

## Press Release

### **Daiichi Sankyo Presents New Data for DS-8201 in Multiple HER2-Expressing Solid Tumors at European Society for Medical Oncology (ESMO) 2017 Congress**

- Preliminary results from subgroup analysis of ongoing phase 1 study demonstrate a 32 percent overall response rate and 82 percent disease control rate with DS-8201 in HER2-expressing metastatic solid tumors such as colon cancer, non-small cell lung cancer and other tumor types
- DS-8201 recently was granted FDA 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)
- Pivotal phase 2 DESTINY-Breast01 study of DS-8201 is currently enrolling patients with HER2-positive unresectable and/or metastatic breast cancer who are resistant or refractory to T-DM1

**Tokyo, Japan, Basking Ridge, NJ, and Munich, Germany – (September 11, 2017)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that DS-8201, an investigational HER2-targeting antibody drug conjugate (ADC), demonstrated preliminary antitumor activity in patients with HER2-expressing solid tumors such as colon cancer, non-small cell lung cancer and other tumor types. These data were presented during a poster session at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain.

Preliminary results from the ongoing DS-8201 phase 1 study showed that DS-8201 demonstrated an overall confirmed response rate of 32 percent and a disease control rate of 82 percent in a subgroup analysis of 22 of 25 evaluable patients with HER2-expressing solid tumors, which included colon cancer (11 patients), non-small cell lung cancer (6 patients), salivary gland cancer (4 patients), Paget's disease (2 patients), cholangiocarcinoma (1 patient) and esophageal cancer (1 patient). Two of 10 evaluable patients with colon cancer, one out of five evaluable patients with non-small cell lung cancer and three of four evaluable patients with salivary gland cancer achieved partial responses. Two additional patients with colon cancer and non-small cell lung cancer with one post baseline scan showed a partial response yet to be confirmed at subsequent scans. A total of 168 patients have been treated in both the dose escalation (24 patients) and dose expansion (144 patients) parts of the study as of August 1, 2017.

Safety data for 168 patients who received at least one dose of DS-8201 in study parts 1 and 2 and across different cohorts of the study also were reported. The most common adverse events (any grade) seen in all patients to date included nausea (67 percent), decreased appetite (56 percent), vomiting (33 percent), anemia (30 percent) and decreased platelet count (29 percent). Grade 3 adverse events occurring in >10 percent of patients included anemia (13 percent), decreased neutrophil count (14 percent) and decreased white blood cell count (11 percent). Grade 4 adverse events occurred in ≤ 3 percent of patients and included decreased

platelet count (3.0 percent), decreased neutrophil count (2.4 percent), decreased white blood cell count (1.8 percent) and anemia (1.2 percent).

“These preliminary results are consistent with other data previously reported in the HER2-positive metastatic breast and gastric cancer cohorts of this study, demonstrating that further study is warranted for DS-8201 across other HER2-expressing solid tumors,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “These data add to the growing body of clinical evidence suggesting that DS-8201 could potentially become an important new treatment option for many different types of solid tumors that overexpress HER2. In addition to initiating our pivotal phase 2 study of DS-8201 in HER2-positive metastatic breast cancer, we are exploring next steps for the development of DS-8201 across multiple HER2-expressing tumor types.”

### **About the DS-8201 Phase 1 Study**

The open-label two-part phase 1 dosing study is currently evaluating DS-8201 in patients with advanced/unresectable or metastatic solid tumors that are refractory or intolerant to standard treatment, or for whom no standard treatment is available. The primary objective of the dose escalation phase of the study was to assess the safety and tolerability of DS-8201 and determine the maximum tolerated dose. In the dose expansion part of the phase 1 study, DS-8201 is given in one of two doses (5.4 mg/kg and 6.4 mg/kg) to patients with HER2-positive advanced or metastatic breast cancer and gastric cancer, HER2 low-expressing breast cancer and other HER2-expressing solid tumors. Patient enrollment in the two breast cancer cohorts is ongoing in the U.S. and Japan. For more information about the study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

### **About DS-8201**

DS-8201 is the lead product in the ADC Franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are a type of targeted cancer medicine 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. 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 (DXd) payload by a tetrapeptide linker. It is designed to deliver enhanced cancer cell destruction upon release inside the cell and reduce systemic exposure to the cytotoxic payload (or chemotherapy) compared to the way chemotherapy is commonly delivered.

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

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to DS-8201 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. DS-8201 is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established, and there is no guarantee DS-8201 will become commercially available.

### **About Daiichi Sankyo Cancer Enterprise**

The vision of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order 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 our Antibody Drug Conjugate (ADC) and Acute Myeloid Leukemia (AML) Franchises, our cancer pipeline includes more than 20 small molecules, monoclonal antibodies and ADCs stemming from our powerful research engines: our 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 development include: quizartinib, an oral FLT3 inhibitor, for newly-diagnosed and relapsed or refractory AML with FLT3-ITD mutations; DS-8201, an ADC for HER2-expressing breast and gastric cancer, and other HER2-expressing solid tumors; and pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), which is also being explored in a range of solid tumors in combination with the anti-PD1 immunotherapy pembrolizumab. For more information, please visit: [www.DSCancerEnterprise.com](http://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](http://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](http://www.dsi.com).

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