EndolucinBeta

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 /		13/05/2026		SmPC 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).

EMA/VR/0000341316	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted C.z (Type IB) – To update section 6.5 of the SmPC and section 6 of the Package Leaflet to remove the description of the tertiary container in line with the 'Guideline on core SmPC and Package Leaflet for Radiopharmaceuticals' (EMA/CHMP/167834/2011). In addition, Annex A is updated to reflect the actual volume range as per SmPC instead of the size of the vial. Furthermore, the MAH took the opportunity to implement editorial changes to the product information, including: • formatting adjustments. • correction of typographical errors, correction of the MAH address (removal of "D-"), and correction of the packaging description in the HR and FI SmPC and PL. • updates to the PT product information, comprising: (1) harmonisation of the term "activity reference time" and its abbreviation "ART" across the texts; (2) alignment of the excipient name "Hydrochloric acid, diluted" in the outer packaging (lead pot) with the wording used elsewhere in the documentation.				

Variation type IB / EMA/VR/0000339157	Outcome: This was an application for a group of variations. Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.d) Other change to an analytical procedure (including replacement or addition) for the active substance - Accepted 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	16/04/2026			
Variation type IB / EMA/VR/0000314197	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	29/01/2026			

Variation type IA / EMA/VR/0000301964	Outcome: This was an application for a group of variations. B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Refused	24/10/2025			
Variation type IB / EMA/VR/0000253998	Outcome: 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 provide a new RMP version to align with the template EMA/164014/2018 and to implement editorial changes and corrections across the	25/03/2025			To provide a new RMP version to align with the template EMA/164014/2018 and to implement editorial changes and corrections across the RMP.

	RMP.				