Wyost

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 /	Outcome:	08/07/2026			

[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).

EMA/VR/0000349400	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.z Other variation - Accepted To update the RMP to align with reference product. The following has been removed: Important identified risks: Hypercalcemia several months after the last dose in patients with giant cell tumor of bone and in patients with growing skeletons Important potential risks: Malignancy, Delay in diagnosis of primary malignancy in giant cell tumor of bone, Missing information, Safety with long-term treatment and with long-term follow-up after treatment in adults and skeletally mature adolescents with giant cell tumor of bone.				
Variation type IA / EMA/VR/0000356005	Outcome: Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Accepted	02/07/2026			
Variation type IB / EMA/VR/0000327480	Outcome: This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	10/04/2026			

	Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.f) Change of an analytical procedure for an in-process control - Accepted				
Variation type IB / EMA/VR/0000315165	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted	18/12/2025			
Variation type IB / EMA/VR/0000295626	Outcome: This was an application for a variation	23/10/2025			

	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted				
Variation type IB / EMA/VR/0000293612	Outcome: B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	03/09/2025			
Variation type IB / EMA/VR/0000288202	Outcome: C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a (Type IB) – To update Section 4.8 of the SmPC to include the frequencies of osteonecrosis of the jaw, atypical fractures of the femur and new primary malignancy in patients with GCTB based on the results	13/08/2025		SmPC	To update Section 4.8 of the SmPC to include the frequencies of osteonecrosis of the jaw, atypical fractures of the femur and new primary malignancy in patients with GCTB based on the results from study 20140114.

	from study 20140114. In addition, the MAH took the opportunity to implement editorial changes to the PI in all languages to align with the reference product PI.				
Variation type IB / EMA/VR/0000245925	Outcome: B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.5.a.2- Type IB- To add new pack-sizes of 3 vials (EU/1/24/1812/002) and 4 vials (EU/1/24/1812/003) for 120 mg solution for injection. Furthermore, Product Information in various languages has been aligned with QRD template.	04/02/2025		SmPC, Labelling and PL	