Press Release

Daiichi Sankyo and Gustave Roussy Enter Innovative Research Collaboration for DXd ADCs DS-1062 and Patritumab Deruxtecan

- Multi-year, multi-study collaboration includes two adaptive phase 2 trials with DS-1062 in lung cancer and patritumab deruxtecan (U3-1402) in breast cancer
- Program to focus on clinical and precision medicine research and potential combination strategies

Tokyo, Basking Ridge, N.J., Munich and Villejuif – (**July 22, 2020**) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and Gustave Roussy today announced a multi-year, multi-study research collaboration to enrich and further enable the development of DS-1062 and patritumab deruxtecan (U3-1402), two of Daiichi Sankyo's lead DXd antibody drug conjugates (ADCs), in lung and breast cancer.

The collaboration will focus on clinical and translational research, including potential combination strategies for DS-1062, a TROP2 directed DXd ADC, in patients with advanced non-small cell lung cancer (NSCLC), and for patritumab deruxtecan, a HER3 directed DXd ADC, in patients with metastatic breast cancer.

"We look forward to engaging and collaborating with the deep expertise and cutting-edge oncology research capabilities of Gustave Roussy, the premier European Cancer Center, to further advance clinical development of DS-1062 and patritumab deruxtecan," said Antoine Yver, MD, MSc, AIHP, ACCA Paris, Global Head, Oncology R&D, Daiichi Sankyo. "This innovative research program includes two precision-medicine rich phase 2 trials designed with an adaptive approach to help determine which patients are most likely to benefit from our ADCs with optimal speed and efficiency. Combination therapy strategies will also be explored in other studies."

"This partnership is strategic for Gustave Roussy and it brings together all the skills which are essential for top quality research in oncology. Launching clinical trials to test two promising molecules in advanced non-small cell lung cancer and metastatic breast cancer is essential for diseases which unfortunately have an increasing incidence and for which there is an urgent need to make progress," said Prof. Jean-Charles Soria, General Director of Gustave Roussy. "It is by pushing the boundaries of innovation that we will further improve the quality of care for our patients."

About the Collaboration

Under the agreement, Daiichi Sankyo, Inc. will provide funding and support to Gustave Roussy for a comprehensive, integrative research program including clinical, translational and preclinical studies for DS-1062 and patritumab deruxtecan in lung and breast cancer, respectively.

Two adaptive phase 2 trials will be conducted, including a multicenter, open-label study to evaluate efficacy, safety and markers of response and resistance to DS-1062 in patients with advanced NSCLC who have progressed on anti-PD-1/PD-L1 therapy and platinum-doublet chemotherapy.

The second multicenter, open-label phase 2 study will evaluate the efficacy, safety and biomarkers of response and resistance to patritumab deruxtecan in patients with HER3 expressing metastatic breast cancer.

Each study will enroll up to 100 patients and will be conducted in several sites in France.

The primary endpoint for both studies is objective response rate as assessed by independent central review. Secondary endpoints include clinical benefit rate, progression-free survival, duration of response, overall survival and safety measures. The studies also will primarily be conducted to analyze biomarker expression and tumor sensitivity; the role of receptor biology in the pharmacological activity of the Daiichi Sankyo DXd ADC platform, as well as factors contributing to treatment resistance; immunogenicity and mechanism of action.

The adaptive trial design includes ongoing clinical and biomarker assessments to identify factors associated with individual patient response and the ability to fine-tune development accordingly.

Additional research to be conducted under the collaboration includes several studies exploring multiple therapeutic combinations for each ADC.

About Gustave Roussy

Gustave Roussy, Europe's leading cancer center, is a global cancer center of expertise entirely dedicated to patients. It brings together 3,100 professionals whose missions are care, research and teaching. The Institute has expertise in the management of rare cancers and complex tumors. It treats all cancers at every stage of life and offers its patients individualized care combining innovation and a humane

approach. Twenty-six percent of its new patients are included in clinical trials. For more information, please visit: www.gustaveroussy.fr/en.

About DS-1062 and Patritumab Deruxtecan (U3-1402)

DS-1062 and patritumab deruxtecan (U3-1402) are two of three lead DXd ADCs in the oncology pipeline of Daiichi Sankyo. 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 with Daiichi Sankyo's proprietary DXd ADC technology, DS-1062 is comprised of a humanized anti-TROP2 monoclonal antibody attached to a topoisomerase I inhibitor payload by a tetrapeptide-based linker. Patritumab deruxtecan is comprised of a human anti-HER3 antibody and the same payload and linker as DS-1062.

DS-1062 is currently being evaluated in a phase 1 trial in patients with advanced solid tumors that are refractory to or relapsed from standard treatment or for whom no standard treatment is available. The study is currently enrolling patients with unresectable advanced NSCLC and unresectable/advanced or metastatic triple negative breast cancer.

Patritumab deruxtecan is currently being evaluated in a phase 1 study in previously treated patients with metastatic or unresectable NSCLC. Patritumab deruxtecan is also being evaluated in a phase 1/2 study in patients with HER3 expressing metastatic breast cancer.

DS-1062 and patritumab deruxtecan 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 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.

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