For treatment-eligible patients with newly diagnosed *FLT3*-ITD+ AML

Start and stay with VANFLYTA—the only FLT3 inhibitor FDA-approved for use in INDUCTION, CONSOLIDATION, and MAINTENANCE[1-3]*

*In patients without prior allogeneic HSCT. Please see Full Indication, including Limitations of Use, below.

In patients with newly diagnosed *FLT3*-ITD+ AML treated with VANFLYTA plus standard chemotherapy

VANFLYTA provided superior overall survival vs standard chemotherapy alone[1,4†]

- HR: 0.78; 95% CI: 0.62–0.98; *P*=0.0324

†See page 5 for additional context.

***FLT3*-ITD is a driver mutation with a high leukemic burden in AML[5]**

Indication

VANFLYTA® (quizartinib) is indicated 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 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:
VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Important Safety Information

WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

- **VANFLYTA prolongs the QT interval in a dose- and concentration-related manner. Prior to VANFLYTA administration and periodically, monitor for hypokalemia or hypomagnesemia, and correct deficiencies. Perform electrocardiograms (ECGs) to monitor the QTc at baseline, weekly during induction and consolidation therapy, weekly for at least the first month of maintenance, and periodically thereafter.**
- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

AML=acute myeloid leukemia; CI=confidence interval; FDA=Food and Drug Administration; FLT3=FMS (feline McDonough sarcoma)–like tyrosine kinase 3; HR=hazard ratio; HSCT=hematopoietic stem cell transplantation; ITD=internal tandem duplication.

Please see additional Important Safety Information on pages 12-13 and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

VANFLYTA®
quizartinib tablets
26.5 mg | 17.7 mg

The *FLT3*-ITD is a driver mutation with a high leukemic burden[5]

~80%

OF ALL *FLT3* MUTATIONS ARE ITD+[6]

In the United States, there are over 70,000 people living with AML, with more than 20,000 new cases estimated in 2025.[7,8]

OVER 10 YEARS, PATIENTS WITH *FLT3*-ITD MUTATIONS WERE

~50%

LESS LIKELY TO SURVIVE

COMPARED TO PATIENTS WITH *FLT3*-TKD MUTATIONS[9]

From a 2007 retrospective analysis of 1107 adult patients with AML from the United Kingdom with a median age of 42 years, OS at 10 years in patients with *FLT3*-ITD and *FLT3*-TKD was 24% (n=257) and 51% (n=100), respectively (OR: 0.53 [95% CI: 0.41-0.69]; *P*<0.001, based on log-rank test).[9]

PATIENTS WITH *FLT3*-ITD MUTATIONS (n=120) WERE

3.4x

MORE LIKELY TO RELAPSE

THAN THOSE WITHOUT *FLT3*-ITD MUTATIONS (n=86) (HR: 3.4 [95% CI: 1.46-7.94; *P*=0.005])[10]

Although the presence of *FLT3*-ITD is correlated with a higher risk of relapse in the context of allogeneic transplant, the 2-year leukemia-free survival and relapse risk observed for allogeneic HSCT favorably compared with outcomes reported after post-remission chemotherapy only.

A different study from 2012 analyzed 206 adult patients (18 years or older) with de novo AML and normal cytogenetics who underwent myeloablative allogeneic HSCT in CR1 and had *FLT3*-ITD analysis available at diagnosis. Data from 2000 to 2008 were obtained from the European Group for Blood and Marrow Transplantation. The purpose of the study was to analyze the impact of *FLT3*-ITD on outcomes in normal cytogenetic AML patients who received allogeneic HSCT.[10]

About 75% of patients with *FLT3*-ITD+ AML at the time of diagnosis continue to have the ITD mutation at relapse, suggesting that ***FLT3*-ITD is associated with disease progression**[5]

CR1=first complete remission; OR=odds ratio; OS=overall survival; TKD=tyrosine kinase domain.

