Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

Quizartinib Added to Chemotherapy Demonstrates Superior Overall Survival Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed *FLT3*-ITD Positive AML

- Global pivotal QuANTUM-First phase 3 trial meets primary endpoint for overall survival
- There is a high unmet medical need for patients with *FLT3*-ITD positive AML, which is associated with poor prognosis

Tokyo, Munich, and Basking Ridge, N.J. – (**November 18, 2021**) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced positive topline results from the global pivotal QuANTUM-First phase 3 trial evaluating quizartinib, a highly potent and selective FLT3 inhibitor, in patients with newly diagnosed *FLT3*-ITD positive acute myeloid leukemia (AML).[1]

QuANTUM-First met its primary endpoint, demonstrating that patients who received quizartinib in combination with standard induction and consolidation chemotherapy and then continued with single agent quizartinib had a statistically significant and clinically meaningful improvement in overall survival (OS) compared to those who received standard treatment alone. The safety of quizartinib was shown to be manageable and consistent with the known safety profile.

AML is one of the most common forms of leukemia in adults, representing about one-third of all cases.[2] The five-year survival rate of AML is about 29%, and patients with *FLT3*-ITD positive AML have a particularly unfavorable prognosis, including an increased risk of relapse and shorter overall survival.[1,3] There remains a high unmet need to improve survival for the majority of patients with AML.[4]

"The results of the phase 3 QuANTUM-First trial showed that adding quizartinib, a potent and selective FLT3 inhibitor, to chemotherapy significantly prolonged overall survival in patients with newly diagnosed *FLT3*-ITD positive AML," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "We look forward to sharing the QuANTUM-First data with the hematology community and will initiate discussions with global regulatory authorities."

Data from QuANTUM-First will be presented at an upcoming medical meeting and shared with regulatory authorities globally.

About QuANTUM-First

QuANTUM-First is a randomized, double-blind, placebo-controlled, multi-center global phase 3 study evaluating quizartinib in combination with standard induction and consolidation chemotherapy and then as continued single agent therapy in adult patients (age 18 – 75) with newly diagnosed *FLT3*-ITD positive AML.

Patients were randomized 1:1 into two treatment groups to receive quizartinib or placebo in combination with standard anthracycline and cytarabine-based induction and consolidation regimens. Eligible patients, including those who underwent allogenic hematopoietic stem cell transplant (HSCT), continued with single agent quizartinib or placebo for up to 36 cycles.

The primary study endpoint is OS. Secondary endpoints include event-free survival (EFS), post-induction rates of complete remission (CR) and composite complete remission (CRc), and the percentage of patients who achieve CR or CRc with *FLT3*-ITD minimal residual disease negativity. Safety and pharmacokinetics, along with exploratory efficacy and biomarker endpoints, were also evaluated.

QuANTUM-First enrolled 539 patients at approximately 200 study sites worldwide including in Asia, Europe, North America, Oceania and South America. For more information, visit ClinicalTrials.gov.

About Acute Myeloid Leukemia (AML)

More than 474,500 new cases of leukemia were reported globally in 2020 with more than 311,500 deaths.[5] AML is one of the most common types of leukemia in adults, representing about one-third of all cases.[2] A heterogenous blood cancer, AML is characterized by a five-year survival rate of about 29%, the lowest by far among the major leukemia subtypes.[6,7]

Treatment guidelines for patients with newly diagnosed AML recommend a cytarabine-based chemotherapy regimen with or without a targeted therapy as determined by the presence of genetic mutations, age and other factors.[8] Patients with newly diagnosed FLT3 mutated AML may receive a FLT3 inhibitor as part of their initial treatment regimen and/or subsequent regimens.[8] While intensive chemotherapy and/or HSCT can improve chances for sustained remission in eligible patients, a substantial proportion of patients are not suitable for either intervention, and cure rates are particularly low for older patients.[1,6] In recent years, new targeted treatments have increased options and improved outcomes for some patients with molecularly defined AML subtypes.[6]

About *FLT3*-ITD

FLT3 (FMS-like tyrosine kinase 3) is a transmembrane receptor tyrosine kinase protein normally expressed by hematopoietic stem cells; FLT3 plays an important role in cell development by promoting cell survival, growth and differentiation through various signaling pathways.[1] Mutations of the FLT3 gene, which occur in approximately 30% of patients with AML, can drive oncogenic signaling.[1] The most common type of FLT3 mutation is the *FLT3*-ITD (internal tandem duplication), which is present in about 25% of all AML patients and contributes to cancer cell proliferation.[1] Patients with *FLT3*-ITD mutations have a particularly unfavorable prognosis, including an increased risk of relapse and shorter overall survival.[1]

About Quizartinib

Quizartinib, an oral, highly potent and selective type II FLT3 inhibitor, is in phase 1/2 clinical development in pediatric and young adult patients with relapsed/refractory *FLT3*-ITD AML in Europe and North America.[1] Several phase 1/2 combination studies with quizartinib are also underway at The University of Texas MD Anderson Cancer Center as part of a strategic research collaboration focused on accelerating development of Daiichi Sankyo pipeline therapies for AML.

Quizartinib is currently approved for use in Japan under the brand name VANFLYTA® for the treatment of adult patients with relapsed/refractory *FLT3*-ITD AML, as detected by an approved test. Quizartinib is an investigational medicine in all countries outside of Japan.

About Daiichi Sankyo Oncology

The oncology portfolio of Daiichi Sankyo is powered by our team of world-class scientists that push beyond traditional thinking to create transformative medicines for people with cancer. Anchored by our DXd antibody drug conjugate (ADC) technology, our research engines include biologics, medicinal chemistry, modality and other research laboratories in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in the U.S. We also work alongside leading academic and business collaborators to further advance the understanding of cancer as Daiichi Sankyo builds towards our ambitious goal of becoming a global leader in oncology by 2025.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 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 to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichisankyo.com.

Media Contacts:

Global/US:
Jennifer Brennan
Daiichi Sankyo, Inc.
jbrennan2@dsi.com
+1 908 992 6631 (office)
+1 908 900 3183 (mobile)

Japan:
Masashi Kawase
Daiichi Sankyo Co., Ltd.
kawase.masashi.a2@daiichisankyo.co.jp
+81 3 6225 1126 (office)

EU:
Lydia Worms
Daiichi Sankyo Europe GmbH
lydia.worms@daiichi-sankyo.eu
+49 (89) 7808751 (office)
+49 176 11780861 (mobile)

Investor Relations Contact:
DaiichiSankyoIR@daiichisankyo.co.jp

References

[1] Daver N et al. *Leukemia*. (2019) 33:299–312.
[2] American Cancer Society. Key Statistics for Acute Myeloid Leukemia. Updated January 2020.
[3] Leukemia and Lymphoma Society. Facts and Statistics. Leukemia: Survival (SEER Data for 2009-2015).
[4] Daver N et al. *Blood Cancer Journal*. (2020) 10:107.
[5] Global Cancer Observatory. Population Fact Sheet: World. Updated November 2020.
[6] Short et al. *Cancer Discov*. (2020);10:506–25.
[7] Leukemia and Lymphoma Society. Facts and Statistics. Leukemia: Survival (SEER Data for 2009-2015).
[8] NCCN Practice Guidelines for Oncology. Acute Myeloid Leukemia. Version 3.2021 (March 2, 2021).