For Immediate Release

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Daiichi Sankyo Launches Novel Osteoporosis Treatment PRALIA® Subcutaneous Injection 60mg Syringe

Tokyo, Japan (June 11, 2013) – Daiichi Sankyo Company, Limited. (hereafter, Daiichi Sankyo) announced today the launch of the osteoporosis treatment PRALIA® Subcutaneous Injection 60mg Syringe (generic name: denosumab (genetic recombination); approved in Japan for manufacture and marketing, March 25, 2013; placed on National Health Insurance drug price list, May 24, 2013).

PRALIA® is a fully human monoclonal antibody that specifically inhibits RANKL*, an essential mediator for bone resorption. It is a subcutaneous injection for use once every six months as a novel treatment for osteoporosis. In a clinical study on osteoporosis patients in Japan, PRALIA® showed efficacy in reducing risk of vertebral fracture.

Fractures resulting from osteoporosis can significantly lower the quality of life of osteoporosis sufferers, including elderly persons confined to bed. Daiichi Sankyo will ensure that information for the appropriate use of PRALIA® is readily available, and we anticipate this new treatment for osteoporosis will contribute to better quality of life for patients while offering healthcare professionals a novel treatment option.

*RANKL: A receptor activator for nuclear factor-k B ligand

Product Outline

(Launch date: June 11, 2013)

Product name	PRALIA® Subcutaneous Injection 60mg Syringe
Generic name (JAN)	Denosumab (genetic recombination)
Therapeutic category	A fully human monoclonal antibody to RANKL
Drug price	28,482 yen (60mg1mL1 syringe) As of May 24, 2013
Indication	Osteoporosis

Dosage and administration	For adults under normal conditions, 60 mg of denosumab (genetic recombination) is injected subcutaneously every six months
Approval for manufacture and marketing	March 25, 2013
Manufacturing and marketing	Daiichi Sankyo Co., Ltd.
Licensed from	Amgen Inc.

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.