The evolving treatment landscape of *FLT3*-ITD+ AML

Intensive induction chemotherapy: the standard of care for fit patients[11,12]

- Chemotherapy remains the first-line approach for patients with *FLT3*-ITD+ AML who are candidates for intensive treatment. Standard care typically includes cytarabine and an anthracycline-based induction (either daunorubicin or idarubicin) chemotherapy (7+3), now often recommended to be administered in combination with targeted therapies such as FLT3 inhibitors

Allogeneic HSCT for consolidation: the gold standard curative treatment option in AML[5,12-15]

- For patients who achieve remission following induction, allogeneic HSCT is the preferred consolidation strategy for those with *FLT3*-ITD mutations who are at a higher risk of relapse. Allogeneic HSCT remains the most effective curative-intent therapy for eligible patients. Other recommended treatment options for consolidation include standard cytarabine chemotherapy in combination with targeted therapies such as FLT3 inhibitors

Up to 60% of patients with AML may not receive a transplant[16,17]

- In patients <70 years of age in the United States and Canada in 2016, based on a retrospective global AML incidence report study analyzing data from 2009 to 2016

Potential barriers to receiving transplant[18,19]:

- Age
- Comorbidities
- Donor availability
- Financial burden
- Logistical barriers

Maintenance therapy: potential role in post-consolidation care[12,17]

- In the post-consolidation setting, maintenance therapy is increasingly recognized as a strategy to reduce relapse risk in patients with *FLT3*-ITD+ AML. Current treatment guidelines recommend chemotherapy or targeted therapy based on previous treatment with chemotherapy or allogeneic HSCT.

VANFLYTA is not indicated as maintenance monotherapy following allogeneic HSCT; improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Consider a targeted FLT3 inhibitor as part of a treatment approach to managing *FLT3*-ITD+ AML

Quizartinib (VANFLYTA) is recommended as a treatment option across all 3 treatment phases specifically for *FLT3*-ITD+ AML[12]*

NCCN CATEGORY 1

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend quizartinib (VANFLYTA) as an NCCN Category 1 treatment option for eligible patients specifically with *FLT3*-ITD+ AML for intensive induction in combination with standard 7+3 chemotherapy (daunorubicin or idarubicin)[12]

Quizartinib (VANFLYTA) in combination with[12]:

Reinduction†:
Standard 7+3 or 5+2 chemotherapy (daunorubicin or idarubicin) for the *FLT3*-ITD mutation only

Consolidation:
Cytarabine‡: For intensive induction–eligible AML with the *FLT3*-ITD mutation only

Quizartinib (VANFLYTA) alone[12]:

Preferred for *FLT3*-ITD

Maintenance post-consolidation therapy*:
For patients with a history of a *FLT3* mutation who previously received a FLT3 inhibitor and if no allogeneic HCT is planned

All recommendations are Category 2A unless otherwise noted.

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.[1]

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

†Reinduction after cytarabine-based induction: consider follow-up BM aspirate and biopsy 14-21 days after start of therapy and residual disease (if ambiguous, repeat BM biopsy within 7 days before proceeding with therapy).[12]

‡Alternate dosing of cytarabine for postremission therapy has been reported. Doses of cytarabine ≥2 g/m^2 should be used with caution in patients ≥60 years and in patients with renal failure due to concern for neurotoxicity.[12]

BM=bone marrow; HCT=hematopoietic cell transplantation; NCCN=National Comprehensive Cancer Network® (NCCN®).

Important Safety Information (cont.)

Contraindications

- VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

Warnings and Precautions

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING)

- VANFLYTA prolongs the QT interval in a dose- and concentration-dependent manner. The mechanism of QTc interval prolongation is via inhibition of the slow delayed rectifier potassium current, I_{Ks}, as compared to all other medications that prolong the QTc interval, which is via the rapid delayed rectifier potassium current, I_{Kr}.
- The level of QTc prolongation with VANFLYTA that predicts the risk of cardiac arrhythmias is unclear. Inhibition of I_{Ks} and I_{Kr} may leave patients with limited reserve, leading to a higher risk of QT prolongation and serious cardiac arrhythmias, including fatal outcomes. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with VANFLYTA.
- Among 1,081 VANFLYTA-treated AML patients in clinical trials, severe cardiac arrhythmias occurred primarily during induction and included torsades de pointes (0.2%), cardiac arrest (0.6%, including 0.4% fatal), and ventricular fibrillation (0.1%).

Please see additional Important Safety Information on pages 12-13 and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

VANFLYTA® quizartinib tablets
26.5 mg | 17.7 mg

QuANTUM-First is the largest and longest clinical trial to specifically study patients with *FLT3*-ITD+ AML through induction, consolidation, and maintenance[1,4*]

VANFLYTA was studied in a wide range of ages, up to 75 years, with 40% of patients over the age of 60 years.[1,4]

In QuANTUM-First, the efficacy and safety of VANFLYTA plus standard chemotherapy vs placebo plus standard chemotherapy were studied in a Phase 3, randomized, double-blind, placebo-controlled, multicenter global study of 539 patients with newly diagnosed *FLT3*-ITD+ AML. Patients were randomized to placebo (n=271) or VANFLYTA (n=268).[1,4]

