

Press Release

Daiichi Sankyo Announces Clinical Research Collaboration to Evaluate DS-8201 in Combination with KEYTRUDA® (pembrolizumab) in HER2 Expressing Breast and HER2 Expressing or HER2 Mutant Lung Cancers

Tokyo and Basking Ridge, NJ – (September 20, 2018) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that it has entered into a clinical trial collaboration agreement with a subsidiary of Merck & Co., Inc., Kenilworth, New Jersey, U.S.A., known as MSD outside the United States and Canada, to evaluate the combination of Daiichi Sankyo’s investigational HER2 targeting antibody drug conjugate DS-8201 and KEYTRUDA® (pembrolizumab) in HER2 expressing advanced/metastatic breast and HER2 expressing or HER2 mutant non-small cell lung cancers (NSCLC).

“We are excited to pursue this opportunity to evaluate the safety, tolerability and activity of DS-8201 in combination with KEYTRUDA and whether this combination may provide a potential new treatment approach for patients with HER2 expressing advanced breast and non-small cell lung cancer,” said Tom Held, Vice President, Head, Antibody Drug Conjugate Task Force, Oncology Research and Development, Daiichi Sankyo. “Strategic collaborations like this support our goal to pursue, investigate and maximize the application of DS-8201 in combination with other compounds that target different pathways to address unmet needs of patients with cancer.”

About the Study

Under the terms of the agreement, Daiichi Sankyo will conduct a two-part phase 1b multicenter, open-label study to:

- Determine the safety, tolerability and dose of DS-8201 in combination with KEYTRUDA and evaluate efficacy of the combination in patients with HER2 expressing advanced/metastatic breast cancer and patients with HER2 expressing or HER2 mutant advanced/metastatic NSCLC.
- Enroll patients into one of four cohorts: patients with HER2 positive advanced breast cancer who have been previously treated with ado-trastuzumab emtansine (T-DM1) (cohort 1); patients with HER2 low expressing advanced breast cancer (IHC 1+ or IHC 2+/ISH-) who have received available standard of care (cohort 2); patients with HER2 expressing advanced NSCLC (IHC 1+, 2+, or 3+) who have not received prior treatment with anti-PD-1 or anti-PD-L1 agents (cohort 3); and patients with HER2 mutant advanced NSCLC who have not received prior treatment with anti-PD-1 or anti-PD-L1 agents (cohort 4).

The primary endpoints of the study are maximum tolerated dose/recommended expansion dose and overall response rate. Secondary endpoints include duration of response, disease control rate, progression-free survival, overall survival, time to response and safety. The study is expected to enroll approximately 125 patients in the U.S. and Europe. Additional details of the agreement were not disclosed.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About DS-8201

DS-8201 is the lead product in the investigational ADC Franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are targeted cancer medicines 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. Designed using Daiichi Sankyo’s proprietary ADC technology, DS-8201 is comprised of a humanized HER2 antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker. It is designed to target and deliver chemotherapy inside cancer cells and reduce systemic exposure to the cytotoxic payload (or chemotherapy) compared to the way chemotherapy is commonly delivered.

DS-8201 is currently in pivotal phase 2 clinical development for HER2 positive unresectable and/or metastatic breast cancer resistant or refractory to T-DM1 ([DESTINY-Breast01](#)) in North America, Europe and Asia; pivotal phase 2 development for HER2 positive advanced gastric cancer resistant or refractory to trastuzumab ([DESTINY-Gastric01](#)) in Japan and South Korea; phase 2 development for HER2 expressing advanced colorectal cancer in North America, Europe and Japan; phase 2 development for unresectable and/or metastatic non-squamous HER2 overexpressing or HER2 mutated non-small cell lung cancer (NSCLC) in North America, Europe and Japan; and phase 1 development for other HER2 expressing advanced/unresectable or metastatic solid tumors in the U.S. and Japan.

DS-8201 has been granted Breakthrough Therapy designation 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 by the U.S. Food and Drug Administration. DS-8201 has also been granted SAKIGAKE Designation by the Japan Ministry of Health, Labour and Welfare for the treatment of HER2 positive advanced gastric or gastroesophageal junction cancer.

DS-8201 is an investigational agent that has 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: 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 *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. 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.

Contact

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