Osenvelt

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:	11/08/2026			

[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).

EMA/VR/0000355158	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 C.9.b (Type IB) – To update the RMP to reflect the revised list of safety concerns based on completed post-authorisation safety studies, in line with the RMP of the reference product (Xgeva).				
Variation type IA / EMA/VR/0000343165	Outcome: Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.a) Minor change in the manufacturing process - Refused	21/05/2026			
Variation type IA / EMA/VR/0000323764	Outcome: This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active	05/02/2026			

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted 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 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 II / EMA/VR/0000296328	Outcome: This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in	15/01/2026	27/04/2026	SmPC, Annex II and PL	The SmPC sections 6.3 and 6.6 have been updated to reflect the changes in shelf-life from 42 months to 4 years and storage conditions (from storage at temperatures up to 25 °C for up to a maximum of 30 days, to storage at temperatures up to 30 °C for up to a maximum of 63 days, with an allowance for re-refrigeration) of Osenvelt 120 mg vial finished product. The Package Leaflet has been updated

	accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted				accordingly.
Variation type II / EMA/VR/0000285991	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.b Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product - Accepted	25/09/2025			
Variation type IB / EMA/VR/0000268596	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	04/09/2025			
Variation type IB / EMA/VR/0000284948	Outcome: C.I.2 Change(s) in the Summary of Product	18/07/2025	27/04/2026	SmPC, Labelling and	To update Section 4.8 of the SmPC to include the frequences of osteonecrosis of the jaw, atypical

	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 frequences of osteonecrosis of the jaw, atypical fractures of the femur and new primary malignancy in patients with giant cell tumour of bone (GCTB) based on the results from study 20140114. The change follows assessment of the same change for the reference product, Xgeva. In addition, the MAH took the opportunity to implement editorial changes, including updating the local representative information for SE, correcting grammatical and typographical errors across the PI, revising the wording of the polysorbate warning as requested by Member States during previous linguistic review, using a more commonly used term for a word in Section 6.5 of the DE SmPC, using a EDQM patient friendly term in the RO Labelling as requested by EMA, and applying equally applicable editorial changes from the PI of the reference product Xgeva to the PI of Osenvelt.			PL	fractures of the femur and new primary malignancy in patients with giant cell tumour of bone (GCTB) based on the results from study 20140114. The change follows assessment of the same change for the reference product, Xgeva.

Article 61(3) / EMA/N/0000266442	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives and removal of grey-shading of manufacturers in section '6. Contents of the pack and other information'.	15/05/2025	27/04/2026	PL	
Variation type IB / EMA/VR/0000263750	Outcome: This was an application for a group of variations. B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	25/04/2025	27/04/2026	SmPC and PL	