- Of patients studied, the majority (72%) had intermediate-risk cytogenetics, and 65.5% had an ECOG performance status of 1 or over at baseline[1,4]
- Median age was 56 years (range, 20-75)[1,4]

A second course of induction was administered to 20% of the patients; 65% of the patients initiated at least 1 cycle of consolidation; and 39% of the patients initiated maintenance treatment with VANFLYTA.[1*]

- Among the patients who entered maintenance, 64% completed at least 12 cycles, 36% completed at least 24 cycles, and 16% completed all 36 planned cycles of maintenance[1*]
- 29% (157/539) of the patients underwent HSCT in first CR[1]

PRIMARY ENDPOINT:	SECONDARY ENDPOINT:	EXPLORATORY† ENDPOINTS:
OS[1]	EFS, CR, and CRc[1,4]	RFS and DoCR[1,4]

Standard chemotherapy included cytarabine- and anthracycline-based induction (either daunorubicin or idarubicin) and consolidation regimens. Eligible patients, including those who underwent allogeneic HSCT, continued with single-agent VANFLYTA or standard chemotherapy. There was no re-randomization at the start of post-consolidation therapy.[1]

Evaluated in QuANTUM-First, VANFLYTA is a potent and selective FLT3 inhibitor that acts on the *FLT3*-ITD mutation[1,20]

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

†Cautious interpretation is recommended, and no conclusions can be drawn from this data.

CR=complete remission; CRc=composite complete remission; DoCR=duration of complete remission; ECOG=Eastern Cooperative Oncology Group; EFS=event-free survival; RFS=relapse-free survival.

Important Safety Information (cont.)

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- Of the 265 patients who received VANFLYTA in the clinical trial, 2.3% had a QTcF >500 ms and 10% had an increase of >60 ms from baseline. The trial excluded patients with a QTcF ≥450 ms or other factors that increased the risk of QT prolongation or arrhythmic events (eg, NYHA Class III/IV congestive heart failure, hypokalemia, or a family history of long QT interval syndrome).
- Avoid use in patients who are at significant risk of developing torsades de pointes, including uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, tachyarrhythmias, uncontrolled hypertension, high-degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.

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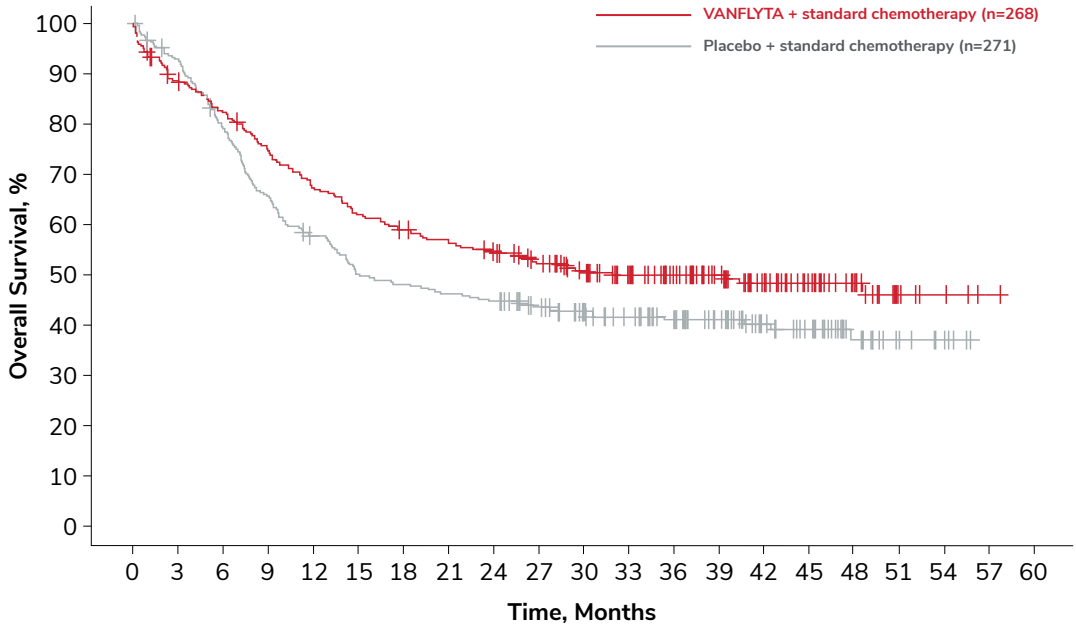
In patients with newly diagnosed *FLT3*-ITD+ AML treated with VANFLYTA plus standard chemotherapy

