Press Release

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Daiichi Sankyo Obtains Approval for Additional Indication for PRALIA® Subcutaneous Injection 60mg Syringe

Tokyo, Japan (July 3, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has obtained approval in Japan for an additional indication for "inhibition of the progression of bone erosion associated with rheumatoid arthritis" for PRALIA® Subcutaneous Injection 60 mg Syringe (generic name: denosumab).

Denosumab is the first fully human monoclonal antibody that inhibits RANKL, an essential mediator of osteoclast formation, function and survival, and suppresses bone resorption.

Daiichi Sankyo aims to contribute further in the field of medicine by providing new options to patients and medical professionals through this additional indication.

About denosumab

Daiichi Sankyo licensed the rights to develop and market denosumab in Japan from Amgen Inc. (United States) in 2007, and began the Japanese sales of a 60 mg preparation as a therapeutic agent for osteoporosis under the product name PRALIA® Subcutaneous Injection 60 mg Syringe in June 2013. In April 2012, Daiichi Sankyo began sales of a 120 mg preparation as a therapeutic agent for bone complications stemming from multiple myeloma and bone metastases from solid tumors under the product name RANMARK® Subcutaneous Injection 120 mg. The 120 mg preparation received approval for additional indication as a treatment for giant cell tumor of bone in May 2014.

Daiichi Sankyo is also participating in global Phase 3 clinical trials of denosumab as adjuvant treatment for women with breast cancer.

Product Outline

Product name	PRALIA® Subcutaneous Injection 60 mg Syringe
Generic name (JAN)	Denosumab (genetic recombination)
Additional indication approved for manufacture and marketing	July 3, 2017
Indication (additions underlined)	1. Osteoporosis 2. Inhibition of the progression of bone erosion associated with rheumatoid arthritis
Dosage and administration (additions underlined)	1. Osteoporosis For adults under normal conditions, 60 mg of denosumab (genetic recombination) is injected subcutaneously every six months. 2. Inhibition of the progression of bone erosion associated with rheumatoid arthritis For adults under normal conditions, 60 mg of denosumab (genetic recombination) is injected subcutaneously every six months. If bone erosion progression occurs when denosumab is injected once every 6 months, denosumab can be injected subcutaneously once every 3 months.