Plegridy

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.I.11 Introduction of, or change(s) to, the	14/11/2025	N/A		To update the RMP by updating the study status

[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/0000307743	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z (Type IB) – To update the RMP by updating the study status and milestones for study 105MS404, drug utilization in pregnancy exposure in second and third trimester of pregnancy, in line with the agreed protocol Version 3.0, submitted within procedure EMA/PAM0000263236. In addition, the MAH took the opportunity to (1) Update the QPPV details, (2) Remove post authorisation exposure data by country (per guidance on anonymisation of personal data, reference EMA/63692/2025, revision 3), (3) Update post authorisation exposure estimates based on the new data lock point, (4) Update clinical trial exposure based on the new data lock point, and (5) Template changes: Include a row for Section VII in the Summary of Significant Changes, confidentiality statements removed.				and milestones for study 105MS404, drug utilization in pregnancy exposure in second and third trimester of pregnancy, in line with the agreed protocol Version 3.0, submitted within procedure EMA/PAM0000263236.
Variation type IA / EMA/VR/0000300515	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	16/10/2025		Annex II	

	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/0000300753	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted	24/09/2025	N/A		
Variation type IB / EMA/VR/0000263823	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	13/05/2025	N/A		