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Daiichi-Sankyo

Press Release

Daiichi Sankyo Cancer Enterprise Pipeline Data Showing Swift Progress in Precision Medicine for Breast Cancer to be Presented at 2017 American Society of Clinical Oncology (ASCO) Annual Meeting

- Antibody Drug Conjugate (ADC) Franchise presentations include clinical data on smart chemotherapy DS-8201 in HER2-expressing tumors including T-DM1 and pertuzumab pre-treated patients with metastatic breast cancer and clinical trial design of U3-1402 in patients with HER3-expressing metastatic breast cancer
- Additional progress will be reported for key Daiichi Sankyo Cancer Enterprise asset pexidartinib in patients with tenosynovial giant cell tumor (TGCT), which includes pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS)
- Daiichi Sankyo Cancer Enterprise is committed to leveraging world-class, innovative science to create meaningful treatments for patients with cancer

Parsippany, NJ – (May 23, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced new data on several investigational products in the Daiichi Sankyo Cancer Enterprise pipeline will be presented during the 2017 American Society for Clinical Oncology (ASCO) Annual Meeting from June 2-6 in Chicago.

Breast cancer precision medicine research on the two lead smart chemotherapy products in the company's Antibody Drug Conjugate (ADC) Franchise, DS-8201 in HER2-expressing tumors and U3-1402 in HER3-expressing tumors, will be shared. New clinical data from the dose expansion study of DS-8201 in ado-trastuzumab emtansine (T-DM1) and pertuzumab pre-treated HER2-positive metastatic breast cancer and other solid HER2-expressing tumors including gastric cancer will be featured in an oral presentation as part of a Clinical Science Symposium.

Poster presentations also will highlight preclinical data examining the role of DS-8201 in combination with immunotherapy, the study design of the phase 1 study of U3-1402 in patients with HER3-expressing metastatic breast cancer and patient-reported outcomes in a phase 1 study of pexidartinib in tenosynovial giant cell tumor (TGCT), which includes pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS).

"These presentations continue to underscore the promise of DS-8201 and U3-1402, which employ our unique ADC technology, to potentially change the standard of care in both HER2-expressing and HER3-expressing metastatic breast cancer," said Antoine Yver, MD, MSc, Executive Vice President and Global Head,

Oncology Research and Development, Daiichi Sankyo. “In the context of recent advances made in the field of molecularly targeted new science for breast cancer, our own research further contributes to providing advanced or metastatic breast cancer with precision medicine options.”

ADC Franchise Presentations

- **Abstract 108: Single agent activity of DS-8201a, a HER2-targeting antibody-drug conjugate, in heavily pretreated HER2 expressing solid tumors** (Clinical Science Symposium: Hitting the Target: Antibody-Drug Conjugates; Monday, June 5, 2017; 9:45 a.m. – 11:15 a.m. CT; Location: Hall D1)
- **Abstract 1031: DS-8201a, a HER2-targeting antibody-drug conjugate, to elicit immune responses and benefits in combination with an anti-PD-1 antibody** (Poster Presentation, Poster Board: #23, Session: Breast Cancer – Metastatic, Sunday, June 4, 2017; 8:00 a.m. – 11:30 a.m. CT; Location: Hall A)
- **Abstract TPS1116: Phase 1/2, multicenter, non-randomized, open-label, multiple-dose first-in-human study of U3-1402 (anti-HER3 antibody drug conjugate) in subjects with HER3-positive metastatic breast cancer** (Poster Presentation, Poster Board: #103a, Session: Breast Cancer – Metastatic, Sunday, June 4, 2017; 8:00 a.m. – 11:30 a.m. CT; Location: Hall A)

Late Stage Program Presentations

- **Abstract 11048: Tumor volume score (TVS), modified RECIST, and tissue damage score (TDS) as novel methods for assessing response in tenosynovial giant cell tumors (TGCT) treated with pexidartinib: Relationship with patient-reported outcomes (PROs)** (Poster Presentation, Poster Board: #371, Session: Sarcoma, Sunday, June 4, 2017; 8:00 a.m. – 11:30 a.m. CT; Location: Hall A)
- **Abstract 10546: Phase I study of pexidartinib (PLX3397) in children with refractory leukemias and solid tumors including neurofibromatosis type I (NF1) related plexiform neurofibromas (PN)** (Poster Presentation, Poster Board: #303, Session: Pediatric Oncology, Sunday, June 4, 2017; 8:00 a.m. – 11:30 a.m. CT; Location: Hall A)
- **Abstract 4000: Second-line tivantinib (ARQ 197) vs placebo in patients (Pts) with MET-high hepatocellular carcinoma (HCC): Results of the METIV-HCC phase III trial** (Oral Presentation, Session: Gastrointestinal (Noncolorectal) Cancer, Sunday, June 4, 2017; 8:00 a.m. – 11:00 a.m. CT; Location: Hall D2)

DS-8201, U3-1402, pexidartinib and tivantinib have not been approved for any indication in any country.

About DS-8201 and U3-1402

Antibody drug conjugates (ADCs) are a type of targeted cancer medicine that deliver cytotoxic chemotherapy ("payload") directly to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. DS-8201 and U3-1402 are ADCs that use Daiichi Sankyo's proprietary payload and linker-payload technology, which has broad application across multiple types of cancer, and are designed to deliver enhanced cancer cell destruction with less systemic exposure to the cytotoxic payload.

DS-8201 is an investigational ADC currently in phase 1 clinical development for HER2-positive advanced or metastatic breast cancer or gastric cancer, HER2-low-expressing breast cancer and other HER2-expressing solid cancers. The U.S. Food and Drug Administration (FDA) granted Fast Track designation to DS-8201 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 ado-trastuzumab emtansine (T-DM1).

U3-1402 is an investigational and potential first-in-class ADC currently in phase 1 clinical development for HER3-expressing metastatic or unresectable breast cancer.

About Pexidartinib

Pexidartinib is an investigational, novel, oral small molecule that potently inhibits CSF-1R (colony stimulating factor-1 receptor), which is a primary growth driver of abnormal cells in the synovium that cause TGCT. Pexidartinib was discovered by Plexxikon Inc., the small molecule structure-guided R&D center of Daiichi Sankyo.

Pexidartinib has been granted Breakthrough Therapy Designation for the treatment of TGCT and Orphan Drug Designation for PVNS/GCT-TS by the U.S. Food and Drug Administration (FDA). Pexidartinib also has received Orphan Designation from the European Commission for the treatment of TGCT.

Pexidartinib is also being evaluated in several additional potential clinical indications, including glioblastoma, melanoma, ovarian, colorectal and pancreatic cancer. It is also being investigated in combination with anti-PD-1 immunotherapy, pembrolizumab, for multiple tumor types, including melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, ovarian cancer and gastrointestinal stromal tumors.

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/refractory AML with FLT3-ITD mutations; DS-8201, an ADC for HER2-expressing breast cancer, 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 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 a 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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