Mochida obtains marketing approval for teriparatide biosimilar in Japan

This material is an English translation of the press release issued on September 20, 2019 in Japanese, and the Japanese release is given priority regarding content and interpretation.

September 20, 2019

Mochida Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that Mochida obtained marketing approval for “Teriparatide BS Subcutaneous Injection Kit 600μg MOCHIDA” (Development code: RGB-10) from the Japanese Ministry of Health, Labour and Welfare on September 20.

The product is a biosimilar of teriparatide (genetical recombination) which Mochida has developed in Japan based on a comprehensive license and collaboration agreement with Gedeon Richter Plc. in Hungary, and is a treatment for osteoporosis that enhances bone formation and improves bone structure. It is a disposable kit preparation with delivery device and available for self-injection.

As the first teriparatide (genetical recombination) biosimilar in Japan, Mochida believes that the product will contribute to improving the Quality of Life and to reducing the financial burden of patients with osteoporosis. Expected launch date will be announced at the National Health Insurance Price Listing.

【References】

Summary of the marketing approval

Brand name	:	Teriparatide BS Subcutaneous Injection Kit 600μg MOCHIDA
Generic Name	:	Teriparatide (Genetical Recombination) [Teriparatide Biosimilar 1]
Indications	:	Osteoporosis at high risk of fracture
Dosage and Administration	:	The usual adult dose is 20 μg of Teriparatide (genetical recombination) [teriparatide biosimilar 1] administered by subcutaneous injection once a day. The maximum total duration of treatment with Teriparatide should be 24 months.