Xbryk

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 /	B.II.f.1.b Extension of the shelf life of the	10/07/2025		SmPC	

[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/0000278769	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				
Variation type IB / EMA/VR/0000278280	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.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted	24/06/2025	N/A		
Variation type IB / EMA/VR/0000268916	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 - To update section 4.8 and 5.1 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	12/06/2025		SmPC, Labelling and PL	To update section 4.8 and 5.1 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, this is a long-term safety follow up study, that was conducted to continue to follow subjects with giant cell tumour of bone (GCTB) who were treated in Study 20062004 for an additional 5 or more years of long-term safety follow up and to further evaluate denosumab treatment in subjects with GCTB. The changes follow assessment of the same change to the reference product Xgeva.

	from study 20140114, this is a long-term safety follow up study, that was conducted to continue to follow subjects with giant cell tumour of bone (GCTB) who were treated in Study 20062004 for an additional 5 or more years of long-term safety follow up and to further evaluate denosumab treatment in subjects with GCTB. The changes follow assessment of the same change to the reference product Xgeva. Additionally, the MAH took the opportunity to align the PI with the QRD template, and to update the PI in BG, FR, MT and SV to correct typographic errors.				