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Daiichi Sankyo submits NDA in Japan for leukemia drug

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Significant unmet medical need exists in Japan for AML with limited targeted treatment options for patients with relapsed/refractory FLT3-ITD AML, a very aggressive form of the disease associated with poor prognosis

Daiichi Sankyo Company, recently announced that it has submitted a New Drug Application (NDA) to Japan's Ministry of Health, Labor and Welfare (MHLW) for marketing approval of quizartinib for the treatment of adult patients with relapsed/refractory *FLT3*-ITD acute myeloid leukemia (AML). The submission to Japan MHLW is based on the results of the pivotal randomized phase 3 QuANTUM-R study in the U.S., EU and Asia excluding Japan, and an open-label phase 2 study of quizartinib in Japan in patients with relapsed/refractory *FLT3*-ITD AML.

"Quizartinib has been designed as a specific inhibitor of FLT3 with high affinity for *FLT3*-ITD, a driver mutation in AML that is linked to poor prognosis and is associated with aggressive disease that results in increased relapse rate and reduced overall survival for patients compared to those without this mutation," said Kouichi Akahane, PhD, MBA, Executive Officer, Head of Oncology Function, R&D Division, Daiichi Sankyo. "We look forward to working closely with the Japan Health Authority on our application for quizartinib in order to bring this important potential new targeted treatment option to patients with relapsed/refractory *FLT3*-ITD AML in Japan."

Quizartinib is the first FLT3 inhibitor to prolong overall survival as an oral, single agent compared to chemotherapy in patients with relapsed/refractory *FLT3*-ITD AML. This was demonstrated in a randomized phase 3 trial (QuANTUM-R) and topline results of QuANTUM-R were presented during the plenary program at the 23rd Congress of the European Hematology Association in June 2018.

The open-label, single arm phase 2 study evaluating quizartinib in Japanese patients with relapsed/refractory *FLT3*-ITD AML met its primary endpoint of achieving a predetermined composite complete remission rate at interim analysis, triggering an early stop of the study due to efficacy. The quizartinib efficacy and safety profile observed in the phase 2 study in Japan appears consistent with that of QuANTUM-R. These data were presented at the 80th Annual Meeting of the Japanese Society

of Hematology (JSH) in October 2018.

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 Ministry of Health, Labour and Welfare (MHLW) for the treatment of *FLT3*-mutated AML.