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Daiichi-Sankyo

Press Release

Daiichi Sankyo to Present New Data on Multiple Compounds Including Antibody Drug Conjugates DS-8201 and U3-1402 at 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

- Updated results from the large ongoing phase 1 study of DS-8201, an investigational HER2-targeting antibody drug conjugate (ADC), in metastatic breast cancer, gastric cancer and other tumors with HER2 as cell surface target to be reported
- First-in-human clinical data from phase 1 study of U3-1402, an investigational and potential first-in-class HER3-targeting ADC, in metastatic breast cancer with HER3 as cell surface target to be presented
- Results from the pivotal phase 3 ENLIVEN study of pexidartinib, the first placebo-controlled trial of a systemic therapy in tenosynovial giant cell tumor (TGCT), to be unveiled
- Data presentations highlight substantial progress of oncology pipeline of Daiichi Sankyo, demonstrating its commitment to translating innovative science into potential new precision medicines for patients with cancer

Basking Ridge, NJ, and Munich – (May 16, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it will present new data for multiple investigational compounds in the Daiichi Sankyo Cancer Enterprise pipeline at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting from June 1-5 in Chicago. Key highlights include new results from ongoing phase 1 studies of antibody drug conjugates, DS-8201 and U3-1402, in breast cancer and other tumors, as well as results from the pivotal, phase 3 ENLIVEN study of pexidartinib in tenosynovial giant cell tumor (TGCT), also known as giant cell tumor of the tendon sheath (GCT-TS) and previously referred to as pigmented villonodular synovitis (PVNS), a rare and debilitating tumor of the joint or tendon sheath.

"We are excited to reveal updated results of DS-8201 in patients with heavily pre-treated solid tumors with HER2 as the cell surface target, as well as initial proof-of-concept results for U3-1402, our second smart chemotherapy in development that utilizes our proprietary DXd ADC technology, in HER3 breast cancer," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "We also will be presenting the pivotal results of pexidartinib, the first systemic therapy examined in a phase 3 study of carefully monitored patients with TGCT, a debilitating and difficult-to-manage non-malignant tumor with treatment options largely limited to surgery. This wealth of data and development candidates showcases our commitment to aligning innovative science with well-characterized disease biology to rapidly develop therapies for patients with cancer."

The following data from the pipeline of Daiichi Sankyo Cancer Enterprise will be presented:

Investigational ADC Franchise Presentations

- **Trastuzumab deruxtecan (DS-8201a) in subjects with HER2-expressing solid tumors: Long-term results of a large phase 1 study with multiple expansion cohorts.** (Abstract 2501; Oral Presentation; Friday, June 1 at 2:57 – 3:09 PM CDT)
- **A phase 2, multicenter, open-label study of trastuzumab deruxtecan (DS-8201a) in subjects with HER2-positive, unresectable and/or metastatic breast cancer previously treated with T-DM1.** (Abstract TPS1102; Poster Session; Saturday, June 2 at 8:00 – 11:30 AM CDT)
- **A randomized phase 2, multicenter, open-label study of trastuzumab deruxtecan (DS-8201a) in subjects with HER2-expressing gastric cancer.** (Abstract TPS4133; Poster Session; Sunday, June 3 at 8:00 – 11:30 AM CDT)
- **Single agent activity of U3-1402, a HER3-targeting antibody-drug conjugate, in breast cancer patients: phase 1 dose escalation study.** (Abstract 2512; Poster Discussion Session; Monday, June 4 at 3:00 – 4:15 PM CDT)
- **Phase 1 study of the anti-HER3 antibody drug conjugate U3-1402 in metastatic or unresectable EGFR-mutant NSCLC.** (Abstract TPS9110; Poster Session; Sunday, June 3 at 8:00 – 11:30 AM CDT)
- **First-in-human phase 1 study of DS-1062a in patients (pts) with advanced solid tumors (AST).** (Abstract TPS2605; Poster Session; Monday, June 4 at 8:00 – 11:30 AM CDT)

