaluation of inducibility of cytochrome P450s by LNP023 using one batch of human hepatocytes.				
Variation type II / EMA/VR/0000278413	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC in order to update clinical efficacy information based on final results from phase 3 studies APPLY-PNH (CLNP023C12301) and APPONT-PNH (CLNP023C12302) 48-week treatment extension. Study CLNP023C12301 is a multicenter, single-arm, open-label trial to evaluate efficacy and safety of oral, twice daily iptacopan in adult PNH patients who are naive to complement inhibitor therapy. Study CLNP023C12302 is a randomized, multicenter, active-comparator controlled, open-label trial to evaluate efficacy and safety of oral, twice daily LNP023 in adult patients with PNH and residual anemia, despite treatment with an intravenous anti-C5 antibody. In addition, the MAH removed the first PSUR commitment following 6 months post authorisation as it has already	18/09/2025		SmPC and Annex II	SmPC new text In Section 5.1 Clinical efficacy and safety section on Paroxysmal nocturnal haemoglobinuria: For study APPLY-PNH: anti-C5 treatment experienced patients with PNH The following text is added: Treatment extension A total of 95 APPLY-PNH patients entered the 24-week treatment extension period, where all patients received iptacopan, resulting in a total exposure of up to 48 weeks. The efficacy results at week 48 were consistent with those at week 24 and demonstrated sustained efficacy of iptacopan treatment. For study APPOINT-PNH: Complement inhibitor-naïve study The following text is added: Treatment extension All 40 APPOINT-PNH patients entered the 24-week treatment extension period, where all patients continued iptacopan treatment, resulting in a total exposure of up to 48 weeks. The efficacy results at week 48 were consistent with those at week 24 demonstrating sustained efficacy of iptacopan treatment. For more information, please refer to the Summary of Product Characteristics.

	been fulfilled.				
Variation type IB / EMA/VR/0000245435	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	20/02/2025		SmPC	
PSUR / EMA/PSUR/0000257901	- -				Maintenance