Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

VANFLYTA® (Quizartinib)Now Available in Norway for Patients with Newly Diagnosed *FLT3*-ITD Positive AML

- The EU approval is based on QuANTUM-First results demonstrating Quizartinib added to chemotherapy improved overall survival
- Quizartinib can now be prescribed by all physicians experienced in cancer treatment and is reimbursed under the Norwegian public healthcare system

Oslo – (28 October 2025) - Daiichi Sankyo's (TSE: 4568) VANFLYTA (Quizartinib) is now available in Norway for use in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by Quizartinib single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukemia (AML) that is *FLT3*-ITD positive[1].

Quizartinib is an oral selective type 2 FLT3 inhibitor for the treatment of patients with newly diagnosed *FLT3*-ITD positive AML, with approximately 25% of all new AML cases being *FTL3*-ITD positive.[1,2]

The authorization by the European Commission (EC) follows the positive opinion of the Committee for Medicinal Products for Human Use and is based on the results of the QuANTUM-First trial, which were published in *The Lancet*. In QuANTUM-First, Quizartinib 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 was 31.9 months for patients receiving Quizartinib (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.[1,2]

The safety profile of Quizartinib in QuANTUM-First was consistent with previous clinical trials with no new safety signals observed. The most common grade 3 or 4 treatment emergent adverse events were decreased platelet count (40%), decreased haemoglobin (35.5%), decreased neutrophil count (21.5%), increased alanine aminotransferase (12.1%), bacteraemia (7.2%) and fungal infections (5.7%).[1,2]

QT prolongation was associated with dose reduction in 10 (3.8%) patients, dose interruption in 7 (2.6%) patients, and discontinuation in 2 (0.8%) patients. QTcF > 500 ms occurred in 2.3% of patients based on central review of ECG data. Two experienced cardiac arrest with recorded ventricular fibrillation, one

with a fatal outcome, both in the setting of severe hypokalaemia. Electrocardiogram, monitoring and correction of hypokalaemia and hypomagnesemia should be performed prior to and during treatment with Quizartinib.[1]

About QuANTUM-First

QuANTUM-First is a randomized, double-blind, placebo-controlled, global phase 3 study evaluating Quizartinib in combination with standard induction and consolidation therapy, including hematopoietic stem cell transplant (HSCT), and as maintenance monotherapy, in adult patients aged 18-75 with newly diagnosed *FLT3*-ITD positive AML. Patients were randomized 1:1 to receive Quizartinib or placebo combined with cytarabine and anthracycline induction and cytarabine consolidation chemotherapy followed by up to three years of treatment with single agent maintenance[2].

The primary study endpoint was overall survival. Secondary endpoints include 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[2].

QuANTUM-First enrolled 539 patients at 193 study sites in 26 countries across Asia, Europe, North America, Oceania and South America[2]. For more information, visit ClinicalTrials.gov.

About *FLT3*-ITD Positive Acute Myeloid Leukemia

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.[5,6] *FLT3*-ITD mutations occur in about 25% of all AML cases, with frequency reported as high as 30%.[5,6] Approximately 150 new cases of acute myeloid leukemia (AML) are diagnosed each year in Norway[7].

About Quizartinib

Quizartinib is an oral, highly potent and selective type II FLT3 inhibitor approved in more than 30 countries in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, and as maintenance monotherapy following consolidation, for the treatment of adult patients with newly diagnosed AML that is *FLT3*-ITD positive based on the results from the QuANTUM-First trial[1,2].

About Daiichi Sankyo

Daiichi Sankyo is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops and delivers new standards of care to enrich the quality of life around the world. With more than 120 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular and other diseases with high unmet medical need. For more information, please visit www.daiichi-sankyo.eu/.

Media Contacts:
EU:
Simone Jendsch-Dowé
Daiichi Sankyo
simone.jendsch-dowe@daiichisankyo.com
+49 176 11780822

References:
1. VANFLYTA Summary of Product Characteristics. Updated December 2024.
2. Erba HP, et al. *Lancet*. 2023;401(10388):1571-1583
3. Heuser M, et al. *Ann Oncol.* (2020) 31(6):697-712.
4. Kennedy VE, et al. *Front Onc.* 23 December 2020;10. Volume 10 – 2020.
5. Daver N, et al. *Leukemia*. (2019) 33:299-312.
6. Gordon J, et al. *Blood Cancer J.* (2024) 14:125.
7. Akutt myelogen leukemi (AML) - Helsedirektoratet