- **Specifically targets** the aggressive *FLT3*-ITD mutation[1-4]
- Studied in a wide range of ages, **up to 75 years of age**[1,5]
- Additional OS benefit in patients **post-allo-HSCT**[6]

Superior overall survival with

22%

in risk of death*[1,5]

HR=0.78; 95% CI: 0.62-0.98 P=0.032

Median duration of complete response

38.6 months

with VANFLYTA® + standard chemo†[7]

95% CI: 21.9-NE; N=147

12.4 months

with placebo + standard chemo†[7]

95% CI: 8.8-22.7; N=150

Study design: QuANTUM-First is a randomised, double-blind, placebo-controlled, global phase 3 study which enrolled patients aged 18-75 with newly diagnosed AML with a *FLT3*-ITD mutation. Patients were randomly assigned (1:1) to VANFLYTA® or placebo group. During the first induction cycle, all patients received standard 7+3 induction regimen with IV cytarabine from days 1-7 and IV anthracycline (daunorubicin or idarubicin) on days 1-3. Patients were randomly assigned on day 7 to receive VANFLYTA® 35.4 mg or placebo orally once daily for 14 days. Patients with persistent leukemia after the first cycle could receive a second cycle of induction chemotherapy with either 7+3 or 5+2 regimen plus VANFLYTA® or placebo. Patients with CR or with CRi could proceed to consolidation, consisting of high-dose cytarabine (on days 1, 3 and 5) plus VANFLYTA® 35.4 mg or placebo and/or allo-HSCT, for up to 4 cycles. During maintenance, patients received VANFLYTA® (26.5 mg once daily for days 1-14, then 53 mg once daily thereafter) or placebo. Primary efficacy outcome was OS. Exploratory outcomes included RFS and DoCR by IRC.[1,5,7]

Indication: VANFLYTA® is indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by VANFLYTA® single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is *FLT3*-ITD positive.[1]

*Median OS of VANFLYTA® plus standard chemotherapy (31.9 months; 95% CI: 21.0-NE) versus placebo plus standard chemotherapy (15.1 months; 95% CI: 13.2-26.2).[5]

†Patients who achieved CR during induction per IRC assessment.[7]

allo-HSCT=allogeneic haematopoietic stem cell transplantation; AML=acute myeloid leukemia; CI=confidence interval; CR=complete remission; CRi=complete remission with incomplete neutrophil or platelet recovery; DoCR=duration of complete remission; *FLT3*=FMS (feline McDonough sarcoma)-like tyrosine kinase 3; HR=hazard ratio; IRC=independent review committee; ITD=internal tandem duplication; IV=intravenous; NE=not estimable; OS=overall survival; RFS=relapse-free survival.

References: 1. VANFLYTA® Hong Kong Prescribing Information. (July 2024v01) **2.** Daver N, et al. Leukemia 2019;33:299-312. **3.** Mead AJ, et al. Blood 2007;110:1262-1270. **4.** Aikawa T, et al. Oncotarget 2020;11:943-955. **5.** Erba H, et al. Lancet 2023;401:1571-1583. **6.** Schlenk R, et al. Presented at: EHA2023 Hybrid Congress. S137. **7.** Supplementary appendix. Erba H, et al. Lancet 2023;401:1571-1583.

Presentation: VANFLYTA 17.7 mg film-coated tablets: Each tablet contains 17.7 mg quizartinib (as dihydrochloride). VANFLYTA 26.5 mg film-coated tablets: Each tablet contains 26.5 mg quizartinib (as dihydrochloride). **Active Ingredient:** Quizartinib (as dihydrochloride). **Indications:** In combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by VANFLYTA single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is FLT3-ITD positive. **Dosage:** Induction: 35.4 mg (2 × 17.7 mg) once daily for two weeks in each cycle (28-day cycle). Patients can receive up to 2 cycles of induction. Consolidation: 35.4 mg (2 × 17.7 mg) once daily for two weeks in each cycle (28-day cycle). Patients can receive up to 4 cycles of consolidation. Maintenance: Starting dose of 26.5 mg once daily for two weeks if QTcF is ≤ 450 ms, then increased to 53 mg (2 × 26.5 mg) once daily if QTcF is ≤ 450 ms. Maintenance therapy may continue for up to 36 cycles (28-day cycle). **Contraindications:** Hypersensitivity to quizartinib or any excipients. Congenital long QT syndrome. Breast-feeding. **Precautions:** QT Interval Prolongation: Monitor ECG and electrolytes regularly. Do not start treatment if QTcF > 450 ms. Infections in Elderly Patients: Monitor closely for severe infections during induction. Contraception: Effective contraception is required for women of childbearing potential and male patients with female partners of childbearing potential. **Undesirable Effects:** Very Common: Upper respiratory tract infections, fungal infections, herpes infections, bacteraemia, thrombocytopenia, anaemia, neutropenia, decreased appetite, headache, epistaxis, diarrhoea, nausea, abdominal pain, vomiting, dyspepsia, increased alanine aminotransferase, oedema, prolonged electrocardiogram QT. Common: Pancytopenia. Uncommon: Cardiac arrest, ventricular fibrillation. Frequencies of undesirable effects vary with dosage. For further detail, please refer to full prescribing information.

Full local prescribing information is available upon request.

Please report Individual Case Safety Report (ICSR)/Adverse Event (AE) to Daiichi Sankyo via pv_hk@daiichisankyo.com

For healthcare professionals only.

HK-DAI-VAN-250405 Approval date: May 2025

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