VANFLYTA provided superior overall survival vs standard chemotherapy alone[1,4]

22% **REDUCTION IN THE RISK OF DEATH WITH VANFLYTA + STANDARD CHEMOTHERAPY** vs placebo + standard chemotherapy
HR: 0.78* (95% CI: 0.62-0.98); *P*=0.0324[1†]

Primary Endpoint: Overall Survival in VANFLYTA[1,4]



Number at risk

VANFLYTA + standard chemotherapy	268	233	216	195	176	162	153	145	139	126	110	96	83	68	53	36	24	8	4	1	0
Placebo + standard chemotherapy	271	249	211	175	151	131	126	121	117	103	91	81	70	56	39	31	17	8	5	0	0

The primary analysis was conducted after a minimum follow-up of 24 months after the randomization of the last patient.[1]

*Hazard ratio is based on stratified Cox proportional hazard model stratified by the stratified factors used in randomization.[4]
†*P* value was calculated using a stratified log-rank test.[4]

Important Safety Information

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- During induction and consolidation, perform an ECG prior to initiation and then once weekly during VANFLYTA treatment or more frequently as clinically indicated. During maintenance, perform ECGs prior to initiation, once weekly for at least the first month following dose initiation and escalation, and as clinically indicated thereafter.
- Perform ECG monitoring of the QT interval more frequently in patients who are at significant risk of developing QT interval prolongation and torsades de pointes, or following dose escalation.

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In patients with newly diagnosed *FLT3*-ITD+ AML treated with VANFLYTA plus standard chemotherapy

VANFLYTA was studied for complete remission and composite complete remission[1,21]

Secondary Endpoints[1,21]

Parameter	VANFLYTA + Standard Chemotherapy (n=268)	Placebo + Standard Chemotherapy (n=271)
CR %; 95% CI	55; (48.7-60.9)	55; (49.2-61.4)
CRc* %; 95% CI	72; (65.8-77.0)	65; (58.9-70.6)

Primary EFS analysis (with ITF defined as not achieving CR by Day 42 from the start of the last induction cycle) did not show a statistical significance between the 2 study arms (HR=0.916 [95% CI=0.75-1.11]).[4,21]

- Since EFS was not statistically significant, formal hierarchical testing on other secondary endpoints, including CR and CRc was stopped; their results are provided descriptively[21]

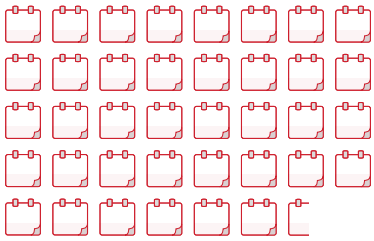
*CRc is equal to complete remission (CR) + CR with incomplete neutrophil or platelet recovery (CRi) after induction.[21]

In patients with newly diagnosed *FLT3*-ITD+ AML treated with VANFLYTA plus standard chemotherapy

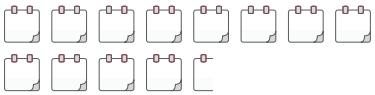
VANFLYTA duration of complete remission vs standard chemotherapy alone[1]

Exploratory Endpoint: Duration of Complete Remission†

38.6 MONTHS
median duration of CR with **VANFLYTA + standard chemotherapy**
(95% CI: 21.9-NE; n=268)



12.4 MONTHS
median duration of CR with **placebo + standard chemotherapy**
(95% CI: 8.8-22.7; n=271)



†By independent review committee.[4]

ITF=induction treatment failure; NE=not estimable.

Important Safety Information

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- Monitor and correct hypokalemia and hypomagnesemia prior to and during treatment. Maintain electrolytes in the normal range. Monitor electrolytes and ECGs more frequently in patients who experience diarrhea or vomiting.

