AsahiKASEI

Press Release

Asahi Kasei Pharma Corp.
September 26, 2011

Approval for manufacture and sale of Teribone™ osteoporosis drug in Japan

Asahi Kasei Pharma obtained approval today for the manufacture and sale of a 56.5 µg subcutaneous injection formulation of Teribone™ (generic name: teriparatide acetate, development code: MN-10-T) for the treatment of osteoporosis with high risk of fracture. Application for approval was filed on October 20, 2010.

Teribone™ is a human parathyroid hormone preparation that facilitates bone formation. A Phase III clinical trial in Japan demonstrated that, with weekly subcutaneous injections for 72 weeks, Teribone™ decreased the risk of developing new vertebral fracture[1] by 78.6% compared to placebo treatment. The efficacy in inhibiting fracture is obtained by increasing bone strength with both improved bone quality and increased bone density.

In Japan, it is estimated that more than 11 million people suffer from osteoporosis, including those not receiving treatment,[2] and the number is increasing as the population ages. Since osteoporosis carries an increased risk of vertebral and femoral fracture, with a high probability of resulting in confinement to bed, the implementation of effective measures against osteoporosis is an important social issue.

Asahi Kasei Pharma believes that, with its efficacy in inhibiting fracture, Teribone™ will make a significant contribution to the treatment of osteoporosis.

[1] Compression fracture of the centrum of vertebra (cylindrical part of the bones of the spine) due to brittleness caused by osteoporosis.

[2] Satoshi Soen, et al., Progress in Medicine, Vol. 27, No. 3, 621–627, 2007.

Outline of approval

Product name:	Teribone™ 56.5 µg for subcutaneous injection
Generic name:	Teriparatide acetate
Indication:	Osteoporosis with high risk of fracture
Dosage and administration:	For adults, ordinarily administered in a single 56.5 µg injection once a week for up to 72 weeks.