Press Release

Daiichi Sankyo Initiates Clinical Development of Sixth DXd ADC DS-6000 with Sarah Cannon Research Institute

Tokyo, Munich and Basking Ridge, NJ and Nashville, Tenn. – **(February 2, 2021)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and Sarah Cannon Research Institute (Sarah Cannon) announced today that the first patient has been dosed in the first-in-human phase 1 study evaluating DS-6000, a CDH6 directed antibody drug conjugate (ADC), in patients with advanced renal cell carcinoma or ovarian cancer with disease progression following standard treatment.

Despite recent advances in targeted treatment, five-year survival rates for both renal cell carcinoma and ovarian cancer remain low and new therapeutic strategies are needed for tumors that continue to progress on currently available medicines.[1,2] CDH6 is a cadherin family protein overexpressed in several cancers, particularly renal cell and ovarian.[3] CDH6 overexpression is associated with tumor growth and proliferation and has been correlated with poor prognosis in renal cell carcinoma.[4] No CDH6 directed cancer therapies are currently approved.

"With DS-6000, we have applied our innovative DXd ADC technology to a promising molecular target, CDH6, and it has potential to serve as a new treatment modality for patients with renal cell or ovarian cancer," said Arnaud Lesegretain, Vice President Oncology R&D and Head, Alpha Portfolio, Daiichi Sankyo. "We are pleased to continue our successful collaboration with Sarah Cannon, working together on advancing the development of another novel ADC with first-in-class potential."

DS-6000 is the sixth DXd ADC from the oncology pipeline of Daiichi Sankyo to enter clinical development and the third being developed in collaboration with Sarah Cannon Research Institute.

"We look forward to developing DS-6000 as a potential treatment option for people facing renal cell carcinoma or ovarian cancer," says Erika Hamilton, MD, Director, Breast Cancer and Gynecologic Cancer Research Program, Sarah Cannon Research Institute at Tennessee Oncology. "In partnership with Daiichi Sankyo, we will further evaluate whether DS-6000 may serve as a new and effective therapy for patients who have progressed on standard treatments."

About the Study

The two-part, multicenter, open-label, first-in-human phase 1 trial will evaluate the safety and efficacy of DS-6000 in adult patients with advanced renal cell carcinoma or ovarian cancer resistant or refractory to standard of care therapy.

The first part of the study (dose escalation) will assess the safety and tolerability of increasing doses of DS-6000 to determine the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE) in approximately 46 patients with advanced renal cell carcinoma or ovarian tumors. The second part of the study (dose expansion) will further evaluate the safety and efficacy of DS-6000 at the RDE in two cohorts including approximately 30 patients with advanced renal cell carcinoma in cohort 1 and 25 patients with advanced ovarian cancer in cohort 2.

The study will evaluate safety endpoints including dose-limiting toxicities and adverse events and efficacy endpoints including overall response rate, duration of response, disease control rate, clinical benefit rate, time to response and progression-free survival. Pharmacokinetic and exploratory biomarker endpoints will also be assessed.

A total of approximately 102 patients are expected to be enrolled in this study at multiple sites in the U.S. For more information, please visit Clinicaltrials.gov.

About Renal Cell Carcinoma and Ovarian Cancer

Renal cell carcinoma accounts for 90 percent of all kidney cancer.[5] There were approximately 431,000 new cases of kidney cancer and over 179,000 deaths reported worldwide in 2020.[6] Ovarian cancer is one of the three most common gynecological malignancies.[7] There were approximately 313,000 new cases of ovarian cancer and over 207,000 deaths reported worldwide in 2020.[8] The five-year survival rate is 13 percent and 30 percent, respectively, for patients diagnosed with metastatic renal cell carcinoma and ovarian cancer.[9,10]

About DS-6000

DS-6000 is a potential first-in-class CDH6 directed antibody drug conjugate (ADC). Designed using Daiichi Sankyo's proprietary DXd ADC technology, DS-6000 is the sixth ADC in the Daiichi Sankyo oncology pipeline to enter clinical development.

DS-6000 is comprised of a humanized anti-CDH6 IgG1 monoclonal antibody attached to a topoisomerase I inhibitor payload, an exatecan derivative, via a tetrapeptide-based cleavable linker. Preclinical research shows that DS-6000 binds to CDH6 on the surface of cancer cells, and it is proposed that DS-6000 is then

brought inside the cell where lysosomal enzymes break down the linker and release the DXd payload to destroy the cell. In preclinical studies, DS-6000 inhibited tumor growth and induced tumor regression in CDH6 expressing renal cell and ovarian tumors.

DS-6000 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 our DXd antibody drug conjugate (ADC) technology, our powerful research engines include biologics, medicinal chemistry, modality and other research laboratories in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. For more information, please visit: www.DSCancerEnterprise.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 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 cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

About Sarah Cannon Research Institute

Sarah Cannon Research Institute is the research arm of HCA Healthcare's Cancer Institute, Sarah Cannon. Focused on advancing therapies for patients, it is one of the world's leading clinical research organizations conducting community-based clinical trials throughout the United States and United Kingdom. A leader in drug development, Sarah Cannon has led more than 450 first-in-human clinical trials since its inception in 1993, and has been a clinical trial leader in the majority of approved cancer therapies over the last 10 years. Additionally, Sarah Cannon offers management, regulatory, and other research support services for drug development and industry sponsors as well as strategic investigator sites through its contract research organization (CRO), Sarah Cannon Development Innovations.

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