Please see additional Important Safety Information on pages 12-13 and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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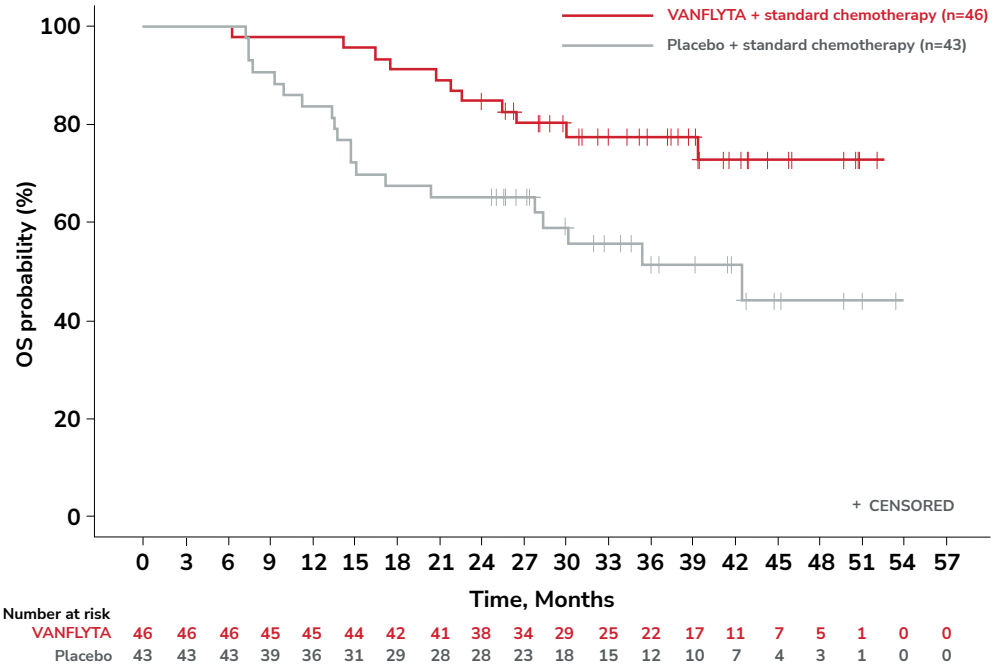
Exploratory subgroup analysis of overall survival in patients who did not undergo allogeneic HSCT and received maintenance therapy*

Overall Survival in Patients Who Received Maintenance Therapy* Without Allogeneic HSCT[22]



- This was an exploratory subgroup analysis of 43% of patients (89/208) who received maintenance therapy* with VANFLYTA or placebo following consolidation chemotherapy. OS HR: 0.40 (95% CI: 0.19-0.84)[1]
- ~60% (170/268) of patients who entered consolidation phase in the VANFLYTA arm did not get a transplant[4]
- Exploratory, subgroup analysis—interpret with caution. Not powered to detect statistical significance

Consider VANFLYTA for maintenance monotherapy* following consolidation chemotherapy in adults with newly diagnosed *FLT3*-ITD+ AML[1]

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Important Safety Information

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- Reduce the VANFLYTA dose if QTc increases to greater than 480 ms and less than 500 ms. Interrupt and reduce the VANFLYTA dose if QTc increases to greater than 500 ms. Permanently discontinue VANFLYTA in patients who develop recurrent QTc greater than 500 ms or QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

Please see additional Important Safety Information on pages 12-13 and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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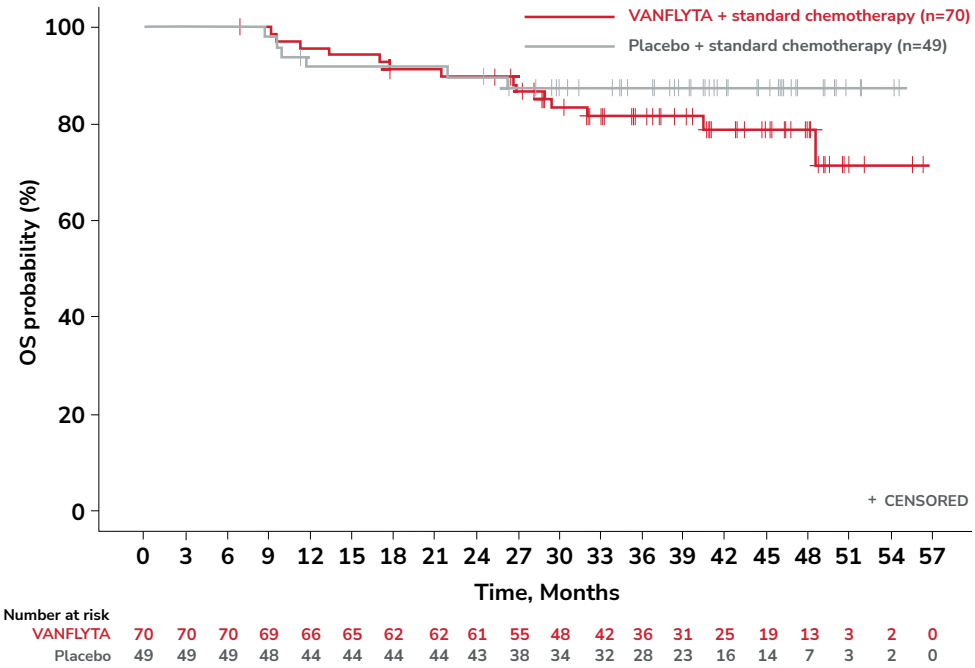
Exploratory subgroup analysis of overall survival in patients who underwent allogeneic HSCT and received maintenance therapy*

