



KOMZIFTI™ (ziftomenib) Added to National Comprehensive Cancer Network® (NCCN) Guidelines for Acute Myeloid Leukemia (AML)

November 25, 2025

KOMZIFTI, the first and only once-daily FDA-approved menin inhibitor for R/R *NPM1*-mutated AML, is now commercially available in the United States

SAN DIEGO and TOKYO, Nov. 25, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced KOMZIFTI™ (ziftomenib), the first and only once-daily oral menin inhibitor to be approved for adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible *NPM1* mutation, has been included in the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a Category 2A recommended treatment option for adults with relapsed/refractory AML with *NPM1* mutation.

KOMZIFTI received full approval by the U.S. Food and Drug Administration on November 13, 2025, for the treatment of adults with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options. The approval was supported by data from the KOMET-001 clinical trial, including a 21.4% CR/CRh rate and median duration of CR/CRh response of 5 months.^{1,2} KOMZIFTI is now commercially available to prescribers in the U.S. and is available for purchase from a limited network of specialty pharmacies and distributors.

"The addition of KOMZIFTI to the NCCN Guidelines® in Oncology underscores the potential impact of KOMZIFTI for patients with R/R *NPM1*-mutated AML and supports our commitment to ensuring that patients have access to this important treatment option," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "*NPM1*-mutated disease carries a substantial risk of relapse and historically poor outcomes in the relapsed or refractory setting. We are pleased to have received inclusion in the NCCN guidelines so rapidly after FDA approval and are committed to making KOMZIFTI available to patients in the United States."

About KOMZIFTI™

KOMZIFTI (ziftomenib) is an oral menin inhibitor approved for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options.

KOMZIFTI is in development for the front-line treatment of AML harboring *NPM1* mutations, *KMT2A* translocations and *FLT3* mutations, with the potential to be combined with approved therapies and benefit a broad spectrum of patients earlier in their disease course.

IMPORTANT SAFETY INFORMATION FOR KOMZIFTI FROM THE U.S. PRESCRIBING INFORMATION

Boxed WARNING: DIFFERENTIATION SYNDROME

Differentiation syndrome, which can be fatal, has occurred with KOMZIFTI. Signs and symptoms may include fever, joint pain, hypotension, hypoxia, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusions, pulmonary infiltrates, acute kidney injury, and rashes. If differentiation syndrome is suspected, interrupt KOMZIFTI, and initiate oral or intravenous corticosteroids with hemodynamic and laboratory monitoring until symptom resolution; resume KOMZIFTI upon symptom improvement.

WARNINGS AND PRECAUTIONS

Differentiation Syndrome

KOMZIFTI can cause fatal or life-threatening differentiation syndrome (DS). DS is associated with rapid proliferation and differentiation of myeloid cells. Symptoms of DS, including those seen in patients treated with KOMZIFTI, may include fever, hypoxia, joint pain, hypotension, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusions, acute kidney injury, and rashes.

In the clinical trial, DS occurred in 29 (26%) of 112 patients with R/R AML with an *NPM1* mutation who were treated with KOMZIFTI at the recommended dosage. DS was Grade 3 in 13% and fatal in two patients. In broader evaluation of all patients with any genetic form of AML treated with KOMZIFTI monotherapy in clinical trials, DS occurred in 25% of patients. Four fatal cases of DS occurred out of 39 patients with *KMT2A*-rearranged AML treated with KOMZIFTI. KOMZIFTI is not approved for use in patients with *KMT2A*-rearranged AML.

In the 112 patients with an *NPM1* mutation, DS was observed with and without concomitant hyperleukocytosis, in as early as 3 days and up to 46 days after KOMZIFTI initiation. The median time to onset was 15 days. Two patients experienced more than one DS event. Treatment was interrupted and resumed in 15 (13%) patients, while it was permanently discontinued in 2 (2%) patients.

Prior to starting treatment with KOMZIFTI, reduce the WBC counts to less than $25 \times 10^9/L$. If DS is suspected, interrupt KOMZIFTI, initiate oral or intravenous corticosteroids (e.g., dexamethasone 10 mg every 12 hours) for a minimum of 3 days with hemodynamic and laboratory monitoring. Resume treatment with KOMZIFTI at the same dose level when signs and symptoms improve and are Grade 2 or lower. Taper corticosteroids over a minimum of 3 days after adequate control or resolution of symptoms. Symptoms of DS may recur with premature discontinuation of corticosteroid treatment.

QTc Interval Prolongation

KOMZIFTI can cause QTc interval prolongation. In the clinical trial, QTc interval prolongation was reported as an adverse reaction in 12% of 112

patients treated with KOMZIFTI at the recommended dosage for R/R AML with an *NPM1* mutation. QTc interval prolongation was Grade 3 in 8% of patients. The heart-rate corrected QT interval (using Fridericia's method) (QTcF) was greater than 500 msec in 9% of patients, and the increase from baseline QTcF was greater than 60 msec in 12% of patients. KOMZIFTI dose reduction was required for 1% of patients due to QTc interval prolongation. QTc prolongation occurred in 14% of the 42 patients less than 65 years of age and in 10% of the 70 patients 65 years of age or older.

Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to treatment with KOMZIFTI. Perform an ECG prior to initiation of treatment with KOMZIFTI, and do not initiate KOMZIFTI in patients with QTcF > 480 msec. Perform an ECG at least once weekly for the first four weeks on treatment, and at least monthly thereafter. Interrupt KOMZIFTI if the QTc interval is > 500 ms or the change from baseline is > 60 ms (Grade 3). In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring may be necessary. Concomitant use of KOMZIFTI with drugs known to prolong the QTc interval may increase the risk of QTc interval prolongation, result in a greater increase in the QTc interval and adverse reactions associated with QTc interval prolongation, including Torsades de Pointes, other serious arrhythmias, and sudden death.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, KOMZIFTI can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with KOMZIFTI and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with KOMZIFTI and for 3 months after the last dose.

