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Daiichi-Sankyo

Press Release

Daiichi Sankyo Provides Update on FDA Review of Quizartinib for the Treatment of Patients with Relapsed/Refractory *FLT3*-ITD AML

Tokyo and Basking Ridge, NJ – **(June 21, 2019)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) of quizartinib for the treatment of adults with relapsed/ refractory *FLT3*-ITD acute myeloid leukemia (AML).

"Daiichi Sankyo is evaluating the Complete Response Letter and will determine next steps in the U.S.," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo.

About Quizartinib

Quizartinib, an oral selective type II FLT3 inhibitor, is the lead product in the AML Franchise of Daiichi Sankyo. Quizartinib was approved by the Ministry of Health, Labor and Welfare (MHLW) of Japan under the brand name of VANFLYTA® for the treatment of adult patients with relapsed/refractory *FLT3*-ITD AML, as detected by an MHLW-approved test, on June 18, 2019.

A broad and comprehensive development program is underway with quizartinib including phase 3 development in combination with standard chemotherapy in newly diagnosed *FLT3*-ITD AML (QuANTUM-First) in the U.S., EU and Japan; phase 1/2 development for pediatric and young adult relapsed/refractory *FLT3*-ITD AML in North America and the EU; and phase 1 development in combination with an investigational MDM2 inhibitor, milademetan, for relapsed/refractory *FLT3*-ITD AML and newly-diagnosed *FLT3*-ITD AML unfit for intensive chemotherapy in the U.S.

Milademetan is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established. Quizartinib is only approved for use in Japan.

About *FLT3*-ITD AML

AML is an aggressive blood and bone marrow cancer that causes uncontrolled growth and accumulation of malignant white blood cells that fail to function normally and interfere with the production of normal blood cells.[1] In the U.S. this year, it is estimated that there will be more than 19,000 new diagnoses of AML and

more than 10,000 deaths from AML.[2] The five-year survival rate of AML reported from 2007 to 2013 was approximately 27 percent, which was the lowest of all leukemias.[1]

FLT3 gene mutations are one of the most common genetic abnormalities in AML.[3] *FLT3*-ITD is the most common FLT3 mutation, affecting approximately one in four patients with AML.[4,5,6,7] *FLT3*-ITD is a driver mutation that presents with high leukemic burden and has poor prognosis and a significant impact on disease management for patients with AML.[5,8] Patients with *FLT3*-ITD AML have a worse overall prognosis, including an increased incidence of relapse, an increased risk of death following relapse and a higher likelihood of relapse following hematopoietic stem cell transplantation as compared to those without this mutation.[9,10]

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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