Overall Survival in Patients Who Received Maintenance Therapy* With Allogeneic HSCT[22†]



- This was an exploratory subgroup analysis of 57% of patients (119/208) who received maintenance therapy* with VANFLYTA or placebo following HSCT. OS HR: 1.62 (95% CI: 0.62-4.22)[1]
- Exploratory, subgroup analysis—interpret with caution. Not powered to detect statistical significance

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

†Received protocol-specified allogeneic HSCT.[4]

Important Safety Information

Warnings and Precautions (cont.)

VANFLYTA REMS

- Requirements include:
  - Prescribers must be certified in the VANFLYTA REMS by enrolling and completing training.
  - Prescribers must counsel patients receiving VANFLYTA about the risk of QT prolongation, torsades de pointes, and cardiac arrest, and provide patients with a Patient Wallet Card.
  - Pharmacies that dispense VANFLYTA must be certified with the VANFLYTA REMS and must verify prescribers are certified through the VANFLYTA REMS.
- Further information is available at www.VANFLYTAREMS.com or by telephone at 1-855-212-6670.

Please see additional Important Safety Information on pages 12-13 and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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In patients with newly diagnosed *FLT3*-ITD+ AML treated with VANFLYTA plus standard chemotherapy

VANFLYTA common adverse reactions in *FLT3*-ITD+ AML[1]

Most Common (>20%) ARs, including laboratory abnormalities[1]

	VANFLYTA + Chemotherapy* (n=265)		Placebo + Chemotherapy* (n=268)	
Laboratory Abnormality/AR	**All Grades %**	**Grade 3 or 4 %**	**All Grades %**	**Grade 3 or 4 %**
Lymphocytes decreased	60	57	55	51
Potassium decreased	59	22	56	18
Albumin decreased	53	1.6	45	4.3
Phosphorus decreased	52	22	48	19
Alkaline phosphatase increased	51	1.6	47	1.9
Magnesium decreased	44	2	42	1.1
Febrile neutropenia	44	43	42	41
Diarrhea	42	8	39	8
Mucositis	38	5	33	4.1
Nausea	34	1.5	31	1.9
Calcium decreased	33	2.4	27	1.6
Abdominal pain	30	2.3	22	1.1
Sepsis	30	19	26	20
Neutropenia	29	26	14	12
Headache	28	0	20	0.7
Creatine phosphokinase increased	26	2.5	7	0.5
Vomiting	25	0	20	1.5
Upper respiratory tract infection	21	2.6	12	3

- Serious ARs in ≥5% of patients who received VANFLYTA plus chemotherapy were: febrile neutropenia (11%). Fatal ARs occurred in 10% of patients who received VANFLYTA plus chemotherapy, including sepsis (5%), fungal infections (0.8%), brain edema (0.8%), and one case each of febrile neutropenia, pneumonia, cerebral infarction, acute respiratory distress syndrome, pulmonary embolism, ventricular dysfunction, and cardiac arrest[1]
- With VANFLYTA, 34% of patients experienced a dose interruption due to ARs, 19% had a dose reduction, and 20% discontinued[1]
  - ARs which required dosage interruption in ≥2% of patients in the VANFLYTA arm included neutropenia (11%), thrombocytopenia (5%), and myelosuppression (3%)
  - ARs which required dosage reductions in ≥2% of patients in the VANFLYTA arm were neutropenia (9%), thrombocytopenia (5%), and electrocardiogram QT prolonged (4%)
  - The most frequent (≥2%) AR which resulted in permanent discontinuation in the VANFLYTA arm was sepsis (5%)

*The denominator used to calculate the rate varied from 199 to 260 in VANFLYTA + chemotherapy and from 187 to 267 in placebo + chemotherapy based on the number of patients with a baseline value and at least one post-treatment value.[1]

AR=adverse reaction.

Important Safety Information

Warnings and Precautions (cont.)

