For Immediate Release

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Daiichi Sankyo Announces Application in Japan for Additional Indication for Anti-RANKL Antibody, Denosumab

Tokyo, Japan (September 23, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), today announced that it has applied for additional indication of denosumab (product name: PRALIA® subcutaneous injection 60mg syringe) for rheumatoid arthritis-related treatment.

Denosumab is the first fully human monoclonal antibody to target RANKL (an essential mediator of osteoclast formation, function, and survival). Daiichi Sankyo has been working on denosumab since 2007, when it licensed the rights from Amgen Inc. (United States) to develop and market this antibody in Japan.

Daiichi Sankyo anticipates this treatment will help meet an unmet need for patients.

About Denosumab

Daiichi Sankyo began sales in Japan of a 60 mg preparation of denosumab as a therapeutic agent for osteoporosis under the product name PRALIA® subcutaneous injection 60mg syringe in June 2013. In addition, from April 2012 Daiichi Sankyo began sales of a 120 mg preparation of denosumab as a therapeutic agent to treat bone complications stemming from multiple myeloma and bone metastases from solid tumors under the product name RANMARK® subcutaneous injection 120 mg, and from May 2014, as a therapeutic agent to treat giant cell tumor of bone under the product name RANMARK® subcutaneous injection 120 mg.
Daiichi Sankyo is also participating in global Phase 3 clinical trials of denosumab as adjuvant treatment for women with breast cancer.