

19 June 2020

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Sondelbay (teriparatide) - EMEA/H/C5233

Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, Accord Healthcare S.L.U. has taken the decision to withdraw the application for Marketing Authorisation of Sondelbay, 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 non-vertebral fractures but not hip fractures have 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 reasons:

- Bioequivalence study data are not considered adequate to support marketing authorization of the medicinal product.

We inform the Agency that there are no consequences for patients in clinical trials using Sondelbay.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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

Yours sincerely,

