

Daiichi Sankyo Provides Update on HER3-Lung Study of Patritumab in Non-Small Cell Lung Cancer (NSCLC)

Tokyo, Japan and Parsippany, NJ– (May 31, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the two-part phase 3 HER3-Lung study of patritumab will not proceed into the second part. This decision followed the recommendation of an independent data monitoring committee (DMC) that concluded that the first part of the study (Part A) did not meet the pre-defined efficacy criteria required to proceed with Part B of the study. There were no safety concerns identified by the DMC.

The HER3-Lung study is a global study evaluating the investigational HER3 inhibitor patritumab, in combination with erlotinib, in patients with locally advanced or metastatic non-small cell lung cancer not selected for EGFR mutation but stratified by tumor expression of heregulin.

“We are disappointed that this study did not confirm the hypothesis that effective HER3 inhibition in combination with erlotinib would provide clinically relevant tumor growth control in subjects with advanced non-small cell lung cancer. Nevertheless, rigorously designed experiments such as Part A of this study in this particular case is at the core of what we do: transform innovative science into value for patients suffering from cancer. The very nature of experiments is to resolve uncertainty and some are bound to not confirm the hypothesis tested,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “This particular result does not directly affect the science of patritumab in other settings. The phase 2 study evaluating patritumab in head and neck cancer, in combination with cetuximab and a platinum agent, remains unchanged and ongoing. At Daiichi Sankyo we will continue to apply rigorous science to create new hope for patients with cancer.”

Daiichi Sankyo has accepted the DMC recommendation and is providing information regarding study discontinuation to health authorities and clinical investigators participating in the HER3-Lung study. Data from this study will be presented at an upcoming scientific meeting.

Daiichi Sankyo will continue to examine the data to better understand the results and determine next steps for the development of patritumab in non-small cell lung cancer. The phase 2 study evaluating patritumab in previously-untreated recurrent or metastatic head and neck cancer is ongoing and enrolling patients.

About HER3-Lung

The first part of the HER3-Lung study (Part A) was designed to assess the progression-free survival benefit of patritumab in patients with locally advanced or metastatic non-small cell lung cancer, and confirm lung cancer expression of heregulin as a predictive biomarker. The second part of the study (Part B) was to determine if patritumab improves overall survival in patients with advanced lung cancer and high expression of heregulin.

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. To stimulate growth of a cancer cell, the HER3 receptor must bind (dimerize) with another HER family receptor such as EGFR or HER2. The HER3 ligand, heregulin, is thought to enhance growth stimulation through the HER dimer. 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 cancer.

About Daiichi Sankyo Oncology

Daiichi Sankyo is focused on the discovery and development of novel oncology agents with the goal of delivering first-in-class and best-in-class treatments that address unmet medical needs. The oncology pipeline of Daiichi Sankyo continues to grow and currently includes both small molecules and monoclonal antibodies with novel targets in both solid and hematological cancers.

Daiichi Sankyo currently has three compounds in phase 3 clinical development each with a unique mechanism of action focusing on rare or orphan indications. These investigational compounds include: quizartinib, an oral FLT3 inhibitor, for newly diagnosed and relapsed/refractory FLT3-ITD-positive acute myeloid leukemia (AML); pexidartinib (PLX3397), 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), and tivantinib, an oral MET inhibitor, for second-line treatment of hepatocellular carcinoma in partnership with ArQule, Inc.

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 its strong portfolio of medicines for hypertension, dyslipidemia, bacterial infections, and thrombotic disorders, the Group's research and development is focused on bringing forth novel therapies in cardiovascular-metabolic diseases, pain management, and

oncology, including biologics. 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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