Daiichi-Sankyo

access central™

A single source for support

VANFLYTA®
(quizartinib) tablets
26.5 mg | 17.7 mg

Patient Enrollment Form

Completing this form allows your patient's eligibility for VANFLYTA support programs to be assessed. If your patient is deemed eligible for a support program, he or she will be informed and automatically enrolled in that particular program. The Physician Attestation on page 4 and Patient Consent on page 5 outline the terms and conditions associated with the completion of this form. Please make sure the patient receives a copy of the Patient Consent and that both the physician and the patient review all of the information provided prior to signing this form.

Important Safety Information

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

- **VANFLYTA® (quizartinib) 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.**

Indication

VANFLYTA 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.

Please see Important Safety Information on pages 6-9 and click here for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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Prior to completing the Patient Enrollment Form on page 3, please review the following information based on the type of pharmacy you will be using to provide VANFLYTA to your patients.

Option 1

If using a network specialty pharmacy, REMS-certified prescribers will submit prescriptions to that pharmacy directly, and the pharmacy will ship the medication to the patient or site of care.

Questions regarding the patient's prescription or need help with patient support services? **Contact your VANFLYTA network specialty pharmacy directly (see information below).**

How to use this form

- Complete all required fields on page 3
- Print it
- Obtain physician's signature
- Obtain patient's/representative's signature
- Fax the completed form to your specialty pharmacy

Upon receiving this form, the specialty pharmacy will

- Conduct a benefits investigation and assist with the completion of a prior authorization
- Assess patient eligibility for the VANFLYTA Savings Program
- Assess patient eligibility for the VANFLYTA QuickStart Program
- Refer the patient to the VANFLYTA Patient Assistance Program, if applicable
- Fill the prescription upon confirmation of coverage and prescriber certification in the VANFLYTA REMS

VANFLYTA Network Specialty Pharmacies

Biologics by McKesson
Phone: 1-800-850-4306
Fax: 1-800-823-4506

Onco360® Oncology Pharmacy
Phone: 1-877-662-6633
Fax: 1-877-662-6355

Option 2

If using an office-, hospital-, or health system-based pharmacy that is REMS-certified, such pharmacy may order VANFLYTA from one of our specialty distributors for subsequent dispensing.

Questions regarding patient support services? **Please contact Daiichi Sankyo Access Central.**

How to use this form

- Request assistance from Daiichi Sankyo Access Central on page 3 (benefits investigation, VANFLYTA QuickStart Program, and/or VANFLYTA Patient Assistance Program eligibility check)
- Complete all required fields on page 3
- Print it
- Obtain physician's signature
- Obtain patient's/representative's signature
- Fax the completed form to Daiichi Sankyo Access Central

Daiichi Sankyo Access Central

Phone: 1-866-4-DSI-NOW (1-866-437-4669)
Fax: 1-833-471-9988
Hours of operation: 8 AM to 6 PM ET, Monday through Friday
Website: www.DSIAccessCentral.com

If you are licensed to practice in the state of New York, you must also submit the prescription via ePrescribing.

If you feel your patient may be eligible for the Patient Assistance Program (PAP), please fax the completed form to DSI Access Central at 1-833-471-9988. This form does not need to be sent to Biologics or Onco360 for patients eligible for the PAP.

Important Safety Information (cont'd)

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.

Please see Important Safety Information on pages 6-9 and click here for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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VANFLYTA patient enrollment form

*Required Fields

For prescribers using network specialty pharmacies
Please select your or your patient's preferred pharmacy:
☐ Biologics by McKesson ☐ Onco360® Oncology Pharmacy

For office-, hospital-, or system-based pharmacies
Which programs does your patient need assistance with?
☐ Benefits Investigation ☐ VANFLYTA QuickStart Program ☐ VANFLYTA Patient Assistance Program

This form is not required for patients to enroll in the VANFLYTA Savings Program for commercially insured patients. Please visit www.dsiaccesscentral.com/hcp/vanflyta to apply.

