Press Release

Daiichi Sankyo Out-Licenses ROS1/NTRK Inhibitor DS-6051 to AnHeart Therapeutics

Tokyo, Japan, Basking Ridge, NJ, and New York, NY – (December 17, 2018) – Daiichi Sankyo Company, Limited (“Daiichi Sankyo”) and AnHeart Therapeutics Inc. (“AnHeart Therapeutics”) announced they have entered into a worldwide exclusive license agreement (“Agreement”) for DS-6051, Daiichi Sankyo’s selective ROS1/NTRK inhibitor, currently in phase 1 development in the United States and Japan.

Under the terms of the agreement, Daiichi Sankyo grants AnHeart Therapeutics worldwide exclusive rights for the development, manufacturing and commercialization of DS-6051. While Daiichi Sankyo and AnHeart Therapeutics will collaborate to continue two ongoing phase 1 studies, AnHeart Therapeutics will be responsible for further development of DS-6051 worldwide. Daiichi Sankyo will receive an upfront payment and is eligible for clinical, regulatory and sales milestone payments, as well as royalties on worldwide net sales of DS-6051. Financial terms of the agreement are not disclosed.

“We continue to look for innovative ways to maximize the potential of promising compounds in our oncology pipeline in order to deliver on our mission of transforming science into value for patients with cancer,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “We are confident that AnHeart Therapeutics will use the resources necessary to deliver a fast-to-market strategy to potentially bring this novel ROS1/NTRK inhibitor to patients as quickly as possible.”

“We thank Daiichi Sankyo for its trust in AnHeart Therapeutics and its continued support in further developing the DS-6051 asset worldwide. DS-6051 is currently being studied in two phase 1 studies for cancers bearing ROS1 or NTRK fusion mutations, and is a leading asset in our pipeline,” commented Junyuan Wang, PhD, Chief Executive Officer, AnHeart Therapeutics. “It is our priority to move DS-6051 through the global regulatory pathways with a fast-to-market approach. We will communicate with regulatory agencies to initiate multiple global phase 2 trials of DS-6051 immediately after the transfer of clinical development responsibilities is completed.”
About DS-6051
DS-6051 is an oral, selective small molecule ROS1/NTRK inhibitor currently being evaluated in two phase 1 clinical studies in patients with solid tumors harboring either a ROS1 or NTRK fusion gene and neuroendocrine tumors in the U.S. and Japan. Preliminary safety and efficacy data of DS-6051 from the first part of the U.S.-based phase 1/1b study were presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.¹

About AnHeart Therapeutics
AnHeart Therapeutics is a clinical-stage biopharmaceutical company focused on the acquisition, development, and commercialization of innovative medicines that improve human health and quality of life. AnHeart Therapeutics intends to optimize the commercial value of clinical assets by leveraging its strong capability of global clinical development and its access to an extensive network of experts across multiple disciplines. AnHeart Therapeutics is building a strong pipeline of innovative products by entering into partnering deals at near-term key value inflection points with large to medium biopharmaceutical companies.

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. 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.

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References