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Press Release

U.S. FDA Grants Fast Track Designation for HER2-Targeting Antibody Drug Conjugate DS-8201 for HER2-Positive Metastatic Breast Cancer

- Novel antibody drug conjugate with proprietary payload and linker-payload technology currently in phase 1 development for the treatment of HER2-positive metastatic breast cancer for patients who progress after prior HER2-targeting therapies including T-DM1
- Second Fast Track designation granted to Daiichi Sankyo Cancer Enterprise investigational compound
- Highlights company commitment to transform science to create treatments for cancer patients that address an unmet medical need

Tokyo, Japan, and Parsippany, N.J. – (December 1, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its investigational HER2-targeting antibody drug conjugate 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).

Fast Track designation is designed to facilitate the development and expedite the review of drugs that treat serious conditions and address an unmet medical need. The designation enables early and frequent communication with the FDA and is intended to accelerate drug approval and patient access to novel treatment options.

"This is an important milestone for DS-8201 that underscores the critical need to develop new and effective therapeutic options for patients with metastatic breast cancer whose tumors are no longer controlled by currently approved targeted HER2 treatments," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "It's our obligation to drive science forward to help bring innovative treatment options to cancer patients with the greatest unmet needs and we look forward to working closely with the FDA to optimize development of DS-8201."

Fast Track designation was granted based on results from the dose escalation part of a two-part phase 1 study that assessed the safety, tolerability and preliminary efficacy of DS-8201. These results were recently presented during a late-breaking poster discussion at the European Society for Medical Oncology (ESMO) 2016 Congress and further highlighted in the concluding summary session.[1]

The second part (dose expansion) of the ongoing phase 1 study is enrolling patients in Japan and the United States to evaluate the safety and efficacy of DS-8201 in four different cohorts of HER2 expressing cancers: patients with HER2+ metastatic breast cancer previously treated with T-DM1; patients with HER2+ gastric or gastroesophageal junction adenocarcinoma previously treated with trastuzumab; patients with HER2 low expressing breast cancer; and patients with other solid cancers that express HER2. For more information about the study visit ClinicalTrials.gov.

About DS-8201

DS-8201 is an investigational HER2-targeting antibody drug conjugate (ADC) currently in phase 1 clinical development for HER2+ advanced or metastatic breast cancer or gastric cancer, HER2 low expressing breast cancer and other HER2 expressing solid cancers.

DS-8201 is comprised of a humanized anti-HER2 antibody attached by a peptide linker to a novel topoisomerase I inhibitor that utilizes Daiichi Sankyo's proprietary linker-payload technology, offering a unique mechanism of action.[2] This linker-payload combination of DS-8201 allows for a higher drug-to-antibody ratio (DAR) of about 8, which may help target low expressing HER2 tumors by supplying more payload per antibody to a tumor.[2]

About HER2+ Metastatic Breast Cancer

Human epidermal growth factor receptor 2 (known as HER2) is a tyrosine kinase receptor growth-promoting protein found on the surface of some cancer cells.[3] About one in five breast cancers overexpress the *HER2/neu* gene, which causes these cancers to grow more aggressively.[3] Several unmet needs remain today in HER2+ metastatic breast cancer. Many tumors advance to the point where no currently approved HER2-targeted treatment continues to control the disease.[4] Additionally, there are no existing options indicated for HER2 low expressing tumors (IHC2+/FISH- or IHC1+), which generally have poor prognosis.[2,5]

About Daiichi Sankyo Cancer Enterprise

The vision of Daiichi Sankyo Cancer Enterprise is to push beyond traditional thinking to align world-class science to create innovative treatments for patients with cancer. The oncology pipeline of Daiichi Sankyo continues to grow and currently includes more than 20 small molecules, monoclonal antibodies and antibody drug conjugates with novel targets in both solid and hematological cancers. Compounds in development include: quizartinib, an oral FLT3 inhibitor, for newly-diagnosed and relapsed/ refractory FLT3-ITD+ acute myeloid leukemia (AML); pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS), which also is being investigated in combination with anti-PD1 immunotherapy, pembrolizumab, in a range of solid tumors; tivantinib, an oral MET inhibitor, for second-line treatment of patients with MET-high hepatocellular carcinoma in partnership with ArQule,

Inc.; and DS-8201, a HER2 targeting antibody drug conjugate, for HER2-expressing breast or gastric cancer or other HER2-expressing solid tumors.

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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