Ebglyss

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 IB /	C.9 Introduction of, or change(s) to, the	20/03/2026			

[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/0000335203	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b – to propose an update in the RMP of the due date for the category 3 Post Authorisation Safety Study (PASS) M-17923-32 (Adlong) from 'August 2026' to 'Q4 2026'.				
Variation type II / EMA/VR/0000303590	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.g Introduction of a new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier - Accepted	15/01/2026			

Article 61(3) / EMA/N/0000320367	- Notification acc. Article 61(3) - Accepted Update of the Package Leaflet with revised contact details of local representatives. The MAH also took the opportunity to include the approved manufacturer for batch release in section 6 of the package leaflet.	14/01/2026		PL	
Variation type IA / EMA/VR/0000316628	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	11/12/2025			

Variation type IB / EMA/VR/0000313047	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	08/12/2025		SmPC	
Variation type II / EMA/VR/0000249804	This was an application for a group of variations. 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 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 • C.I.4: Update of sections 4.8, and 5.1 of the SmPC in order to update information on clinical efficacy and the long-term safety based on final results from study J2T-DM-KGAA (ADjoin) listed as a category 3 study in the RMP; this is a long-term study to assess the long-term safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis over 100 weeks;	02/10/2025		SmPC and Annex II	With this submission, data on long-term safety has been strengthened. Additional information on the long term efficacy and safety of lebrikizumab is provided in the PI: • In adults and adolescents with moderate-to-severe AD treated continuously with lebrikizumab for up to 3 years: study J2T-DM-KGAA (ADjoin) and • In adults and adolescents with moderate-to-severe AD who were not adequately controlled with ciclosporin (also known as cyclosporine) or for whom ciclosporin was not medically advisable: study J2T-AP-KGBQ (Advantage). In ADjoin, a 100-week extension study to assess the long-term safety and efficacy of lebrikizumab for adults and adolescents with moderate-to-severe AD, a total of 1153 participants (including 292 adolescents) were exposed to lebrikizumab. The incidence and severity of TEAEs were similar to those previously reported. ADvantage was a Phase 3 clinical trial to assess the efficacy and safety of lebrikizumab in combination with topical corticosteroids (TCS) up to 52 weeks in adults and adolescents with moderate-to-severe AD who were not adequately controlled with ciclosporin or for whom ciclosporin use was not medically advisable. 331 patients were randomized; from

	• C.I.4: Update of section 5.1 of the SmPC in order to update information on clinical efficacy based on final results from study J2T-AP-KGBQ (Advantage); this is a randomised, double-blind, placebo-controlled phase 3 clinical trial to assess the efficacy and safety of lebrikizumab in combination with topical corticosteroids up to 52 weeks in patients with moderate to-severe atopic dermatitis who were not adequately controlled with ciclosporin or non-eligible for cyclosporine. The RMP version 1.2 is approved. In addition, the MAH took the opportunity to introduce changes following PEI linguistic review (clarification of acronyms and QRD updates), and editorial changes to the PI.				them, 68.4% of patients in the lebrikizumab group and 40.8% in the placebo group achieved EASI 75 at Week 16 (primary endpoint); 42.0% of patients in lebrikizumab group and 24.5% in placebo group achieved IGA 0 or 1 and ≥2-point improvement at week 16, and 49.9% of patients in lebrikizumab group and 29.7% in placebo group achieved ≥4 point improvement in Pruritus NRS from baseline at week 16 (key secondary endpoints). The incidence and severity of TEAEs reported during the induction phase of ADvantage were similar to those reported in previous studies. The nature, incidence and severity of TEAEs reported in ADjoin and ADvantage were similar to those previously reported. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000287025	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	02/10/2025		SmPC and PL	As a result of this variation, section 6.6 of the SmPC is being updated to remove the warm-up period. The Package Leaflet (PL) and IFU has been updated accordingly.
Variation type IA_IN / EMA/VR/0000301550	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	30/09/2025			

Variation type IB / EMA/VR/0000291266	B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.b Other changes to a test procedure (including replacement or addition) - Accepted	27/08/2025			
Variation type IB / EMA/VR/0000278725	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	01/07/2025			
Variation type IA_IN / EMA/VR/0000261461	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted	10/04/2025		SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000261559	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update sections 2 and 4.4 of the SmPC and section 2 of the Package Leaflet with the current Excipients Guideline for excipient polysorbate (Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) - Revision 4). In addition, the MAH took the opportunity to introduce some minor editorial changes in the whole Product Information in all EU	01/04/2025	17/07/2025	SmPC, Labelling and PL	

	languages.				
Variation type IA_IN / EMA/VR/0000253475	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.a Secondary packaging site - Accepted	18/02/2025			
Variation type IB / EMA/VR/0000244577	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	31/01/2025			
PSUR / EMA/PSUR/0000248530	n/a				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing lebrikizumab remains unchanged and therefore recommends the maintenance of the marketing authorisation.