Daiichi Sankyo Announces Results of Phase 3 International Joint Trial (RApsody) of Investigational Etanercept Biosimilar

TOKYO, Japan (January 12, 2016) – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) today announced that they have achieved major objectives in the Phase 3 international joint trial (RApsody) of CHS-0214, an investigational etanercept (genetical recombination) biosimilar*1 in rheumatoid arthritis (RA) under development with the U.S. company, Coherus BioSciences, Inc. (hereinafter, Coherus).

The trial compares the efficacy and safety of CHS-0214 with Enbrel® [generic name: etanercept (genetical recombination); hereinafter, reference product] in RA patients (including Japanese patients) with inadequate response to methotrexate.

The primary endpoint (ACR20*2), evaluating the disease activity of rheumatoid arthritis at 24 weeks after the administration of CHS-0214, met the criteria of equivalence as defined in advance in CHS-0214 and reference product groups, achieving the intended purpose. No significant difference was noted in the reported adverse events between CHS-0214 and reference product groups. Currently, this trial is continued in open-label extension study following the 24-week double-blind phase.

Daiichi Sankyo will continue the development of CHS-0214 based on the strategic alliance with Coherus, concluded for the biosimilar business in Japan in 2012, aiming to enter the biosimilar market to meet diverse medical needs.

*1 Biosimilars are biologic medical products that are similar to already approved biotechnology applied pharmaceuticals but are developed by a different manufacturer.

*2 ACR20 is 20% improvement according to American College of Rheumatology criteria. Subjects will be considered an ACR20 responder if: compared to Baseline (Day 0), they achieve: 20% decrease in swollen joint count, 20% decrease in tender joint count, and 20% improvement in 3 of the following 5 measures: 1) CRP 2) Health Assessment Questionnaire – Disability Index 3) Subject’s pain assessment 4) Subject’s Global Assessment 5) Physician’s Global Assessment.
About Coherus BioSciences, Inc.

1. Representative: Dennis M. Lanfear
2. Head office: California, USA
3. Established year: 2010
4. Business: Coherus is a leading pure-play global biosimilar platform company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products.