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Daiichi-Sankyo

Press Release

Data at SABCS and ASH Demonstrate Daiichi Sankyo Commitment to Advancing Science in Breast and Blood Cancer

- Updated DS-8201 data in HER2-positive metastatic breast cancer as well as HER2 low-expressing breast cancer to be highlighted at SABCS
- Preliminary phase 1 data on DS-3201, a dual EZH1/2 inhibitor, in relapsed or refractory non-Hodgkin's lymphomas to be presented at ASH
- Daiichi Sankyo Cancer Enterprise is committed to advancing science to create meaningful treatments for patients with various types of cancer

Basking Ridge, NJ, and Munich – (November 14, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced it will present data on multiple investigational compounds in the Daiichi Sankyo Cancer Enterprise pipeline at the 2017 San Antonio Breast Cancer Symposium (SABCS), San Antonio, from December 5-9, and the 59th Annual Meeting of the American Society of Hematology (ASH), Atlanta, December 9-12.

Updated data from the ongoing phase 1 study of DS-8201, an investigational HER2-targeting antibody drug conjugate (ADC), in HER2-positive metastatic breast cancer as well as patients with HER2 low-expressing breast cancer will be highlighted as a Spotlight Poster Discussion at SABCS.

Data to be presented at ASH comprises multiple abstracts including preliminary phase 1 data on DS-3201, an investigational dual EZH1/2 inhibitor, in relapsed or refractory non-Hodgkin's lymphomas, a bone marrow and peripheral blood concordance analysis for assessing FLT3-ITD mutated acute myeloid leukemia (AML) from screened patients in the global, randomized phase 3 QUANTUM-R study of quizartinib monotherapy versus salvage chemotherapy in relapsed/refractory AML, and preclinical data supporting the potential role of inhibiting MDM2-p53 interaction as a novel therapeutic strategy for hematological malignancies.

"These data reinforce our commitment to advancing science and accelerating development of several compounds for patients suffering from breast or blood cancer," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "We look forward to sharing further insights on our smart chemotherapy ADC platform and its flagship DS-8201 for HER-2 expressing tumors at SABCS as well as presenting preliminary clinical data on DS-3201, our dual EZH1/2 inhibitor, at ASH."

San Antonio Breast Cancer Symposium Presentation

- **Safety and efficacy results from a phase 1 study of DS-8201a in patients with HER2 expressing breast cancers** (Abstract #1094; Spotlight Poster Discussion; Thursday, December, 7, 2017; 7:00 a.m. – 9:00 a.m. CST)

American Society of Hematology Presentations

- **First-in-Human Study of EZH1/2 Dual Inhibitor DS-3201b in Patients with Relapsed or Refractory Non Hodgkin Lymphomas – Preliminary Results** (Abstract #4070; Poster Presentation; Monday, December 11, 2017; 6:00 p.m. – 8:00 p.m. EST)
- **Concordance between Bone Marrow and Peripheral Blood Samples for Assessment of FLT3 Internal Tandem Duplication (ITD) Mutations: Data from Patients Screened for Participation in QuANTUM-R, a Global, Randomized, Open-Label, Phase 3 Study Examining the Effect of Quizartinib Monotherapy Vs Salvage Chemotherapy on Overall Survival in Patients with FLT3-ITD - Mutated AML Who Are Refractory to or Have Relapsed after First-Line Therapy** (Abstract #1424; Poster Presentation; Saturday, December 9, 2017; 5:30 p.m. – 7:30 p.m. EST)
- **Economic Burden of Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) in the US** (Abstract #3386; Poster Presentation; Sunday, December 10, 2017; 6:00 p.m. – 8:00 p.m. EST)
- **A Retrospective Real-World Study of Incident Comorbidities and Complications Among Acute Myeloid Leukemia Patients and Non-Cancer Comparison Patients in the US** (Abstract #3448; Poster Presentation; Sunday, December 10, 2017; 6:00 p.m. – 8:00 p.m. EST)
- **Population Pharmacokinetic and Exposure-Response Modeling for EZH1/2 dual inhibitor DS-3201b in patients with Non-Hodgkin Lymphomas** (Abstract #2544; Poster Presentation; Sunday, December 10, 2017; 6:00 p.m. – 8:00 p.m. EST)
- **Development and Characterization of the Novel Orally Bioavailable EZH1/2 Dual Inhibitor DS-3201** (Abstract #2073; Poster Presentation; Saturday, December 9, 2017; 5:30 p.m. – 7:30 p.m. EST)
- **Novel stem cell-targeted therapy for multiple myeloma based on dual inhibition of EZH1/2** (Abstract #590; Oral Presentation; Monday, December 11, 2017; 7:00 a.m. – 8:30 a.m. EST)
- **EZH1/2, SWI/SNF, and MLL2 Dependent Heterochromatin Formation and Abnormal Transcriptome in Hematological Malignancies** (Abstract #1200; Poster Presentation; Saturday, December, 9, 2017; 5:30 p.m.–7:30 p.m. EST)
- **A p53-MDM2 Interaction Inhibitor, DS-5272, Inhibits the Development of MLL-Fusion Leukemia with the Assistance of Tumor Immunity** (Abstract #796; Oral Presentation; Monday, December 11, 2017; 4:30 p.m. – 6:00 p.m. EST)
- **Activation of p53 Enhances Antileukemia Activity of Bcr-Abl Tyrosine Kinase Inhibitors in a Murine Model of CML** (Abstract #4170; Poster Presentation; Monday, December, 11, 2017; 6:00 p.m. – 8:00 p.m.; EST)

DS-8201, quizartinib, DS-3201 and DS-5272 are investigational agents that have not been approved for any indication in any country. Safety and efficacy of these investigational agents have not been established.

About DS-8201

DS-8201 is the lead product in the 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. 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-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 phase 2 clinical development for HER2-positive unresectable and/or metastatic breast cancer resistant or refractory to T-DM1 (DESTINY-Breast01) 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).

About Quizartinib

The lead product in the AML Franchise of the Daiichi Sankyo Cancer Enterprise, quizartinib is an investigational oral selective FLT3 inhibitor currently in phase 3 development for relapsed or refractory (QuANTUM-R) and newly-diagnosed (QuANTUM-First) AML with FLT3-ITD mutations. Quizartinib has been granted Orphan Drug Designation by the FDA and European Medicines Agency (EMA) for the treatment of AML. Quizartinib also has been granted Fast Track designation by the FDA for the treatment of relapsed or refractory AML.

About DS-3201

Part of the AML Franchise of the Daiichi Sankyo Cancer Enterprise, DS-3201 is the first investigational dual EZH1/2 inhibitor currently in phase 1 clinical development for hematologic cancers including acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL) and non-Hodgkin's lymphoma (NHL).

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.

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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