Embryo-Fetal Toxicity

- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

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26.5 mg | 17.7 mg

For eligible patients with newly diagnosed *FLT3*-ITD+ AML

VANFLYTA is a once-daily oral treatment from induction through consolidation and maintenance[1]*

VANFLYTA Dosing Snapshot[1]

	Induction	Consolidation	Maintenance*
Dose	 35.4 mg orally once daily	 35.4 mg orally once daily	 26.5 mg orally once daily for Days 1-14 of the first cycle if QTcF is ≤450 ms  Increase to 53 mg once daily on Day 15 of the first cycle if QTcF is ≤450 ms  Maintain 26.5 mg once daily if QTcF >500 ms was observed during induction or consolidation
Administration	Once daily orally, with or without food		
Initiation	Day 8 for 7+3 regimen Day 6 for 5+2 regimen†	Day 6	Day 1
Duration	2 weeks Days 8-21	2 weeks Days 6-19	Once daily with no breaks between cycles
Cycles (28 days)	Up to 2	Up to 4	Up to 36

Tablets shown are not actual size.

For patients who proceed to HSCT, VANFLYTA should be stopped 7 days before the start of a conditioning regimen.[1]

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

LEARN MORE about VANFLYTA dosing
VANFLYTAhcp.com/en/dosing

†For 5+2 regimen as the second induction cycle, VANFLYTA will be given on Days 6-19.[1]

QTcF=the QT interval corrected by Fridericia's formula.

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VANFLYTA® quizartinib tablets
26.5 mg | 17.7 mg

Indication and Important Safety Information

Indication

VANFLYTA® (quizartinib) is indicated 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 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:
VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Important Safety Information

WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

- **VANFLYTA prolongs the QT interval in a dose- and concentration-related manner. Prior to VANFLYTA administration and periodically, monitor for hypokalemia or hypomagnesemia, and correct deficiencies. Perform electrocardiograms (ECGs) to monitor the QTc at baseline, weekly during induction and consolidation therapy, weekly for at least the first month of maintenance, and periodically thereafter.**
- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

Contraindications

- VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

Warnings and Precautions

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING)

- VANFLYTA prolongs the QT interval in a dose- and concentration-dependent manner. The mechanism of QTc interval prolongation is via inhibition of the slow delayed rectifier potassium current, I_{Ks}, as compared to all other medications that prolong the QTc interval, which is via the rapid delayed rectifier potassium current, I_{Kr}.
- The level of QTc prolongation with VANFLYTA that predicts the risk of cardiac arrhythmias is unclear. Inhibition of I_{Ks} and I_{Kr} may leave patients with limited reserve, leading to a higher risk of QT prolongation and serious cardiac arrhythmias, including fatal outcomes. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with VANFLYTA.
- Among 1,081 VANFLYTA-treated AML patients in clinical trials, severe cardiac arrhythmias occurred primarily during induction and included torsades de pointes (0.2%), cardiac arrest (0.6%, including 0.4% fatal), and ventricular fibrillation (0.1%).
- Of the 265 patients who received VANFLYTA in the clinical trial, 2.3% had a QTcF >500 ms and 10% had an increase of >60 ms from baseline. The trial excluded patients with a QTcF ≥450 ms or other factors that increased the risk of QT prolongation or arrhythmic events (eg, NYHA Class III/IV congestive heart failure, hypokalemia, or a family history of long QT interval syndrome).
- Avoid use in patients who are at significant risk of developing torsades de pointes, including uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, tachyarrhythmias, uncontrolled hypertension, high-degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.

Please see Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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Indication and Important Safety Information (cont.)

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- During induction and consolidation, perform an ECG prior to initiation and then once weekly during VANFLYTA treatment or more frequently as clinically indicated. During maintenance, perform ECGs prior to initiation, once weekly for at least the first month following dose initiation and escalation, and as clinically indicated thereafter.
- Perform ECG monitoring of the QT interval more frequently in patients who are at significant risk of developing QT interval prolongation and torsades de pointes, or following dose escalation.
- Monitor and correct hypokalemia and hypomagnesemia prior to and during treatment. Maintain electrolytes in the normal range. Monitor electrolytes and ECGs more frequently in patients who experience diarrhea or vomiting.
- Reduce the VANFLYTA dose if QTc increases to greater than 480 ms and less than 500 ms. Interrupt and reduce the VANFLYTA dose if QTc increases to greater than 500 ms. Permanently discontinue VANFLYTA in patients who develop recurrent QTc greater than 500 ms or QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

VANFLYTA REMS

- Requirements include:
  - Prescribers must be certified in the VANFLYTA REMS by enrolling and completing training.
  - Prescribers must counsel patients receiving VANFLYTA about the risk of QT prolongation, torsades de pointes, and cardiac arrest, and provide patients with a Patient Wallet Card.
  - Pharmacies that dispense VANFLYTA must be certified with the VANFLYTA REMS and must verify prescribers are certified through the VANFLYTA REMS.
- Further information is available at www.VANFLYTAREMS.com or by telephone at 1-855-212-6670.

