Rystiggo

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0009/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to	16/01/2025	19/03/2025	SmPC, Labelling and PL	

[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).

	new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/216/202406	Periodic Safety Update EU Single assessment - rozanolixizumab	16/01/2025	n/a		PRAC Recommendation - maintenance
IB/0010	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	10/01/2025	n/a		
IA/0011	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	19/12/2024	n/a		
IB/0008	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	15/11/2024	n/a		
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	31/10/2024	19/03/2025	SmPC, Annex II and PL	
II/0003	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	18/07/2024	19/03/2025	SmPC, Labelling and PL	The SmPC and Annex A have been updated to introduce three additional vial presentations (3 ml, 4 ml and 6 ml, EU/1/23/1780/002-004) in addition to the approved 2 ml vial presentation. All vial presentations have a nominal concentration of 140 mg/ml of rozanolixizumab. The Labelling and PL have been updated accordingly.
IB/0005	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/07/2024	n/a		

II/0002	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/06/2024	19/03/2025	SmPC and PL	Sections 4.4 subsection aseptic meningitis has been updated to reflect that the post-marketing cases (hence reference to a higher dose has been removed). Section 4.8 is updated to add aseptic meningitis as adverse drug reaction with frequency not known based on post-marketing cases. For more information, please refer to the Summary of Product Characteristics.
IB/0004	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	12/06/2024	n/a		
IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	25/03/2024	19/03/2025	SmPC	