For Immediate Release

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Daiichi Sankyo Receives Approval in Japan for Additional Indication Related to RANMARK® for Treatment of Giant Cell Tumor of Bone

Tokyo, Japan (May 23, 2014) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has received approval in Japan for partial modification to RANMARK® (subcutaneous injection 120mg) (JAN: 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. With the approval for this additional indication, Daiichi Sankyo aims to benefit patients and healthcare professionals by providing a new treatment option. Furthermore, in order to promote the safe and efficient use of this additional indication for GCTB, a specific use survey will be conducted for all medicated patients until data for a set number of cases has been accumulated.

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 120mg) name as a treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors. In June 2013, Daiichi Sankyo also launched the osteoporosis treatment PRALIA® subcutaneous injection 60mg syringe. Denosumab is currently in domestic phase 3 clinical studies in Japan for postoperative adjuvant breast cancer therapy and rheumatoid arthritis.

Product Overview

Name	RANMARK® subcutaneous injection 120mg
Generic name(JAN)	Denosumab (genetic recombination)
Approval date for partial modification	May 23, 2014
Indication (modified content underlined)	1. Bone complications stemming from multiple myeloma and bone metastases from solid tumors. 2. Giant cell tumor of bone
Dosage and administration (modified content underlined)	1. Denosumab should be injected subcutaneously with a 120mg dose once every 4 weeks for adults. 2. Denosumab should be injected subcutaneously with a 120mg dose on day 1, day 8, day 15 and day 29 of treatment, and then once every 4 weeks.