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ASIA EDITION

Daiichi Sankyo's VANFLYTA® receives approval for the treatment of Relapsed/Refractory FLT3-ITD AML

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VANFLYTA® (quizartinib) is a FLT3 inhibitor MHLW-approved based on a survival benefit compared to salvage chemotherapy in adult patients with relapsed/refractory FLT3-ITD AML.

Daiichi Sankyo Company has announced that the Ministry of Health, Labor and Welfare (MHLW) of Japan has approved VANFLYTA® (quizartinib), an oral FLT3 inhibitor, for the treatment of adult patients with relapsed/refractory FLT3-ITD acute myeloid leukemia (AML), as detected by an MHLW-approved test.

Approval of VANFLYTA in Japan is based on the results from the global pivotal phase 3 QuANTUM-R study and a phase 2 study of VANFLYTA in Japan in patients with relapsed/refractory FLT3-ITD AML. Results from QuANTUM-R, which was the first randomized phase 3 study to show that a FLT3 inhibitor prolonged overall survival as an oral, single agent compared to chemotherapy in patients with relapsed/ refractory FLT3-ITD AML, were recently published in The Lancet Oncology.

Wataru Takasaki, PhD, Corporate Officer, Head of Oncology Function and Head of R&D Division in Japan, Daiichi Sankyo said, "With the approval of VANFLYTA, patients with relapsed/refractory FLT3-ITD AML in Japan will now have access to this important new treatment option that specifically targets the underlying driver of disease, and has a proven survival benefit compared to chemotherapy. We arproud that VANFLYTA is the first of seven new molecular entities we are committed to delivering by 2025 with the goal of transforming science into innovative treatments for patients with cancer."

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. AML is the most common adult leukemia in Japan, with approximately 5,500 new cases diagnosed each year. The five-year survival rate of AML reported from 2005 to 2011 was approximately 26 percent, which was the lowest of all leukemias.

FLT3 gene mutations are one of the most common genetic abnormalities in AML. FLT3-ITD is the most common FLT3 mutation, affecting approximately one in four patients with AML. 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.

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.