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Daiichi Sankyo Submits Application to Manufacture and Market RANMARK[®] for Treatment of Giant Cell Tumor Of Bone in Japan

Tokyo, Japan (August 29, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), today announced that it has filed an application for approval in Japan to manufacture and market RANMARK[®] (subcutaneous injection 120 mg) (INN: Denosumab (genetic recombination)), a gene recombinant drug to treat giant cell tumor of bone(hereafter, GCTB). Denosumab was designated as a pharmaceutical for the treatment of rare diseases by the Ministry of Health, Labour and Welfare in June 2013 for efficacy against GCTB.

Denosumab is the world's first fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation. Daiichi Sankyo has been working on denosumab since 2007, when it acquired the rights from Amgen Inc. to develop and market this antibody in Japan. Daiichi Sankyo launched denosumab in Japan in April 2012 under the RANMARK[®] (subcutaneous injection 120 mg) name as a treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors. In June 2013, Daiichi Sankyo launched the osteoporosis treatment PRALIA[®] subcutaneous injection 60mg syringe. Denosumab is also currently in global phase 3 clinical studies for postoperative adjuvant breast cancer therapy and domestic phase 2 clinical studies in Japan for rheumatoid arthritis.

About Giant Cell Tumor of Bone(GCTB)

GCTB is a rare bone tumor, but once it occurs, it is characterized by rapid growth, severe destruction of bone, and extension into the surrounding soft tissues. In addition, it may metastasize to the lungs. There have been no approved definitive therapies for GCTB and surgery is only possible option with resectable GCTB.