Skyrizi

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	Commission Decision Issued[2] /	Product Information affected[3]	Summary

[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).

						on	**amended on**	
Variation type IB / EMA/VR/0000296296					C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To update section 7 “Instructions for Use” for the On-body Delivery System (OBDS) of the Risankizumab 180 mg/1.2 ml and 360 mg/2.4 ml solution for injection in cartridge in the package leaflet.	14/10/ 2025		PL
Variation type II / EMA/VR/0000269736	This was an application for a group of variations. 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.	02/10/ 2025		Annex II	The Annex II has been updated to add AbbVie Operations Singapore PTE Ltd, 23 Tuas South Avenue 6, Singapore, 637022 (ABS) as an alternative site responsible for manufacture of the active substance.			

	Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - 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				

	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 B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted				
Variation type II / EMA/VR/00002696	C.I HUMAN AND VETERINARY MEDICINAL	25/09/		SmPC	The efficacy and safety of risankizumab was assessed in a multicenter, randomised, double-blind, placebo-controlled study (UNLIMMITED) that enrolled subjects 18 years of age and older with

65	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 efficacy and safety information based on interim results from stud M23-702 (UNLIMMITED); this is a phase 4 multicenter, randomized, double-blind study of risankizumab for the treatment of adult subjects with moderate to severe genital psoriasis (UNLIMMITED-G) or moderate to severe scalp psoriasis (UNLIMMITED-S).	2025			moderate to severe scalp psoriasis (UNLIMMITED-S), defined as Psoriasis Scalp Severity Index (PSSI) ≥12, scalp Investigator Global Assessment (scalp IGA) ≥3, and ≥30% of the scalp affected, or moderate to severe genital psoriasis (UNLIMMITED-G), defined as static Physician's Global Assessment of Genitalia (sPGA-G) ≥3 at baseline. All subjects had BSA ≥1% and sPGA ≥3 at baseline. In UNLIMMITED, subjects were randomised to receive either risankizumab 150 mg or placebo subcutaneously at weeks 0 and 4. Starting at week 16, all subjects received risankizumab 150 mg every 12 weeks until the last dose at week 40. UNLIMMITED-S enrolled 105 subjects. Baseline BSA involvement was ≥10% for 61.9% of the subjects and <10% for 38.1% of the subjects. Mean baseline BSA involvement was 16.8%. At baseline, 76.2% of subjects had sPGA = 3 and 23.8% had sPGA = 4. At baseline, 54.3% of subjects were naïve to any systemic therapy (including non-biologic and biologic), 0% of subjects had received prior phototherapy, 15.2% had received prior non-biologic systemic therapy, and 37.1% had received prior biologic therapy. The primary endpoint (sPGA-G of 0 or 1) and key secondary endpoints (PSSI 90, PSSI 75, PSSI 100, Mean change from baseline in PSS) at Week 16 were met. UNLIMMITED-G enrolled 109 subjects. Baseline BSA involvement was ≥10% for 63.3% of the subjects and <10% for 36.7% of the subjects. Mean baseline BSA involvement was 17.2%. At baseline, 80.7% of subjects had sPGA = 3 and 19.3% had sPGA = 4. At baseline, 61.5% of subjects were naïve to any systemic therapy (including non-biologic and biologic), 2.8% of subjects had received prior phototherapy, 16.5% had received prior non-biologic systemic therapy, and 25.7% had received prior biologic therapy. The primary endpoint (sPGA-G of 0 or 1) and key secondary endpoints sPGA-G of 0, DLQI of 0 or 1, GPI-NRS reduction of ≥4-point from baseline, GenPs-SFQ item 2 score of 0 (never) or 1 (rarely)) at Week 16 were met. The safety profile of risankizumab in studies UNLIMMITED-S and UNLIMMITED-G was consistent with the safety profile observed in previous studies of patients with plaque psoriasis. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000293212	B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	29/08/2025	N/A		

Variation type IB / EMA/VR/0000261926	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (IB) - To reclassify serious hypersensitivity reactions from an important potential risk to an important identified risk. The MAH also took the opportunity to amended Studies P23-654 and P23-653 protocols to add the ulcerative colitis study population to the approved Crohn's disease studies that are currently under review and the due dates for KEEPsAKE 1 was updated from Q3 2025 to Q1 2027 and KEEPsAKE 2 was updated from Q3 2025 to Q4 2026.	11/06/ 2025	N/A		To reclassify serious hypersensitivity reactions from an important potential risk to an important identified risk. The MAH also took the opportunity to amended Studies P23-654 and P23-653 protocols to add the ulcerative colitis study population to the approved Crohn's disease studies that are currently under review and the due dates for KEEPsAKE 1 was updated from Q3 2025 to Q1 2027 and KEEPsAKE 2 was updated from Q3 2025 to Q4 2026.