

Prof. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 06.05.2025

Subject: Withdrawal of Teriparatide Ascend, (Teriparatide), 20 micrograms/80 microliters solution for injection in prefilled pen, EMEA/H/C/005687

Dear Prof. Bruno Sepodes,

I would like to inform you that, at this point of time, Ascend GmbH has taken the decision to withdraw the application for Marketing Authorisation of Teriparatide Ascend, (*teriparatide*), 20 micrograms/80 microliters solution for injection in prefilled pen, which was intended to be used for

- Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and nonvertebral fractures but not hip fractures has been demonstrated.
- Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture

This withdrawal is based on the following reason

- Identification of major issue with high background on bioequivalence assay

We reserve the right to make further Marketing Authorisation Application submission at a future date in this or other therapeutic indication(s)

I agree for this letter to be published on the EMA website.

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