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# Press Release

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# Daiichi Sankyo to Present Data from AML Franchise Including FLT3 Inhibitor Quizartinib at ASH Annual Meeting

- Final results from pivotal QuANTUM-R study comparing single agent quizartinib to salvage chemotherapy, the first randomized phase 3 study to demonstrate a survival benefit with a FLT3 inhibitor in patients with relapsed/refractory *FLT3*-ITD AML, to be presented
- Updated data from a phase 1 study of valemetostat (DS-3201), an investigational and potential first-in-class EZH1/2 dual inhibitor, in relapsed/refractory non-Hodgkin lymphomas to be reported
- Preclinical research data evaluating the combination of quizartinib and investigational MDM2 inhibitor milademetan (DS-3032) in *FLT3*-ITD AML to be reported
- Quizartinib marketing application currently under accelerated review with Japan Ministry of Health, Labour and Welfare (MHLW); submissions in the U.S. and EU remain on track for the second half of fiscal year 2018
- Research presented at ASH reflects the commitment of the investigational AML Franchise of Daiichi Sankyo to define a new standard of care for patients with AML

**Munich and Basking Ridge, NJ – (November 1, 2018) –** Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that it will present data on investigational compounds in the AML Franchise pipeline of the Daiichi Sankyo Cancer Enterprise at the 60th Annual Meeting of the American Society of Hematology (ASH) from December 1-4 in San Diego.

Final results from the pivotal phase 3 QuANTUM-R study of quizartinib will be presented during an oral presentation, which will include sensitivity analyses of overall survival and event-free survival, key subgroup analyses and exploratory endpoints of response rates, duration of composite complete response rate and transplant rate. Additional poster presentations will include updated phase 1 data on valemetostat (DS-3201), an investigational EZH1/2 dual inhibitor, in patients with relapsed/refractory non-Hodgkin lymphomas, and preclinical research evaluating the combination of quizartinib and milademetan (DS-3032), an investigational MDM2 inhibitor, in *FLT3*-ITD AML.

"This is an exciting time in the advancement of science to treat patients with AML, and we look forward to presenting additional data from the QuANTUM-R study of quizartinib in patients with relapsed/refractory *FLT3*-ITD AML, a difficult-to-treat form of the disease," said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. "Our research presented at ASH demonstrates our commitment to developing compounds that may have the potential to represent meaningful treatment advances for patients with cancer."

Quizartinib is currently under accelerated regulatory review with the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of adult patients with relapsed/refractory *FLT3*-ITD AML. Submissions in the U.S. and EU remain on track for the second half of fiscal year 2018.

In the QuANTUM-R study, the median treatment duration with quizartinib was 4 cycles of 28 days each versus 1 cycle in the salvage chemotherapy arm. Incidence of treatment-emergent adverse events was comparable between patients who received single agent quizartinib and those who received salvage chemotherapy. The most common adverse drug reactions (>30 percent, any Grade) in patients treated with quizartinib included infections, bleeding, nausea, asthenic conditions, pyrexia, febrile neutropenia and vomiting, and the most common Grade ≥ 3 adverse drug reactions (>20 percent) were infection and febrile neutropenia. The most common laboratory adverse reactions (incidence >50 percent) were decreased white blood cell count, decreased lymphocyte count, decreased hemoglobin, decreased neutrophil count and decreased platelet count. The safety profile observed in QuANTUM-R appears consistent with that observed at similar doses in the quizartinib clinical development program.

The following data from the pipeline of Daiichi Sankyo Cancer Enterprise will be presented at ASH:

- **Efficacy and Safety of Single-Agent Quizartinib (Q), a Potent and Selective FLT3 Inhibitor (FLT3i), in Patients (pts) with *FLT3*-Internal Tandem Duplication (*FLT3*-ITD)-Mutated Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) Enrolled in the Global, Phase 3, Randomized Controlled QuANTUM-R Trial.** (Abstract 563; Oral Presentation; Monday, December 3, 2018 at 8:00 AM PST)
- **DS-3201, a Potent EZH1/2 Dual Inhibitor, Demonstrates Antitumor Activity in Non-Hodgkin Lymphoma Regardless of EZH2 Mutation.** (Abstract 2217; Poster Presentation; Saturday, December 1, 2018 at 6:15 PM – 8:15 PM PST)
- **Combination of FLT3 Inhibitor Quizartinib and MDM2 Inhibitor Milademetan Results in Greater Preclinical Antileukemic Activity in *FLT3*-ITD Mutant/P53 Wild-type Acute Myeloid Leukemia Models.** (Abstract 2720; Poster Presentation; Sunday, December 2, 2018 at 6:00 – 8:00 PM PST)
- **Development of a Novel Next-Generation Sequencing (NGS)-Based Assay for Measurable Residual Disease (MRD) in *FLT3*-ITD AML and Its Potential Clinical Application in Patients Treated with Chemotherapy Plus FLT3 Inhibitors.** (Abstract 1459; Poster Presentation; Saturday, December 1, 2018 at 6:15 PM – 8:15 PM PST)
- **Real-World Differences in Characteristics and Survival of Relapsed AML Patients With and Without Transplant.** (Abstract 2297; Poster Presentation; Saturday, December 1, 2018 at 6:15 PM – 8:15 PM PST)

- **Characterization of Health Care Resource Utilization Among Commercially Insured Relapsed Acute Myeloid Leukemia Patients in the United States.** (Abstract 5860; Online Abstract Publication)

**About Quizartinib**

Quizartinib, the lead investigational agent in the AML Franchise of the Daiichi Sankyo Cancer Enterprise, is an oral selective FLT3 inhibitor currently in phase 3 development for relapsed/refractory *FLT3*-ITD AML (QuANTUM-R) in the U.S. and EU; phase 3 development for newly-diagnosed *FLT3*-ITD AML (QuANTUM-First) in the U.S., EU and Japan; and, phase 2 development for relapsed/refractory *FLT3*-ITD AML in Japan.

Quizartinib has been granted Breakthrough Therapy designation for the treatment of adult patients with relapsed/refractory *FLT3*-ITD AML, and Fast Track designation for the treatment of relapsed/refractory AML by the U.S. Food and Drug Administration (FDA). Quizartinib also has been granted Orphan Drug designation by both the FDA and the European Commission (EC) for the treatment of AML and by the Japan MHLW for the treatment of *FLT3*-mutated AML.

**About Milademetan**

Milademetan (DS-3032) is an oral selective MDM2 inhibitor currently in phase 1 development for solid and hematologic malignancies with ongoing studies in the U.S. and Japan.

**About Valemetostat**

Valemetostat (DS-3201) is an investigational and potential first-in-class EZH1/2 dual inhibitor currently in phase 1 clinical development, including one study in AML and acute lymphocytic leukemia (ALL) in the U.S. and one study in B-cell and T-cell non-Hodgkin lymphomas (NHL) in Japan.

Quizartinib, milademetan and valemetostat are investigational agents that have not been approved for any indication in any country. Safety and efficacy of these investigational agents 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 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.

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