Investigational Breakthrough Science Presentations

- **Final results of ENLIVEN: a global, double-blind, randomized, placebo-controlled, phase 3 study of pexidartinib in advanced tenosynovial giant cell tumor (TGCT).** (Abstract 11502; Oral Presentation; Monday, June 4 at 8:24 – 8:36 AM CDT)
- **Treatment patterns of tenosynovial giant cell tumor among commercially insured patients: a retrospective claims analysis.** (Abstract e18737; Publication Only)
- **Phase 1b/2 study of pexidartinib (PEX) in combination with radiation therapy (XRT) and temozolomide (TMZ) in newly diagnosed glioblastoma** (Abstract 2015; Poster Discussion Session; Saturday, June 2 at 4:45 – 6:00 PM CDT)
- **A phase 1 pharmacokinetic (PK) and pharmacodynamics (PD) study of PLX9486 alone and in combination (combo) with the KIT inhibitors pexidartinib (pexi) or sunitinib (su) in patients (pts) with advanced solid tumors and gastrointestinal stromal tumor (GIST).** (Abstract 11509; Poster Discussion Session; Saturday, June 2 at 3:00 – 4:15 PM CDT).
- **Phase 1/2 precision medicine study of next-generation BRAF inhibitor PLX8394.** (Abstract 2583; Poster Session; Monday, June 4 at 8:00 – 11:30 AM CDT).
- **Randomized phase 2 trial of patritumab (P) or placebo (PBO) + cetuximab (C) + cisplatin (CIS) or carboplatin (CAR) for recurrent and/or metastatic (R/M) squamous cell carcinoma of the**

head and neck (SCCHN). (Abstract 6045; Poster Session; Saturday, June 2 at 1:15 – 4:45 PM CDT)

- **The use of exosome and immune profiling to analyze a phase 2 study on the addition of patritumab or placebo to cetuximab and a platinum agent for recurrent/metastatic head and neck cancer (R/M HNSCC) patients.** (Abstract 6043; Poster Session; Saturday, June 2 at 1:15 – 4:45 PM CDT)
- **First-in-human study of DS-6051b in patients (pts) with advanced solid tumors (AST) conducted in the US.** (Abstract 2514; Poster Discussion Session; Monday, June 4 at 3:00 – 4:15 PM CDT)

Investigational AML Franchise Presentations

- **Post hoc exploratory analysis of two phase 2 trials of quizartinib monotherapy in patients (pts) with *FLT3*-ITD–mutated (mu) relapsed/refractory (R/R) AML with or without prior 1st-generation FLT3 tyrosine kinase inhibitors (TKI) treatment.** (Abstract 7017; Poster Discussion Session; Monday, June 4 at 11:30 – 12:45 PM CDT)
- **A phase 1 study of the MDM2 inhibitor DS-3032b in patients with well/de-differentiated liposarcoma (WD/DD LPS), solid tumors (ST) and lymphomas (L).** (Abstract 11514; Poster Discussion Session; Saturday, June 2 at 3:00 – 4:15 PM CDT)
- **Phase ib/2a study of PLX51107, a small molecule BET inhibitor, in subjects with advanced hematological malignancies and solid tumors.** (Abstract 2550; Poster Session; Monday, June 4 at 8:00 – 11:30 AM CDT).
- **A retrospective study of comorbidities and complications in elderly acute myeloid leukemia (AML) patients in the U.S.** (Abstract 7032; Poster Presentation; Monday, June 4 at 8:00 – 11:30 AM CDT)
- **Impact of remission and stem cell transplant (SCT) on survival outcomes in elderly relapsed acute myeloid leukemia (rAML) patients: U.S. cancer registry experience.** (Abstract e19002; Publication Only)

These 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 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, 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. Compounds in pivotal stage development include: DS-8201, an antibody drug conjugate (ADC) for HER2-expressing breast, gastric and other cancers; quizartinib, an oral selective FLT3 inhibitor, for newly-diagnosed and relapsed/refractory acute myeloid leukemia (AML) with *FLT3*-ITD mutations; and pexidartinib, an oral CSF1R inhibitor, for tenosynovial giant cell tumor (TGCT). 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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