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Press Release

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Daiichi Sankyo's HER2-Targeting Antibody Drug Conjugate DS-8201 Receives SAKIGAKE Designation for Gastric Cancer from Japan MHLW

- SAKIGAKE Designation for HER2-positive advanced gastric cancer follows Breakthrough Therapy and Fast Track Designations for DS-8201 from the U.S. FDA for HER2-positive metastatic breast cancer
- There is a high unmet medical need for patients with HER2-positive gastric cancer whose tumors are no longer controlled by trastuzumab as there is no other approved HER2-targeted therapy
- Pivotal phase 2 DESTINY-Gastric01 study of DS-8201 is currently enrolling patients in Japan and South Korea with HER2-positive advanced gastric cancer who have progressed on two prior regimens including fluoropyrimidine agents, platinum agents and trastuzumab

Tokyo, Basking Ridge, NJ, and Munich– (March 27, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that DS-8201, an investigational HER2-targeting antibody drug conjugate (ADC), has received SAKIGAKE Designation for the treatment of HER2-positive advanced gastric or gastroesophageal junction cancer by the Japan Ministry of Health, Labour and Welfare (MHLW).

"There are no HER2-targeting treatment options currently available for patients with HER2-positive gastric cancer whose tumors are no longer controlled by trastuzumab," said Koichi Akahane, PhD, MBA, Executive Officer, Head of Oncology Function, R&D Division, Daiichi Sankyo. "We look forward to working closely with the Japan Ministry of Health, Labour and Welfare under the terms of the SAKIGAKE program to accelerate the development of DS-8201 particularly since Japan has one of the highest incidence rates of gastric cancer worldwide."

The SAKIGAKE Designation System promotes R&D in Japan, driving early practical application for innovative pharmaceutical products, medical devices and regenerative medicines. As a designated medicine under the SAKIGAKE Designation system, DS-8201 will have prioritized consultation, a dedicated review system to support the development and review process, as well as reduced review time from the normal 12 to 6 months.

"We are pleased that DS-8201 has received SAKIGAKE Designation for advanced HER2-positive gastric cancer, which follows the Breakthrough Therapy and Fast Track designations granted by the U.S. FDA for HER2-positive metastatic breast cancer," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "These three designations for DS-8201 underscore our commitment to active and close collaborations with health

authorities in order to potentially bring DS-8201 as a new treatment option to patients with different types of HER2-expressing cancers worldwide as quickly as possible."

SAKIGAKE Designation was granted based on the results of an ongoing phase 1 study assessing the safety, tolerability and preliminary efficacy of DS-8201. Updated preliminary results of DS-8201 from a subgroup analysis of HER2-positive advanced gastric cancer previously treated with trastuzumab and chemotherapy were recently presented at the 2018 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium.[1]

Unmet Need in Gastric Cancer

Gastric cancer is the fifth most common cancer worldwide, with nearly one million new cases reported in 2012.[2] Approximately half of all gastric cancer cases occur in eastern Asia, with Japan having the third highest incidence rate worldwide.[2,3] Gastric cancer is the third leading cause of cancer-related death worldwide, and the second leading cause of cancer-related death in Japan.[2,4]

Approximately one in five gastric cancers overexpress HER2, a tyrosine kinase receptor growth-promoting protein found on the surface of some cancer cells.[5] HER2-expressing gastric cancer is an area of unmet medical need as advances in the treatment of the disease have been limited, largely due to its genetic complexity and heterogeneity.[6] Currently, there are no approved HER2-targeting therapy options for patients with HER2-positive advanced gastric cancer after treatment with trastuzumab.

About DS-8201

DS-8201 is the lead product in the investigational ADC Franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are targeted cancer medicines that deliver cytotoxic chemotherapy ("payload") to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. Designed using Daiichi Sankyo's proprietary ADC technology, DS-8201 is a smart chemotherapy comprised of a humanized HER2 antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker. It is designed to target and deliver chemotherapy inside cancer cells and reduce systemic exposure to the cytotoxic payload (or chemotherapy) compared to the way chemotherapy is commonly delivered.

DS-8201 is currently in pivotal phase 2 clinical development for HER2-positive unresectable and/or metastatic breast cancer resistant or refractory to T-DM1 (DESTINY-Breast01), pivotal phase 2 development for HER2-positive advanced gastric cancer resistant or refractory to trastuzumab (DESTINY-Gastric01), phase 2 development in advanced colorectal cancer and phase 1 development for other HER2-expressing advanced/unresectable or metastatic solid tumors.

DS-8201 has been granted Breakthrough Therapy designation for the treatment of patients with HER2-positive, locally advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after ado-trastuzumab emtansine (T-DM1), and Fast Track designation for the treatment of HER2-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with HER2-targeted therapies including T-DM1 by the U.S. Food and Drug Administration (FDA). DS-8201 is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established.

About Daiichi Sankyo Cancer Enterprise

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by three pillars including our investigational Antibody Drug Conjugate Franchise, Acute Myeloid Leukemia Franchise and Breakthrough Science Franchise, we aim to deliver seven distinct new molecular entities over eight years during 2018 to 2025. Our powerful research engines include two laboratories for biologic/immuno-oncology and small molecules in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. Compounds in pivotal stage development include: DS-8201, an antibody drug conjugate (ADC) for HER2-expressing breast, gastric and other cancers; quizartinib, an oral selective FLT3 inhibitor, for newly-diagnosed and relapsed/ refractory acute myeloid leukemia (AML) with FLT3-ITD mutations; and pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT). For more information, please visit: www.DSCancerEnterprise.com.

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 15,000 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 Basking Ridge, 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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