Embryo-Fetal Toxicity

- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

Adverse Reactions

- The most common (>20%) adverse reactions, including laboratory abnormalities, were lymphocytes decreased (60%), potassium decreased (59%), albumin decreased (53%), phosphorus decreased (52%), alkaline phosphatase increased (51%), magnesium decreased (44%), febrile neutropenia (44%), diarrhea (42%), mucositis (38%), nausea (34%), calcium decreased (33%), abdominal pain (30%), sepsis (30%), neutropenia (29%), headache (28%), creatine phosphokinase increased (26%), vomiting (25%), and upper respiratory tract infection (21%).

Drug Interactions

- **Strong CYP3A Inhibitors:** Reduce the VANFLYTA dose due to increased quizartinib systemic exposure.
- **Strong or Moderate CYP3A Inducers:** Avoid concomitant use due to decreased quizartinib systemic exposure.
- **QT Interval Prolonging Drugs:** VANFLYTA Prolongs the QT/QTc interval. Monitor patients more frequently with ECG if co-administration with drugs known to prolong the QT interval is required.
- **Breast Cancer Resistant Protein (BCRP) substrates:** Avoid concomitant use as it may increase the risk of BCRP substrate-associated adverse reactions. If concomitant use is unavoidable, monitor patients more frequently for BCRP substrate-associated adverse reactions and decrease the BCRP substrate dosage(s) according to their respective Prescribing Information.

Use in Specific Populations

- Advise women not to breastfeed during treatment with VANFLYTA and for one month after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc., at 1-877-437-7763 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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For treatment-eligible patients with newly diagnosed *FLT3*-ITD+ AML

Start and stay with VANFLYTA—the only FLT3 inhibitor FDA-approved for use in INDUCTION, CONSOLIDATION, AND MAINTENANCE[1-3]*

*In patients without prior allogeneic HSCT. Please see Full Indication, including Limitations of Use, below.

Quizartinib (VANFLYTA) is recommended as a treatment option across all 3 treatment phases specifically for *FLT3*-ITD+ AML[1,2]†

†See the NCCN Guidelines® at NCCN.org for the full recommendations.

Superior overall survival with a 22% reduction in risk of death vs placebo[1,4]

- QuANTUM-First is a Phase 3, randomized, double-blind, placebo-controlled study of 539 patients, ages 18-75, with newly diagnosed *FLT3*-ITD+ AML. Patients were randomized to placebo (n=271) or VANFLYTA (n=268). Primary endpoint was overall survival[1]
- Patients with newly diagnosed *FLT3*-ITD+ AML taking VANFLYTA in combination with standard chemotherapy demonstrated superior overall survival vs placebo plus standard chemotherapy alone. HR: 0.78‡ (95% CI: 0.62-0.98); 2-sided *P*=0.0324[1,4]

Exploratory subgroup analysis: QuANTUM-First efficacy in maintenance phase[1,22]

- In an exploratory subgroup analysis of patients (89/208) who received maintenance therapy* with VANFLYTA or placebo following consolidation chemotherapy, the OS HR was 0.40 (95% CI: 0.19-0.84)[1]
- Of 57% of patients (119/208) who received maintenance therapy* with VANFLYTA or placebo following HSCT, the OS HR was 1.62 (95% CI: 0.62-4.22)[1]
- Exploratory, subgroup analysis—interpret with caution. Not powered to detect statistical significance

‡Hazard ratio is based on stratified Cox proportional hazard model stratified by the stratified factors used in randomization.[4]

Indication

VANFLYTA® (quizartinib) is indicated 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 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:
VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Important Safety Information

WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

- **VANFLYTA prolongs the QT interval in a dose- and concentration-related manner. Prior to VANFLYTA administration and periodically, monitor for hypokalemia or hypomagnesemia, and correct deficiencies. Perform electrocardiograms (ECGs) to monitor the QTc at baseline, weekly during induction and consolidation therapy, weekly for at least the first month of maintenance, and periodically thereafter.**
- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

Contraindications

- VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

START AND STAY with VANFLYTA
for your eligible *FLT3*-ITD+ AML patients—visit VANFLYTAhcp.com

ENROLL TODAY to prescribe VANFLYTA
at www.VANFLYTAREMS.com or by calling 1-855-212-6670

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