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Daiichi-Sankyo

Press Release

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Daiichi Sankyo Highlights Clinical Data of Two Novel Hematological Agents at the 58th Annual Meeting of the American Society of Hematology

- Preliminary results from a phase 1 study of MDM2 inhibitor DS-3032 in relapsed/refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) to be presented
- Monotherapy dosing strategy of FLT3 inhibitor quizartinib identified by laboratory and clinical investigations for FLT3-ITD+ AML
- Development of DS-3032 and quizartinib underscores Daiichi Sankyo commitment to AML

Parsippany, NJ, and Munich, Germany – (November 30, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that data from two of its investigational targeted therapies, DS-3032 and quizartinib, will be presented during the 58th Annual Meeting of the American Society of Hematology (ASH) taking place on December 3-6 in San Diego.

Preliminary safety and efficacy phase 1 data on DS-3032, an investigational oral selective MDM2 inhibitor, in patients with relapsed/refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) will be featured as an oral presentation. Data outlining the dosing strategy for quizartinib, an oral FLT3 inhibitor, in patients with relapsed/refractory FLT3-ITD+ AML also will be presented.

"Given that there has been little change in the treatment of AML for the past 30 years, we are committed to identifying novel treatments that could potentially change the standard of care for these patients," said Ken Kobayashi, MD, Executive Director, Global Oncology Research and Development, Daiichi Sankyo. "We look forward to presenting the results of the DS-3032 and quizartinib studies to the scientific community at ASH."

Abstract #593: Phase 1 Dose Escalation Study of MDM2 Inhibitor DS-3032 in Patients with Hematological Malignancies – Preliminary Results

Preliminary results from the dose escalation part of a phase 1 study of DS-3032 will be part of an oral presentation session on Monday, December 5, 2016 from 7:00 AM-8:30 AM at the San Diego Ballroom AB (Marriott Marquis San Diego Marina). The primary objectives are to examine the safety and tolerability of DS-3032 and determine the maximum tolerated dose or tentative recommended phase 2 dose. Secondary objectives include evaluating the pharmacokinetics and pharmacodynamics effects of DS-3032. Exploratory objectives include evaluating the efficacy of DS-3032. Data on 38 patients with relapsed/refractory AML and high-risk MDS will be presented.

Abstract#4042: Laboratory and Clinical Investigations to Identify the Optimal Dosing Strategy for Quizartinib (AC220) Monotherapy in FLT3-ITD–Positive (+) Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML)

An overview of pre-clinical, pharmacokinetic (PK) and clinical study results used to establish and justify monotherapy dosing strategy for quizartinib will be part of a poster session on Monday, December 5, 2016 from 6:00 PM-8:00 PM in Hall GH (San Diego Convention Center). This dosing strategy is currently being used in the phase 3 QuANTUM-R study examining the role of quizartinib monotherapy in patients with relapsed/refractory FLT3-ITD+ AML.

DS-3032 and quizartinib have not been approved by any regulatory authority for uses under investigation.

About DS-3032

DS-3032 is an investigational oral selective inhibitor of the murine double minute 2 (MDM2) protein currently being investigated in three phase 1 clinical trials for solid and hematological malignancies including acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), chronic myeloid leukemia (CML) in blast phase, lymphoma, and myelodysplastic syndrome (MDS).

About Quizartinib

Quizartinib is an investigational oral FLT3 inhibitor currently being evaluated in two global, pivotal phase 3 trials in patients with newly-diagnosed (QuANTUM-First) and relapsed/refractory (QuANTUM-R) FLT3-ITD+ AML. Quizartinib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the treatment of AML. Quizartinib has also been granted Fast Track Designation by the FDA for the treatment of relapsed/refractory AML.

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 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-8201, 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 a 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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