For Immediate Release

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Positive Phase 3 Study Results for Denosumab on Fracture Risk in Japanese Patients with Osteoporosis Presented at ASBMR

Tokyo, Japan (October 15, 2012) – Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) today announced that the results from a 24-month randomized, double-blind, placebo-controlled multi-center phase 3 clinical trial with AMG 162 (denosumab) (DIRECT* study) were presented on October 14 at the 34th ASBMR (The American Society for Bone and Mineral Research; USA, Minneapolis; abstract number 1098).

* DIRECT: Denosumab fracture Intervention RandomizEd placebo Controlled Trial

The 1,262 Japanese subjects with prevalent vertebral fractures (VFXs) and low bone marrow density (BMD) were randomly assigned to denosumab 60 mg every 6 months (SC), or placebo every 6 months (SC), or open-label oral alendronate 35 mg every week as referential group in a 2:2:1 ratio. The primary endpoint was the incidence of new or worsening VFXs for two years after commencement of the treatment. Other study endpoints were incidences of new VFXs and predefined major non-VFXs. Safety of the compound compared to placebo was also assessed.

Denosumab significantly reduced the incidence of new or worsening VFXs (3.6%) compared to placebo (10.3%); hazard ratio [HR]=0.343; 95% CI:0.194, 0.606; p=0.0001). The risk reduction of denosumab compared to placebo was 65.7%. Denosumab also significantly reduced incidences of new VFXs and major non-VFXs. Adverse events were at similar rates between the denosumab group and the placebo group, and denosumab was well tolerated in Japanese subjects.

In March 2012, Daiichi Sankyo filed an application in Japan to market denosumab for osteoporosis based on this study. With denosumab, Daiichi Sankyo aims to benefit patients and medical professionals by providing a new approach to therapy for osteoporosis.

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.

**About Daiichi Sankyo**
The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimise growth opportunities across the value chain. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com).

**About Amgen**
Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about Amgen’s pioneering science and vital medicines, visit [www.amgen.com](http://www.amgen.com). Follow them on [www.twitter.com/amgen](http://www.twitter.com/amgen).