1 PATIENT INFORMATION

***First Name:** ***Last Name:** ***Date of Birth:** - - ***Sex:** ☐ Male ☐ Female
***Phone:** - - **Phone Type:** ☐ Home ☐ Mobile ☐ Work **Email:**
***Address:** ***City:** ***State:** ***ZIP:**
Permission to contact patient? ☐ Yes ☐ No **Best time to contact patient?** ☐ Morning ☐ Afternoon ☐ Evening
Alternate Contact/Caregiver: **Relationship:** **Phone:** - -

2 PATIENT INSURANCE INFORMATION

☐ Uninsured **Insurance Type:** ☐ Commercial/Private ☐ Medicare ☐ Medicaid ☐ Other

HEALTH PLAN INFORMATION
***Plan Name:**
***Plan Phone Number:** - -
***Subscriber First Name:** ***Last Name:**
***Subscriber Date of Birth:** - -
***Policy ID:** **Group No.:**
Prior authorization submission date:

PRESCRIPTION COVERAGE INFORMATION
Plan Name:
Plan Phone Number: - -
Prescription Policy ID:
Prescription Group No.:
RxBIN: **RxPCN:**

3 HEALTHCARE PROVIDER INFORMATION

***First Name:** ***Last Name:** ***Practice Name:**
***UPIN/NPI:** **Office Contact:** ***Phone:** - -
***Fax:** - - **Email:**
***Address:** ***City:** ***State:** ***ZIP:**

4 VANFLYTA PRESCRIPTION INFORMATION

Completing the QuickStart prescription is optional but allows shipment of a 14-day supply, at no cost, to eligible patients with an FDA-approved diagnosis, who do not receive a coverage decision within 5 business days. Call Daiichi Sankyo Access Central at 1-866-437-4669 for more information.

***First Name:** ***Last Name:** ***Date of Birth:** - - ***Diagnosis Code (ICD-10-CM):**
Product Name: VANFLYTA (quizartinib) tablets **DISPENSE AS WRITTEN** **FLT3 Test Date:** - -
Therapy to be provided: ☐ Inpatient ☐ Outpatient Hospital ☐ Outpatient Physician's Office ☐ Other (specify)
Therapy will be: ☐ In combination with chemo ☐ Maintenance Monotherapy **Planned date of VANFLYTA therapy:** - -

***DOSING INSTRUCTIONS**
*Take ☐ **26.5 mg** / ☐ **17.7 mg** tablet(s) of *once daily *Quantity: *Refills:

✓ ***Prescriber Signature:** _____
Date: - -

QuickStart prescription (optional)
Select one of the following: Dispense 14-day supply. Up to 1 refill.
☐ Take **26.5-mg** tablet(s) once daily for 14 days.
☐ Take **17.7-mg** tablet(s) once daily for 14 days.

Prescriber Signature: _____
Date: - -

Prescriber DEA Number: **Collaborating Provider Name:** **UPIN/NPI:**

5 PHYSICIAN ATTESTATION

I confirm that I have read and understood the Physician Attestation on page 4 of this form and agree to the terms explained therein.

✓ ***Physician Signature:** _____ **Date:** - -

6 PATIENT CONSENT

I confirm that I have read and understood the Patient Consent on page 5 of this form and agree to the terms explained therein.

***Name:**

✓ ***Patient Signature:** _____ **Date:** - -

For Representatives: If a representative for the patient needs to sign this form, please indicate the representative's authority to sign on behalf of the patient (eg, healthcare power of attorney, healthcare proxy, court-appointed legal guardian). Healthcare office staff cannot sign on behalf of the patient.

Reason for Authority:

Representative Attestation: I confirm that I have the legal right to sign this form (as stated above) on behalf of the patient. I confirm that I have read and understood the Patient Consent on page 5 of this form and agree to the terms explained therein.

