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Press Release

Positive Pivotal Data for Daiichi Sankyo's DS-8201 ([Fam]-Trastuzumab Deruxtecan) in Patients with HER2 Positive Metastatic Breast Cancer to be Presented at SABCS

- Objective response rate, progression-free survival, duration of response and safety data from DS-8201 pivotal study in HER2 positive metastatic breast cancer (DESTINY-Breast01) to be unveiled
- Trial-in-progress updates from phase 3 development program of DS-8201 in HER2 positive and HER2 low metastatic breast cancer, along with phase 1/2 trial of U3-1402 in HER3 expressing metastatic breast cancer, to be highlighted
- Daiichi Sankyo to hold first-ever U.S.-based R&D Day to discuss DS-8201 SABCS data and provide future clinical development plans across its investigational ADC portfolio

Munich and Basking Ridge, NJ – (November 19, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it will present new data across its investigational ADC portfolio at the 2019 San Antonio Breast Cancer Symposium (#SABCS19), December 10-14, 2019 in San Antonio, Texas.

Positive data from the pivotal phase 2 DESTINY-Breast01 trial of DS-8201 ([fam-] trastuzumab deruxtecan), an investigational HER2 targeting antibody drug conjugate (ADC), will be unveiled, highlighting objective response rate, progression-free survival, duration of response and safety seen in patients with HER2 positive metastatic breast cancer previously treated with ado-trastuzumab emtansine.

Trial-in-progress updates from the pivotal phase 3 development program of DS-8201 in patients with HER2 positive metastatic breast cancer, including a head-to-head study with ado-trastuzumab emtansine, and in patients with HER2 low metastatic breast cancer, also will be presented. An overview of the phase 1/2 trial for U3-1402, an investigational HER3 targeting ADC, in HER3 expressing advanced/unresectable or metastatic breast cancer also will be featured at SABCS.

"Following the recent Priority Review acceptance of our BLA by the FDA and our regulatory submission in Japan, we look forward to presenting the pivotal results of DS-8201 monotherapy in patients with HER2 positive metastatic breast cancer at SABCS," said Antoine Yver, MD, MSc, EVP and Global Head, Oncology Research and Development, Daiichi Sankyo. "These data, coupled with other important scientific discussions surrounding our other pivotal studies in HER2 positive and HER2 low metastatic breast cancer, underscore the commitment we have in bringing DS-8201 to as many patients as possible."

The ADC portfolio of Daiichi Sankyo currently consists of seven novel ADCs, with four in clinical development across multiple types of cancer, including DS-8201, which is being co-developed and co-commercialized globally with AstraZeneca; U3-1402 (targeting HER3); DS-1062 (targeting TROP2) and DS-7300 (targeting B7-H3). Each ADC is engineered and designed using Daiichi Sankyo's proprietary DXd ADC technology, which consists of a monoclonal antibody attached by a tetrapeptide-based linker to a novel topoisomerase I inhibitor payload. Each ADC is constructed to target and deliver chemotherapy inside cancer cells that express a specific cell surface antigen, and each has a customized drug to antibody ratio (DAR) designed to optimize the risk-benefit ratio for the intended patient population.

Following SABCS, Daiichi Sankyo will hold its first-ever U.S.-based R&D Day for investors and analysts on Thursday, December 19, 2019 at 10:30 AM ET at the New York Hilton Midtown in New York, NY. Company executives will provide an overview of the DS-8201 data presented at SABCS, unveil a new R&D strategy, including updated clinical development plans across the investigational ADC portfolio, and address questions from investors and analysts. Investors are invited to register for R&D Day by emailing DaiichiSankyoIR@daiichisankyo.co.jp prior to the event.

Following is an overview of data from Daiichi Sankyo to be presented at SABCS:

SABCS Abstract	**Presentation Details**
[Fam-] trastuzumab deruxtecan (T-DXd; DS-8201 in subjects with HER2-positive metastatic breast cancer (MBC) previously treated with T-DM1: A phase 2, multicenter, open-label study (DESTINY-Breast01)	Session Title: General Session 1 Date/Time: Wednesday, December 11, 2019; 9:15-9:30 AM CT Location: Hall 3
A phase 1, multicenter, open-label study to assess the effect of [fam-] trastuzumab deruxtecan (T-DXd; DS-8201) on QTc and pharmacokinetics in subjects with HER2-expressing metastatic and/or unresectable breast cancer	Program Number: P1-18-12 Session Title: Poster Session 1 Date/Time: Wednesday, December 11, 2019; 5:00-7:00 PM CT Location: Hall 1
A phase 3, multicenter, randomized, open-label trial of [fam-] trastuzumab deruxtecan (T-DXd; DS-8201) vs. investigator's choice in HER2-low breast cancer (DESTINY-Breast04)	Program Number: OT1-07-02 Session Title: Antibody-Drug Conjugates Date/Time: Wednesday, December 11, 2019; 5:00-7:00 PM CT Location: Hall 1
[Fam-] trastuzumab deruxtecan (T-DXd; DS-8201) vs. ado-trastuzumab emtansine (T-DM1) in subjects with HER2-positive, unresectable and/or metastatic breast cancer who previously received trastuzumab and a taxane: a phase 3, randomized trial (DESTINY-Breast03)	Program Number: OT1-07-01 Session Title: Antibody-Drug Conjugates Date/Time: Wednesday, December 11, 2019; 5:00-7:00 PM CT Location: Hall 1
[Fam-] trastuzumab deruxtecan (T-DXd; DS-8201) vs. investigator's choice of treatment in subjects with HER2-positive, unresectable and/or metastatic breast cancer who previously received TDM-1: a randomized, phase 3 trial (DESTINY-Breast02)	Program Number: OT1-07-04 Session Title: Antibody-Drug Conjugates Date/Time: Wednesday, December 11, 2019; 5:00-7:00 PM CT Location: Hall 1
Phase 1/2 first-in-human study of U3-1402, an anti-human epidermal growth factor receptor 3 (HER3) antibody-drug conjugate, in HER3-expressing advanced/unresectable or metastatic breast cancer,	Program Number: OT1-07-06 Session Title: Antibody-Drug Conjugates Date/Time: Wednesday, December 11, 2019; 5:00-7:00 PM CT Location: Hall 1

including those with triple negative breast cancer (TNBC) or HER3-low disease	
Evaluation of patritumab/paclitaxel/trastuzumab over standard paclitaxel/trastuzumab in early stage, high-risk HER2 positive breast cancer: Results from the neoadjuvant I-SPY 2 TRIAL	Program Number: P3-11-02 Session Title: Poster Session 3 Date/Time: Thursday, December 12, 2019; 5:00-7:00 PM CT Location: Hall 1

About DESTINY-Breast01

DESTINY-Breast01 is a pivotal phase 2, open-label, global, multicenter, two-part trial evaluating the safety and efficacy of DS-8201 in patients with HER2 positive unresectable and/or metastatic breast cancer previously treated with ado-trastuzumab emtansine. The primary endpoint of the trial is objective response rate, as determined by independent central review. Secondary objectives include duration of response, disease control rate, clinical benefit rate, progression-free survival and overall survival. Enrollment into DESTINY-Breast01 was completed in September 2018 with 253 patients at more than 100 sites across North America, Europe, Japan and other countries in Asia.

The safety and tolerability profile of DS-8201 in DESTINY-Breast01 was consistent with the phase 1 trial data published in *The Lancet Oncology*,[1] in which the most common adverse events (≥30 percent, any grade) included nausea, decreased appetite, vomiting, alopecia, fatigue, anemia, diarrhea and constipation. Cases of drug-related interstitial lung disease (ILD) and pneumonitis, including grade 5 events, have also been reported in the clinical development program.

About DS-8201

DS-8201 (fam-trastuzumab deruxtecan in U.S. only; trastuzumab deruxtecan in other regions of world) is the lead product in the investigational ADC Franchise of the Daiichi Sankyo Cancer Enterprise and the most advanced program in AstraZeneca's ADC scientific platform.

In March 2019, Daiichi Sankyo and AstraZeneca entered into a global collaboration to jointly develop and commercialize DS-8201 as a potential new medicine worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for the manufacturing and supply.

A comprehensive development program for DS-8201 is underway globally with five pivotal trials in HER2 expressing metastatic breast and gastric cancer, including a trial in patients with metastatic breast cancer and low levels of HER2 expression (HER2 low). Phase 2 trials are underway for HER2 expressing advanced colorectal cancer as well as metastatic non-squamous HER2 overexpressing or HER2 mutated non-small cell lung cancer. Trials in combination with other anticancer treatments, such as immunotherapy, also are underway.

The U.S. Food and Drug Administration (FDA) recently granted Priority Review for the Biologics License Application (BLA) for DS-8201 for the treatment of HER2 positive metastatic breast cancer, which previously received Breakthrough Therapy and Fast Track Designations. A regulatory submission for DS-8201 also has been made to Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of HER2 positive metastatic breast cancer, and it has previously received SAKIGAKE designation for the treatment of advanced HER2 positive gastric or gastroesophageal junction cancer by Japan's MHLW.

About U3-1402

U3-1402 is an investigational and potential first-in-class HER3 targeting ADC currently in phase 1/2 development for HER3 expressing metastatic or unresectable breast cancer in the U.S. and Japan and phase 1 development for metastatic or unresectable non-small cell lung cancer in the U.S.

DS-8201, U3-1402, DS-1062 and DS-7300 are investigational agents that have 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 pipeline, 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. For more information, please visit: www.DSCancerEnterprise.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 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 cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

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Reference:
[1] Tamura, K, et al. Trastuzuamb deruxtecan (DS-8201a) in patients with advanced HER2-positive breast cancer previously treated with trastuzumab emtansine: a dose-expansion, phase 1 study. *Lancet Oncol*. 2019;20(6):816-826.