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Withdrawal of application for the marketing authorisation of Sondelbay (teriparatide)

Accord Healthcare S.L.U. withdrew its application for a marketing authorisation of Sondelbay for the treatment of osteoporosis (a disease that makes bones fragile).

The company withdrew the application on 19 June 2020.

What is Sondelbay and what was it intended to be used for?

Sondelbay was to be used for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. It was also to be used in men and women who are at an increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

Sondelbay contains the active substance teriparatide and was to be available as a solution for injection in prefilled pens.

How does Sondelbay work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down, as may happen in women after the menopause. Gradually, the bones become fragile, and more likely to break. Osteoporosis can also occur in both sexes as a side effect of glucocorticoid treatment.

The active substance in Sondelbay, teriparatide, is identical to part of the human parathyroid hormone and acts on osteoblasts (bone-forming cells) in a similar way to stimulate bone formation. It also increases the absorption of calcium from food and prevents too much calcium being lost in the urine.

Sondelbay was a 'biosimilar medicine'. This means that it was expected to be highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Sondelbay was Forsteo.

What did the company present to support its application?

The company presented laboratory studies comparing Sondelbay with Forsteo that were intended to show that the active substance in Sondelbay is highly similar to that in Forsteo in terms of structure,

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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purity and biological activity. Because Sondelbay was a biosimilar medicine, the studies on effectiveness and safety of teriparatide carried out with Forsteo did not need to be repeated for Sondelbay. However, a study was carried out in 50 healthy men and 49 healthy post-menopausal women, to show that Sondelbay and Forsteo were distributed in the body in the same way.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information supplied by the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency still had some concerns and its provisional opinion was that Sondelbay could not have been authorised for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

It was concerned that the distribution of the medicine in the body had not been fully established as an inspection revealed problems with the way the main study was carried out. The findings identified during the inspection cast doubts on the reliability of the study results, and hence on whether the product could be considered highly similar to Forsteo. In addition, the Agency noted that more data was needed on how the prefilled pen was to be manufactured and assembled.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Sondelbay did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was withdrawing its application because of the issues with the main study comparing the distribution of its product and Forsteo in the body.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Sondelbay.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.