Representative Signature: _____ **Date:** - -

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Physician attestation

By providing my signature on page 3 of this form, I attest that I am the prescribing healthcare provider and have determined that prescribing VANFLYTA (quizartinib) tablets is medically appropriate and have explained the reasons for doing so to my patient. I also agree to submit requests to Daiichi Sankyo Access Central on behalf of my patient so that his or her eligibility can be evaluated to determine access to various assistance programs.

I certify that I have received the necessary consent from my patient to release the information referenced above and other protected health information (as defined by the Health Insurance Portability and Accountability Act [HIPAA] of 1996) to Daiichi Sankyo Access Central and/or its service providers. The patient has confirmed his or her consent by reading page 5 of this form and providing his or her signature on page 3 of this form. I authorize Daiichi Sankyo Access Central and its service providers, on behalf of my patients, to forward a prescription for VANFLYTA by fax or another mode of delivery to a pharmacy that Daiichi Sankyo has authorized to dispense VANFLYTA. I also certify that this prescription complies with all applicable state and local laws.

I agree to notify Daiichi Sankyo Access Central or its service providers if I become aware at any time of changes in my patient's circumstances that would affect his or her eligibility for any Daiichi Sankyo Access Central programs, including but not limited to changes in health insurance status or coverage, financial status, residency status in the United States, or the indication for which VANFLYTA has been prescribed for my patient. I understand that Daiichi Sankyo reserves the right to change or terminate any Daiichi Sankyo Access Central services (including the VANFLYTA Copay Program or VANFLYTA Patient Assistance Program) at any time or to refuse to provide VANFLYTA to any patient under the VANFLYTA Patient Assistance Program.

If my patient obtains VANFLYTA via the VANFLYTA Patient Assistance Program, I attest that I understand the following:

- No third party or patient can be charged for VANFLYTA under such program
- No free product should be sold, traded, or distributed for sale
- Any free drug provided is not contingent upon future purchase or prescribing of VANFLYTA

By signing page 3 of this form, I certify that a copy of the Patient Consent has been given to the patient named on page 3 or his or her representative.

Patient consent

Release of personal information

By providing my signature on page 3 of this form, I authorize my physician(s), healthcare provider(s), health insurance company, and my pharmacy to disclose information about me (for example, my name, address, and insurance policy number) and my medical condition (for example, my diagnosis or medications) to Daiichi Sankyo and its third-party vendors, suppliers, and other service providers supporting Daiichi Sankyo Access Central (herein described collectively as "service providers"). I authorize my specialty pharmacy and other service providers supporting Daiichi Sankyo Access Central to share information about me with each other. I recognize that this type of personally identifiable information (PII) could include spoken or written facts about my health or healthcare or copies of records about my health and insurance benefits provided by my healthcare provider(s) or health plan. My decision to sign this form (or to not sign this form) will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage.

Use of personal information

I understand that the service providers or pharmacy could use or provide my information in one or more of the following ways:

- Assess my eligibility and assist with my enrollment in a Daiichi Sankyo support program, including the VANFLYTA Copay Program or the VANFLYTA Patient Assistance Program, and contact me (and/or my legal representative) about my eligibility and enrollment status
- Verify, investigate, and help coordinate my coverage for VANFLYTA with my health insurance company
- Make referrals to other independent programs or alternate funding sources that may be able to provide me with assistance as allowed under the law, if necessary
- Assist with analyses of the efficiencies and performance of the services provided by service providers
- Provide me (and/or my legal representative) with educational materials, information, and support relating to the Daiichi Sankyo Access Central services
- Provide support to appeal any insurance denials

In some instances, the service providers may de-identify my information and use or disclose the de-identified information (in individual or aggregated form) for any legitimate business purposes. I understand that the service providers will make reasonable efforts to keep my information private; however, I understand that once my information has been disclosed to the service providers, how the service providers further disclose my information may no longer be protected under federal and state privacy laws. I understand that Daiichi Sankyo Access Central is a component of Daiichi Sankyo and that the service providers may be compensated by Daiichi Sankyo. My healthcare providers and my pharmacy may also receive remuneration, or payment, for disclosing my information pursuant to this consent document.

