# Rystiggo

## 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 |
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| Variation type IB / | Outcome: | 20/08/2026 | | | |

[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).

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| EMA/VR/0000362796 | C.9 Introduction of, or change(s) to, the 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<br><br>C.9.b (Type IB) – To update the RMP by removing the MG0027 post-authorisation safety study, in accordance with the Assessment Report for non-imposed non-interventional PASS protocol- Post-Authorisation Measure EMA/PAM/0000262838. In addition, two newly approved products for the treatment of myasthenia gravis in the EU have been added to the list of approved MG therapies, and the cumulative post-authorisation exposure by region is updated. | | | | |
| Variation type IB / EMA/VR/0000355580 | Outcome:<br>Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.d) Other change to an analytical procedure for a finished product (including replacement or addition) - Accepted | 13/07/2026 | | | |

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| Variation type II / EMA/VR/0000327370 | Outcome: Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product - Q.II.d.1.e) Change outside of the specification acceptance criteria of the finished product - Accepted | 23/04/2026 | | | |
| Variation type IA / EMA/VR/0000320683 | Outcome: A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted | 16/01/2026 | 17/08/2026 | SmPC | |
| PSUR / EMA/PSUR/0000296581 | EURD: PSUSA/00000216/202506 Active substance: rozanolixizumab Outcome: Maintenance | 15/01/2026 | | | maintenance |
| Variation type IA / EMA/VR/0000320222 | Outcome: This was an application for a group of variations.<br><br>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.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted<br>A. ADMINISTRATIVE CHANGES - A.4 Change | 08/01/2026 | | | |

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| | 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 | | | | |
| Variation type IA / EMA/VR/0000314616 | Outcome: A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Refused | 01/12/2025 | | | |
| Variation type II / EMA/VR/0000282401 | Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted | 18/09/2025 | 17/08/2026 | SmPC, Labelling and PL | The SmPC sections 6.4 and 6.6 have been updated to add information on short-term storage conditions/excursion (20 days at room temperature) of the biological medicinal product. The Labelling and PL have been updated accordingly. |
| Variation type IA / EMA/VR/0000291983 | Outcome: B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted | 25/08/2025 | | | |
| Variation type II / EMA/VR/0000271895 | Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, | 24/07/2025 | 17/08/2026 | SmPC and PL | |

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| | Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted<br><br>Update of sections 4.4 and 4.8 of the SmPC in order to add 'Herpes viral infection' to the list of adverse drug reactions (ADRs) with frequency 'not known', based on new cases of herpes zoster reported in clinical studies and from spontaneous post-marketing in generalised myasthenia gravis (gMG), as well as to add 'Nausea' and 'Vomiting' to the list of ADRs with frequency 'common'. The Package Leaflet is updated accordingly. | | | | |
| Article 61(3) / EMA/N/0000269426 | Outcome:<br>- Notification acc. Article 61(3) - Accepted<br><br>Update of the package leaflet with revised contact details of local representatives. | 08/05/2025 | 17/08/2026 | PL | |
| PSUR / EMA/PSUR/0000257792 | EURD: PSUSA/00000216/202412 Active substance: rozanolixizumab Outcome: Maintenance | 10/07/2025 | | | Maintenance |