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Daiichi-Sankyo

Press Release

Daiichi Sankyo Showcases New Insights on Multiple Oncology Compounds at the European Society for Medical Oncology (ESMO) 2017 Congress

- Presentation to highlight DS-8201 data in subgroup of patients with HER2-expressing solid tumors including colon cancer, non-small cell lung cancer and salivary gland cancer
- Non-small cell lung cancer preclinical data with AXL inhibitor DS-1205 to be highlighted
- QuANTUM-First trial of quizartinib for newly-diagnosed acute myeloid leukemia (AML) with FLT3-ITD mutations phase 3 clinical trial design to be presented
- Daiichi Sankyo Cancer Enterprise is driving innovation to advance treatment options across various types of cancer

Basking Ridge, NJ, and Munich, Germany – (August 31, 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 European Society for Medical Oncology (ESMO) 2017 Congress from September 8-12 in Madrid, Spain.

Poster presentations will highlight additional phase 1 results evaluating DS-8201 in patients with HER2-expressing metastatic non-breast and non-gastric solid tumors including colon, non-small cell lung and salivary gland cancer as well as the study design of the global phase 3 QuANTUM-First trial, assessing quizartinib in patients with newly-diagnosed acute myeloid leukemia (AML) with FLT3-ITD mutations. Preclinical data examining the antitumor activity of AXL inhibitor DS-1205 in EGFR-mutant non-small cell lung cancer also will be presented in a poster.

“We look forward to presenting additional preliminary results of DS-8201 in patients with several different HER2-expressing tumors to the scientific community at ESMO,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “We also will share information about our second ongoing pivotal study of quizartinib, QuANTUM-First, which demonstrates our commitment to addressing the significant unmet need in the treatment of patients with AML with FLT3-ITD mutations.”

The following data from the pipeline of the Daiichi Sankyo Cancer Enterprise, including flagship assets DS-8201 from the ADC Franchise and quizartinib from the AML Franchise, will be presented:

- **Updated results of phase 1 study of DS-8201a in patients with HER2 expressing non-breast, non-gastric malignancies** (Poster Display session, Monday, September 11, 2017; 1:15 p.m. – 2:15 p.m. CEST; Location: Hall 8; Poster Board #409P)

- **QuANTUM-First: phase 3, double-blind, placebo-controlled study of quizartinib in combination with induction and consolidation chemotherapy, and as maintenance therapy in patients (pts) with newly diagnosed (NDx) FLT3-ITD acute myeloid leukemia (AML)** (Poster Display session, Saturday, September 9, 2017; 1:15 p.m.– 2:15 p.m. CEST; Location: Hall 8; Poster Board #1040TiP)
- **DS-1205b, a novel, selective, small-molecule inhibitor of AXL, delays the onset of resistance and overcomes acquired resistance to EGFR-TKIs in a human EGFR-mutant NSCLC (T790M-negative) xenograft model** (Poster Display Session, Monday, September 11, 2017; 1:15 p.m. – 2:15 p.m. CEST; Location: Hall 8; Poster Board #395P)
- **Safety and clinical activity of DS-6051b, a ROS1/NTRK inhibitor, in Japanese patients with NSCLC harboring ROS1 fusion gene** (Poster Display session, Saturday, September 9, 2017; 1:15 p.m. – 2:15 p.m. CEST; Location: Hall 8; Poster Board #1362P)

Quizartinib, DS-8201, DS-1205 and DS-6051 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, and there is no guarantee that quizartinib, DS-8201, DS-1205 and DS-6051 will become commercially available.

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 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.

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-1205 and DS-6051

DS-1205 is an investigational AXL inhibitor currently in preclinical development for metastatic or unresectable epidermal growth factor mutant (EGFRm) non-small cell lung cancer (NSCLC). DS-6051 is an investigational NTRK/ROS1 inhibitor currently in phase 1 development for non-small cell lung cancer (NSCLC) and other solid 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 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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