ADVERSE REACTIONS

Fatal adverse reactions occurred in 4 (4%) patients who received KOMZIFTI, including 2 with differentiation syndrome, 1 with infection, and 1 with sudden death. Serious adverse reactions were reported in 79% of patients who received KOMZIFTI. Serious adverse reactions occurring in ≥ 5% of patients included infection without an identified pathogen (29%), febrile neutropenia (18%), bacterial infection (16%), differentiation syndrome (16%), and dyspnea (6%).

Dosage interruption of KOMZIFTI due to an adverse reaction occurred in 54% of patients. Adverse reactions that required dose interruption in ≥ 2% of patients included infection without an identified pathogen (15%), differentiation syndrome (13%), febrile neutropenia (5%), pyrexia (4%), electrocardiogram QT prolonged (4%), leukocytosis (4%), bacterial infection (3%), cardiac failure (2%), cholecystitis (2%), diarrhea (2%), pruritus (2%), and thrombosis (2%). Dose reduction of KOMZIFTI due to an adverse reaction occurred in 4% of patients. Permanent discontinuation of KOMZIFTI due to an adverse reaction occurred in 21% of patients. Adverse reactions that required permanent discontinuation of KOMZIFTI in ≥ 2% of patients were infection without an identified pathogen (8%), bacterial infection (4%), cardiac arrest (2%), and differentiation syndrome (2%).

Most common (≥ 20%) adverse reactions, including laboratory abnormalities, were aspartate aminotransferase increased (53%), infection without an identified pathogen (52%), potassium decreased (52%), albumin decreased (51%), alanine aminotransferase increased (50%), sodium decreased (49%), creatinine increased (45%), alkaline phosphatase increased (41%), hemorrhage (38%), diarrhea (36%), nausea (35%), fatigue (34%), edema (30%), bacterial infection (28%), musculoskeletal pain (28%), bilirubin increased (27%), potassium increased (26%), differentiation syndrome (26%), pruritus (23%), febrile neutropenia (22%), and transaminases increased (21%).

DRUG INTERACTIONS

Drug interactions may occur when KOMZIFTI is concomitantly used with:

- Strong or Moderate CYP3A4 Inhibitors: Monitor patients more frequently for KOMZIFTI-associated adverse reactions.
- Strong or Moderate CYP3A4 Inducers: Avoid concomitant use of KOMZIFTI.
- Gastric Acid Reducing Agents: Avoid concomitant use of KOMZIFTI with proton pump inhibitors (PPIs), H2 receptor antagonists (H2RAs), or locally acting antacids. If concomitant use with H2RAs or locally acting antacids cannot be avoided, modify KOMZIFTI administration time.
 - Take KOMZIFTI 2 hours before or 10 hours after administration of an H2 receptor antagonist.
 - Take KOMZIFTI 2 hours before or 2 hours after administration of a locally acting antacid.
- Drugs that Prolong the QTc Interval: Avoid concomitant use of KOMZIFTI. If concomitant use cannot be avoided, obtain ECGs when initiating, during concomitant use, and as clinically indicated. Interrupt KOMZIFTI if the QTc interval is > 500 ms or the change from baseline is > 60 ms.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on findings in animals and its mechanism of action, KOMZIFTI can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to starting KOMZIFTI.

Lactation: Because of the potential for adverse reactions in the breastfed child, advise women not to breastfeed during treatment with KOMZIFTI and for 2 weeks after the last dose.

Infertility: Based on findings in animals, KOMZIFTI may impair fertility in females and males of reproductive potential.

Please see full [Prescribing Information](#), including **Boxed WARNING**.

About Kura Oncology

Kura Oncology is a biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Kura's pipeline of small molecule drug candidates is designed to target cancer signaling pathways and address high-need hematologic malignancies and solid tumors. Kura developed and is commercializing KOMZIFTI™, the FDA-approved once-daily, oral menin inhibitor for the treatment of adults with relapsed or refractory *NPM1*-mutated acute myeloid leukemia, and continues to pioneer advancements in menin inhibition and farnesyl transferase inhibition. For additional information, please visit the Kura website at <https://kuraoncology.com/> and follow us on [X](#) and [LinkedIn](#).

About Kyowa Kirin

Kyowa Kirin aims to discover and deliver novel medicines and treatments with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, Kyowa Kirin has invested in drug discovery and biotechnology innovation for more than 70 years and is currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients with high unmet medical needs, such as bone & mineral, intractable hematological diseases/hemato-oncology and rare diseases. A shared commitment to Kyowa Kirin's values, to sustainable growth, and to making people smile unites Kyowa Kirin across the globe. You can learn more about the business of Kyowa Kirin at www.kyowakirin.com.

Kura Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the potential impact of KOMZIFTI for patients with R/R *NPM1*-mutated AML and Kura's ability to provide patients with access to KOMZIFTI. Factors that may cause actual results to differ materially include the risk that KOMZIFTI may have unintended side effects; risks associated with market competition, market acceptance and commercialization of KOMZIFTI; the risk that the collaboration with Kyowa Kirin is unsuccessful; and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties Kura faces, please refer to Kura's periodic and other filings with the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Kura assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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1. KOMZIFTI (ziftomenib). Prescribing Information. San Diego, CA: Kura Oncology, Inc.; 2025.
2. [Wang et al. J Clin Oncol 43. 3381-3390 \(2025\)](#).



Source: Kura Oncology, Inc.