Press Release

Daiichi-Sankyo

Vanflyta® Approved in China as First and Only FLT3 Inhibitor for Patients with Newly Diagnosed *FLT3*-ITD Positive AML

- Based on results from the QuANTUM-First phase 3 trial that demonstrated Vanflyta added to chemotherapy improved overall survival
- Third innovative medicine from the oncology pipeline of Daiichi Sankyo approved in China

Tokyo – (June 15, 2026) – Vanflyta® (quizartinib) has been approved in China for use in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is *FLT3*-ITD positive as detected by an adequate validated test. Vanflyta is a FLT3 inhibitor being developed and commercialized by Daiichi Sankyo (TSE: 4568).

Approximately 82,000 new cases of leukemia were diagnosed in China in 2022.[1] AML is a common and aggressive subtype, accounting for approximately 50% of leukemia cases in China.[2] Up to 37% of newly diagnosed patients with AML have a *FLT3* gene mutation and approximately 80% of these are *FLT3*-ITD mutations, which drive cancer growth and contribute to increased risk of relapse and shorter overall survival.[3,4] The five-year survival rate for patients with *FLT3*-ITD positive AML has been reported at approximately 20%.[5]

The approval of Vanflyta by China's National Medical Products Administration (NMPA) is based on results from the QuANTUM-First phase 3 trial published in *The Lancet*. In QuANTUM-First, Vanflyta combined with standard cytarabine and anthracycline induction and standard cytarabine consolidation, and continued as maintenance monotherapy following consolidation, demonstrated a 22% reduction in the risk of death compared to standard chemotherapy alone (HR = 0.78 [95% CI: 0.62-0.98; p=0.032]) in patients with newly diagnosed *FLT3*-ITD positive AML. Median overall survival (OS) was 31.9 months for patients receiving Vanflyta (n=268; 95% CI: 21.0-NE) compared to 15.1 months for patients in the control arm (n=271; 95% CI: 13.2-26.2) at a median follow-up of 39.2 months.

"Newly diagnosed *FLT3*-ITD positive AML has long been associated with poor outcomes, even with intensive chemotherapy," said Professor Wang Jianxiang, Institute of Hematology & Blood Diseases Hospital, Chinese Academy of Medical Sciences and leading primary investigator in China of the QuANTUM-First trial. "In the QuANTUM-First study, Vanflyta in combination with standard chemotherapy, followed by monotherapy maintenance treatment, significantly extended survival of patients. The approval of Vanflyta in China now brings a new treatment option for eligible patients with this aggressive and difficult-to-treat form of leukemia."

"The approval of Vanflyta as the first FLT3 inhibitor available for use in the newly diagnosed setting in China marks an important milestone for patients. *FLT3*-ITD positive AML is a subtype of AML associated with rapid disease progression and historically limited treatment options," said Michio Hayashi, China President, Daiichi Sankyo. "As the third oncology medicine from our pipeline approved in China, Vanflyta reflects our commitment to delivering innovation for patients."

The safety profile of Vanflyta was evaluated in 268 patients with newly diagnosed *FLT3*-ITD positive AML. The most common grade 3 or 4 adverse reactions (occurring in ≥10% of patients) were decreased platelet count (40%), decreased hemoglobin (35.5%), decreased neutrophil count (21.5%) and increased alanine aminotransferase (12.1%). QTcF > 500 ms occurred in 2.3% of patients receiving Vanflyta and 0.8% of patients discontinued Vanflyta due to QT prolongation. Ventricular arrhythmia events with Vanflyta were uncommon. Two (0.8%) patients receiving Vanflyta experienced cardiac arrest with recorded ventricular fibrillation on ECG (one with fatal outcome), both in the setting of severe hypokalemia.

About QuANTUM-First

QuANTUM-First is a randomized, double-blind, placebo-controlled, global phase 3 study evaluating Vanflyta in combination with standard induction and consolidation therapy, including hematopoietic stem cell transplant, and as maintenance monotherapy, in adult patients aged 18-75 with newly diagnosed *FLT3*-ITD positive AML. Patients were randomized 1:1 to receive Vanflyta or placebo combined with cytarabine and anthracycline induction and cytarabine consolidation chemotherapy followed by up to three years of treatment with single-agent maintenance. There was no re-randomization at the start of post-consolidation therapy.

The primary study endpoint was OS. Secondary endpoints included event-free survival, 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 measurable residual disease negativity. Safety and pharmacokinetics, along with exploratory efficacy and biomarker endpoints including duration of CR, also were evaluated.

QuANTUM-First enrolled 539 patients in Asia, Europe, North America, Oceania and South America. For more information, visit ClinicalTrials.gov.

About *FLT3*-ITD Positive Acute Myeloid Leukemia

More than 487,000 new cases of leukemia were reported globally in 2022, with more than 305,000 deaths.[6] AML accounts for 23.1% of total leukemia cases worldwide and is most common in adults.[7,8] In China, nearly 82,000 people were diagnosed with leukemia in 2022 and more than 50,000 people died from the disease, making it the tenth deadliest cancer.[1] AML is a common and aggressive subtype, accounting for approximately 50% of leukemia cases in China.[2]

A number of gene mutations have been identified in AML and *FLT3* (FMS-like tyrosine kinase 3) mutations are the most common.[4] Approximately 80% of *FLT3* mutations are *FLT3*-ITD mutations, which drive cancer growth and contribute to particularly unfavorable prognosis, including increased risk of relapse and shorter overall survival.[3,4] *FLT3*-ITD mutations occur in about 25% of all AML cases, with frequency reported as high as 30%.[9]

About Vanflyta

Vanflyta (quizartinib) is an oral, highly potent type II FLT3 inhibitor that targets *FLT3*-ITD mutations.

Vanflyta is approved in more than 35 countries/regions in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation therapy, for the treatment of adult patients with newly diagnosed *FLT3*-ITD positive AML based on the results from the QuANTUM-First trial.

Vanflyta also is approved in Japan as a monotherapy for the treatment of patients with relapsed/refractory AML that is *FLT3*-ITD mutation positive, as detected by an approved test, based on results from the QuANTUM-R trial.

About the Vanflyta Clinical Development Program

The Vanflyta clinical development program includes the QuANTUM-Wild phase 3 trial in adult patients with newly diagnosed *FLT3*-ITD negative AML, a phase 1/2 trial in pediatric and young adult patients with relapsed/refractory *FLT3*-ITD positive AML in Asia, Europe and North America and several phase 1/2 combination studies as part of a strategic collaboration with The University of Texas MD Anderson Cancer Center.

About Daiichi Sankyo

Daiichi Sankyo (TSE: 4568) is a global healthcare company committed to becoming a trusted healthcare innovator, transforming the lives of people through its strength in science and technology. The company discovers and develops new standards of care to address diverse medical needs to fulfill its purpose of contributing to the enrichment of quality of life around the world. With a strategic focus on oncology, Daiichi

Sankyo is advancing an industry-leading antibody drug conjugate portfolio along with identifying new breakthrough generating technologies to deliver practice-changing medicines to patients, healthcare professionals and society. For more information, please visit www.daiichisankyo.com.

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