Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

Daiichi Sankyo Data Presentations at 2019 ASCO Annual Meeting Highlight Depth of ADC Pipeline and Promises of Oncology Portfolio

- First-in-human data with DS-1062, a TROP2 targeting antibody drug conjugate, in patients with advanced non-small cell lung cancer to be unveiled
- First phase 1 results for U3-1402, a HER3 targeting ADC, in EGFR mutated, TKI resistant metastatic non-small cell lung cancer to be reported
- Long-term treatment data for pexidartinib in tenosynovial giant cell tumor and first-in-human data for DS-1001 in IDH1 mutant gliomas also to be presented
- ASCO presentations highlight depth of ADC pipeline and steady advancement across the Daiichi Sankyo oncology portfolio

Tokyo, Munich and Basking Ridge, NJ – (May 15, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it will present new data for several investigational compounds in the Daiichi Sankyo oncology pipeline at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting to be held May 31 to June 4 in Chicago.

Highlights include new data for two investigational antibody drug conjugates (ADCs) being evaluated in patients with non-small cell lung cancer (NSCLC), including first-in-human results for DS-1062, a TROP2 targeting ADC in advanced NSCLC, and the first phase 1 results for U3-1402, a HER3 targeting ADC, in EGFR mutated, TKI resistant metastatic NSCLC.

“We look forward to showcasing the broad applicability of our proprietary DXd ADC technology with initial results for DS-1062, our third ADC, which we designed to target TROP2 in lung and other cancers, and for U3-1402, which is being studied in lung and breast cancers,” said Antoine Yver, MD, MSc, EVP and Global Head, Oncology Research and Development, Daiichi Sankyo. “The ASCO meeting presentations demonstrate the depth of our ADC pipeline beyond [fam-] trastuzumab deruxtecan (DS-8201), as well as the breadth of opportunities across our portfolio to translate our innovative science into potential new targeted cancer therapies.”

Both DS-1062 and U3-1402 are designed using Daiichi Sankyo’s proprietary DXd ADC technology, which consists of a humanized monoclonal antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker. The ADCs were constructed to target and deliver chemotherapy inside cancer cells that express a specific cell surface antigen.

Additional data to be reported at ASCO includes a pooled analysis of long-term treatment data from the phase 3 ENLIVEN and phase 1 extension study of pexidartinib in tenosynovial giant cell tumor (TGCT) and first-in-human phase 1 results with DS-1001 in patients with IDH1 mutant gliomas. An overview of data from the Daiichi Sankyo oncology pipeline to be presented includes:

- **First-in-human phase 1 study of DS-1062a in patients with advanced solid tumors** (Abstract 9051. Poster Session: Lung Cancer – Non-Small Cell Metastatic. Sunday, June 2, 8:00 - 11:00 AM CDT)
- **Safety and preliminary antitumor activity of U3-1402: A HER3-targeted antibody drug conjugate in EGFR TKI-resistant, EGFRm NSCLC** (Abstract 9010. Clinical Science Symposium: EGFR and ROS1: Targeting Resistance. Lung Cancer – Non-Small Cell Metastatic. Friday, May 31, 1:00 - 2:30 PM CDT)
- **A phase III, multicenter, randomized, open label trial of [fam-] trastuzumab deruxtecan (DS-8201a) versus investigator's choice in HER2-low breast cancer** (Abstract TPS1102. Poster Session: Breast Cancer – Metastatic. Sunday, June 2, 8:00 - 11:00 AM CDT)
- **Phase 1 study of a brain penetrant mutant IDH1 inhibitor DS-1001b in patients with recurrent or progressive IDH1 mutant gliomas** (Abstract 2004. Oral Abstract Session: Central Nervous System Tumors. Monday, June 3, 1:15 - 4:15 PM CDT)
- **Pexidartinib for advanced tenosynovial giant cell tumor (TGCT): Long-term efficacy and safety from the phase 3 ENLIVEN and phase 1 PLX108-01 (TGCT cohort) studies** (Abstract 11042. Poster Session: Sarcoma. Saturday, June 1, 8:00 - 11:00 AM CDT)
- **Responder analysis of Patient-Reported outcomes Measurement Information System (PROMIS) physical function (PF) and worst stiffness among patients with tenosynovial giant cell tumors (TGCT) in the ENLIVEN study** (Abstract e18236; Publication Only)
- **Work productivity loss in patients with Tenosynovial Giant Cell Tumors (TGCT) in the United States** (Abstract e22527; Publication Only)
- **A phase 1 study of milademetan in combination with quizartinib in patients with newly diagnosed or relapsed/refractory *FLT3*-ITD acute myeloid leukemia (AML)** (Abstract TPS7067. Poster Session: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allotransplant. Monday, June 3, 8:00 - 11:00 AM CDT)

These 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, 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: [fam-] trastuzumab deruxtecan, 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 *FLT3*-ITD acute myeloid leukemia (AML); 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.

Contact

Jennifer Brennan
Daiichi Sankyo, Inc.
jbrennan2@dsi.com
+1 908 992 6631 (office)
+1 201 709 9309 (mobile)

Kim Wix
Daiichi Sankyo, Inc.
kwix@dsi.com
+1 908 992 6633 (office)
+1 908 656 5447 (mobile)