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Press Release

Anti-HER3 Monoclonal Antibody Patritumab Selected for I-SPY 2 TRIAL in Breast Cancer

Tokyo, Japan, Parsippany, NJ, and San Francisco, CA – (October 25, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) and QuantumLeap Healthcare Collaborative announced today that a new treatment arm of the I-SPY2 TRIAL will include patritumab, an investigational anti-HER3 monoclonal antibody.

The I-SPY 2 TRIAL, sponsored by QuantumLeap Healthcare Collaborative (QLHC), is a standing phase 2 randomized, controlled, multicenter study with an innovative adaptive design aimed to rapidly screen and identify promising new treatments in specific subgroups of women with newly-diagnosed, locally-advanced breast cancer (Stage II/III). Patritumab in combination with standard trastuzumab (anti-HER2 monoclonal antibody) and paclitaxel (chemotherapy) treatment will be compared to standard therapy alone in the new treatment arm. Women with HER2+ breast cancer will be randomized to one of the treatment arms and receive treatment for 12 weeks prior to undergoing surgery to remove the breast tumor.

“The evaluation of patritumab in I-SPY 2 will inform our understanding of how agents with unique mechanisms of action, like HER3 inhibition, can combine with proven HER2 antagonists,” said Melissa C. Paoloni, DVM, DACVIM-O, Executive Director of Clinical Activities, QuantumLeap Healthcare Collaborative, Sponsor of the I-SPY 2 TRIAL. “The results will help enhance the understanding of the treatment for patients with HER2-positive disease.”

“Research suggests that the combination of a HER3 inhibitor with other inhibitors of HER family receptors may be a promising approach in treating breast cancer,” said Dale E. Shuster, PhD, Executive Director, Clinical Development, Oncology, Daiichi Sankyo. “We are excited about the inclusion of patritumab in I-SPY 2 as this study is a prime example of how a unique scientific collaboration can aid in the evaluation of promising investigational agents for patients with unmet needs.”

About I-SPY 2 Trial

The I-SPY 2 TRIAL (NCT01042379) (**I**nvestigation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging **A**nd mo**L**ecular Analysis **2**) employs a unique adaptive trial design to match experimental therapies with patients, while testing whether adding investigational drugs to standard chemotherapy is better than standard chemotherapy alone in the neoadjuvant setting (prior to surgery).

The innovative adaptive design utilizes biological markers (biomarkers) from each woman to assign her to a particular investigational drug. The trial learns as it goes, as each patient's response to a particular drug informs how the next patient will be assigned to a treatment arm. Drugs with a strong efficacy threshold for a particular patient group may "graduate" to a more focused phase 3 drug registration trial, while drugs found to be ineffective or with significant side effects are dropped from the trial quickly. This high efficacy bar (85% likelihood of success in a 300-person phase 3 trial) and rapid evaluation allow the trial to identify the right drug for the right patient in the most expeditious fashion.

The trial is conducted by a consortium that brings together the Food and Drug Administration (FDA), National Cancer Institute (NCI), pharmaceutical and biotech companies, leading academic medical centers, and patient advocates under its umbrella.

About Patritumab

Patritumab is an investigational fully human monoclonal antibody that inhibits HER3, a unique member of the HER family that is abnormally activated in several types of cancer.[1,2] To stimulate growth of a cancer cell, the HER3 receptor binds (dimerizes) with another HER family receptor such as EGFR or HER2. [1, 2] Preclinical evidence suggests that the combination of a HER3 inhibitor with other inhibitors of HER family receptors may be a promising therapeutic approach in treating certain cancers.[2] In addition to inclusion in the I-SPY 2 TRIAL, a phase 2 study evaluating patritumab in previously-untreated recurrent or metastatic head and neck cancer is ongoing and enrolling patients.

About QuantumLeap Healthcare Collaborative

QuantumLeap Healthcare Collaborative, a non-profit foundation, was established in 2005 as a collaboration between medical researchers at University of California at San Francisco, and Silicon Valley entrepreneurs. QuantumLeap's mission is to accelerate transfer of high-impact research in clinical processes and systems technology into widespread adoption so that patients and physicians can benefit from the research as soon as practicable. QuantumLeap provides operational, financial and regulatory oversight to I-SPY 2 and is also the sponsor of its companion phase 3 confirmatory trial, I-SPY 3. For more information, visit: http://www.quantumleaphealth.org.

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-ITD 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-8201a, 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 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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