For Immediate Release

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Daiichi Sankyo Receives Approval in Japan for Manufacture and Marketing of PRALIA®, a New Treatment for Osteoporosis

Tokyo, Japan (March 25, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), announced today that it has received approval from Japan's Ministry of Health, Labour and Welfare to manufacture and market the osteoporosis treatment PRALIA® subcutaneous injection 60mg syringe (INN: Denosumab; genetic recombination) for the treatment of osteoporosis.

PRALIA® is a subcutaneous injection for use once every six months as a novel treatment for osteoporosis that specifically inhibits RANKL, an essential mediator for bone resorption. In a phase 3 clinical study on osteoporosis patients (DIRECT study) in Japan, PRALIA® significantly reduced the risk of new or worsening vertebral fracture compared to placebo. Additionally, no apparent difference in the risk of adverse events was found between PRALIA® and the placebo. PRALIA® was also well tolerated and effective in reducing the vertebral fracture risk in Japanese patients with osteoporosis.

Fractures resulting from osteoporosis can significantly lower the quality of life of osteoporosis sufferers, including elderly persons confined to bed. We anticipate that this new treatment for osteoporosis will contribute to better quality of life for patients while offering healthcare professionals a novel, new treatment option.

Overview

Name	PRALIA® subcutaneous injection 60 mg syringe
Generic name (JAN)	Denosumab (genetic recombination)
Indication	Osteoporosis
Dosage and administration	For adults under normal conditions, 60 mg of denosumab (genetic recombination) is injected subcutaneously every six months
Approval date	March 25, 2013
Licensed from	Amgen Inc.

*For more about Phase 3 Study Results for Denosumab, please see our news release from October 15, 2012: http://www.daiichisankyo.com/news/detail/004487.html

About Denosumab

Denosumab is the world's first fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation, function and survival approved for therapeutic use. Daiichi Sankyo has been working on denosumab since 2007, when it licensed the rights from Amgen to develop and market this antibody in Japan. Daiichi Sankyo received approval to market denosumab as a 120 mg preparation in January 2012 in Japan as a treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors and RANMARK® (subcutaneous injection 120 mg) was launched in Japan in April 2012. Denosumab is currently in global phase 3 trials for adjuvant treatment for women with early-stage breast cancer, and Daiichi Sankyo is conducting phase 2 trials for Japanese patients with rheumatoid arthritis and giant cell tumor of bone, respectively.