Consent terms

This consent will last for 3 years from the date on this form or until I am no longer receiving VANFLYTA or enrolled in any Daiichi Sankyo Access Central services. I recognize that I do not have to sign the consent on page 3, but if I do not, I will not be able to have my insurance coverage verified, be given referrals for alternative funding sources, or have access to other services provided by or on behalf of Daiichi Sankyo Access Central. My decision to sign this form will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage. I may cancel this consent at any time by contacting Daiichi Sankyo Access Central at 1-866-4-DSI-NOW. By doing so, I revoke my consent for my healthcare provider to disclose my health information to Daiichi Sankyo or its service providers as well as discontinue my participation in the support program. I recognize that revoking my consent will not affect the use or the disclosure of health information that was already disclosed before my cancellation. I confirm that I have received a copy of this consent, and I know I have a right to see or copy the information my healthcare providers or payers have given to the service providers.

Additional information to assess eligibility for the VANFLYTA Patient Assistance Program

I agree to allow Daiichi Sankyo and its associated service providers to use my demographic information, including but not limited to my name, date of birth, and/or address as needed to access my credit information and information derived from public and other sources. This includes information from a consumer reporting agency (credit bureau) to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility under the VANFLYTA Patient Assistance Program. Daiichi Sankyo and its associated service providers reserve the right to request additional documents and information at any time. I agree to notify my healthcare providers if I undergo any changes that would, to my knowledge, affect my eligibility, including, but not limited to, changes in health insurance status or coverage, financial status, and my residing status in the United States.

The terms of this document are governed by and interpreted in accordance with the laws of the state of New Jersey, excluding New Jersey conflict of law rules, and applicable federal law.

Important Safety Information

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

- **VANFLYTA® (quizartinib) 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.**

Indication

VANFLYTA 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.

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}.

Therefore, 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.

Of the 1,081 patients with AML treated with VANFLYTA in clinical trials, torsades de pointes occurred in approximately 0.2% of patients, cardiac arrest occurred in 0.6% of patients, including 0.4% with a fatal outcome, and 0.1% of patients experienced ventricular fibrillation. These severe cardiac arrhythmias occurred predominantly during the induction phase.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Of the 265 patients with newly diagnosed FLT3-ITD–positive AML treated with VANFLYTA in combination with chemotherapy in the clinical trial, 2.3% were found to have a QTcF greater than 500 ms and 10% of patients had an increase from baseline QTcF greater than 60 ms. The clinical 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 or IV congestive heart failure, hypokalemia, family history of long QT interval syndrome).

Therefore, 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.

Do not initiate treatment with VANFLYTA if the QTcF interval is greater than 450 ms. Do not use VANFLYTA in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes. Perform an ECG and correct electrolyte abnormalities prior to initiation of treatment with VANFLYTA.

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.

Do not escalate the dose if QTcF is greater than 450 ms. 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 with VANFLYTA. Maintain electrolytes in the normal range. Monitor electrolytes and ECGs more frequently in patients who experience diarrhea or vomiting. Monitor patients more frequently with ECGs if coadministration of VANFLYTA with 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. Reduce VANFLYTA if QTc increases to greater than 480 ms and less than 500 ms. Interrupt and reduce VANFLYTA 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 is available only through a restricted program under a REMS.

VANFLYTA REMS

VANFLYTA is available only through a restricted distribution program under a REMS called the VANFLYTA REMS because of the serious risk of QT prolongation, torsades de pointes, and cardiac arrest.

Notable requirements of the VANFLYTA REMS include the following:

- 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 about the VANFLYTA REMS is available at www.VANFLYTAREMS.com or by telephone at 1-855-212-6670.

