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Daiichi-Sankyo

Press Release

Daiichi Sankyo to Present at ESMO 2016 Late-Breaking Clinical Data for Novel HER2-Targeting Antibody Drug Conjugate in T-DM1 Pre-Treated Breast Cancer

Tokyo, Japan – (September 28, 2016), Parsippany, NJ, and Munich, Germany – (September 27, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that safety and preliminary efficacy phase 1 data evaluating DS-8201a, a novel HER2-targeting antibody drug conjugate, will be presented during a late-breaking poster discussion session during the European Society for Medical Oncology (ESMO) 2016 Congress from October 7 -11 in Copenhagen, Denmark.

"We are looking forward to presenting these results for DS-8201a to the scientific community at ESMO," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "Additionally, for the first time we will be showcasing our innovative in-house antibody drug conjugate technology that was used to develop DS-8201a."

LBA17: Single Agent Activity of DS-8201a, a HER2-Targeting Antibody-Drug Conjugate, in Breast Cancer Patients Previously Treated with T-DM1: Phase 1 Dose Escalation
Results from part 1 (dose escalation) of a two-part phase 1 study of DS-8201a by Kenji Tamura, MD, PhD, Chairman, Department of Breast and Medical Oncology, National Cancer Center Hospital, Tokyo will be presented on Sunday, October 9 at 4:30 pm CEST. The primary objective of the dose escalation part of the study was to examine the safety and tolerability of DS-8201a along with determining the maximum tolerated dose. Secondary objectives include evaluating the pharmacokinetics and efficacy of DS-8201a. Additional sub-group analyses of preliminary efficacy of DS-8201a in advanced or metastatic breast cancer patients previously treated with ado-trastuzumab emtansine (T-DM1) will be presented.

About DS-8201a
DS-8201a is an investigational antibody drug conjugate comprised of a humanized anti-HER2 antibody attached by a peptide linker to a novel topoisomerase I inhibitor, utilizing Daiichi Sankyo's proprietary payload and linker-payload technology. It is currently in phase 1 clinical development for HER2 expressing advanced or metastatic breast cancer or gastric cancer and other HER2 expressing solid cancers.

The second part (dose expansion) of the phase 1 clinical trial evaluating the safety and efficacy of DS-8201a is currently underway, and will enroll patients in the United States and Japan into one of four treatment cohorts: patients with HER2+ breast cancer previously treated with T-DM1; patients with

HER2+ gastric or gastroesphageal junction adenocarcinoma previously treated with trastuzumab; patients with HER2-low expressing breast cancer; and, patients with other solid cancers that express HER2. For more information about the study visit ClinicalTrials.gov.

About Daiichi Sankyo Cancer Enterprise

The vision of Daiichi Sankyo Cancer Enterprise is to push beyond traditional thinking to align world-class science to create innovative treatments for patients with cancer. The oncology pipeline of Daiichi Sankyo continues to grow and currently includes more than 20 small molecules and monoclonal antibodies with novel targets in both solid and hematological cancers. Compounds in phase 3 development include: quizartinib, an oral FLT3-ITD inhibitor, for newly-diagnosed and relapsed/ refractory FLT3-ITD+ acute myeloid leukemia (AML); pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS), which also is being investigated in combination with anti-PD1 immunotherapy, pembrolizumab, in a range of solid tumors; and tivantinib, an oral MET inhibitor, for second-line treatment in patients with MET-high hepatocellular carcinoma in partnership with ArQule, Inc.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.

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