# Press Release

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**Daiichi Sankyo Announces Update on Amgen Inc.'s Phase 3 Clinical Trial Evaluating Denosumab as Adjuvant Breast Cancer Treatment**

**Tokyo, Japan (February 2, 2018)** - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that on February 1, 2018 in PST Amgen Inc. made an announcement regarding the top-line results from its Global Phase 3 D-CARE trial in which Daiichi Sankyo also participated. Amgen Inc.'s D-CARE, placebo-controlled trial, evaluated AMG162 (generic name: denosumab) as adjuvant treatment for women with high-risk, early stage breast cancer receiving standard of care neoadjuvant or adjuvant cancer therapy.

The trial did not meet its primary endpoint of bone metastasis-free survival.
Adverse events observed in patients treated with denosumab were generally consistent with the known safety profile.

Detailed results will be submitted to a future medical conference or publication.

Daiichi Sankyo continues to contribute the field of medicine to patients and medical professionals.

**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. PRALIA® received approval for additional indication as a treatment for inhibition of the progression of bone erosion associated with rheumatoid arthritis in July 2017. 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. RANMARK® received approval for additional indication as a treatment for giant cell tumor of bone in May 2014.

**About the D-CARE Study**

The D-CARE (Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of **D**enosumab as Adjuvant Treatment for Women with Early-Stage Breast **Ca**ncer at High Risk of **Re**currence) study is an international, randomized, double-blind placebo-controlled trial of denosumab as adjuvant treatment for 4,509 women with early-stage breast cancer at high-risk of recurrence receiving standard of care neoadjuvant or adjuvant therapy. In this five year landmark study, patients were randomized to receive either subcutaneous denosumab 120mg or placebo every 3 or 4 weeks (Q3W or Q4W) for six months, followed by subcutaneous denosumab 120mg or placebo every three months for four and a half years, for a total treatment duration of five years (approximately 60 months). The primary endpoint for the study was bone metastasis-free survival and secondary endpoints included disease-free survival (DFS), DFS in the subset of post-menopausal women, overall survival and distant recurrence-free survival. Safety and tolerability were also evaluated.