Important Safety Information (cont'd)

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 safety of VANFLYTA (35.4 mg orally once daily with chemotherapy, 26.5 mg to 53 mg orally once daily as maintenance) in adult patients with newly diagnosed FLT3-ITD positive AML is based on QuANTUM-First.

Serious adverse reactions in ≥5% of patients who received VANFLYTA plus chemotherapy were: febrile neutropenia (11%). Fatal adverse reactions 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.

Permanent discontinuation due to an adverse reaction in patients in the VANFLYTA plus chemotherapy arm occurred in 20% of patients. The most frequent (≥2%) adverse reaction which resulted in permanent discontinuation in the VANFLYTA arm was sepsis (5%).

Dosage interruptions of VANFLYTA due to an adverse reaction occurred in 34% of patients. Adverse reactions which required dosage interruption in ≥2% of patients in the VANFLYTA arm included neutropenia (11%), thrombocytopenia (5%), and myelosuppression (3%).

Dose reductions of VANFLYTA due to an adverse reaction occurred in 19% of patients. Adverse reactions which required dosage reductions in ≥2% of patients in the VANFLYTA arm were neutropenia (9%), thrombocytopenia (5%), and electrocardiogram QT prolonged (4%).

The most common adverse reactions (≥10% with a difference between arms of ≥2% compared to placebo), including laboratory abnormalities, were decreased lymphocytes, decreased potassium, decreased albumin, decreased phosphorus, increased alkaline phosphatase, decreased magnesium, febrile neutropenia, diarrhea, mucositis, nausea, decreased calcium, abdominal pain, sepsis, neutropenia, headache, increased creatine phosphokinase, vomiting, upper respiratory tract infections, hypertransaminasemia, thrombocytopenia, decreased appetite, fungal infections, epistaxis, increased potassium, herpesvirus infections, insomnia, QT prolongation, increased magnesium, increased sodium, dyspepsia, anemia, and eye irritation.

Drug Interactions

Strong CYP3A Inhibitors

VANFLYTA is a CYP3A substrate. Concomitant use of VANFLYTA with a strong CYP3A inhibitor increases quizartinib systemic exposure, which may increase the risk of VANFLYTA adverse reactions. Reduce the dosage of VANFLYTA.

Strong or Moderate CYP3A Inducers

Concomitant use of VANFLYTA with strong or moderate CYP3A inducers decreases quizartinib systemic exposure, which may reduce VANFLYTA efficacy. Avoid concomitant use of VANFLYTA with strong or moderate CYP3A inducers.

QT Interval–Prolonging Drugs

VANFLYTA prolongs the QT/QTc interval. Coadministration of VANFLYTA with other drugs that prolong the QT interval may further increase the incidence of QT prolongation. Monitor patients more frequently with ECG if coadministration of VANFLYTA with drugs known to prolong the QT interval is required.

Important Safety Information (cont'd)

Use in Specific Populations

Pregnancy

VANFLYTA can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus.

Lactation

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

Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential within 7 days before starting treatment with VANFLYTA.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

Infertility

Females

Based on findings from animal studies, VANFLYTA may impair female fertility. These effects on fertility were reversible.

Males

Based on findings from animal studies, VANFLYTA may impair male fertility. These effects on fertility were reversible.

Pediatric Use

Safety and effectiveness of VANFLYTA have not been established in pediatric patients.

Geriatric Use

No overall differences in safety or efficacy were observed between patients 65 years of age and older and younger adult patients.

Renal Impairment

No dosage adjustment is recommended in patients with mild to moderate renal impairment (CLcr 30 to 89 mL/min). VANFLYTA has not been studied in patients with severe renal impairment (CLcr <30 mL/min).

Hepatic Impairment

No dosage adjustment is recommended in patients with mild hepatic impairment or moderate hepatic impairment. VANFLYTA has not been studied in patients with severe hepatic impairment.

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 click here for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

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