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Daiichi develops antibody to prevent fracture

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Denosumab shows positive result for fracture risk



Singapore: Daiichi Sankyo's 24-month randomized, double-blind, placebo-controlled multi-center phase III clinical trial with AMG 162 (denosumab) (Denosumab fracture Intervention Randomized placebo Controlled Trial -DIRECT) significantly reduced the incidence of new or worsening vertebral fractures (VFXs) compared to placebo.

The 1,262 Japanese subjects with prevalent vertebral fractures low bone marrow density (BMD) were randomly assigned to denosumab 60 mg every six months (SC), or placebo every six months (SC), or open-label oral alendronate 35 mg every week. 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.

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.

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.