Kura Oncology and Kyowa Kirin Report Combination Data for KOMZIFTI™ (Ziftomenib) with Venetoclax and Azacitidine in Newly Diagnosed and Relapsed/Refractory AML

December 8, 2025

– 86% (32/37) CRc and 73% (27/37) CR in newly diagnosed NPM1-m AML, with 68% (17/25) of CRc responders achieving molecular MRD negativity by central NGS

– Median duration of complete response and overall survival not yet reached in newly diagnosed NPM1-m patients as of data cutoff –

– 65% (31/48) ORR in R/R NPM1-m AML, 83% (19/23) ORR in venetoclax-naïve –

– 41% (13/32) ORR in R/R KMT2A-r AML, 70% (7/10) ORR in venetoclax-naïve –

– Triplet combination was well tolerated in both newly diagnosed and relapsed/refractory settings; addition of ziftomenib did not increase toxicity beyond that expected with venetoclax/azacitidine alone –

– Ziftomenib's broad clinical development program spans multiple front-line and relapsed/refractory regimens across NPM1-m, FLT3-m and KMT2A-r AML subtypes –

– Company-sponsored registrational trials of ziftomenib in front-line AML are ongoing in both intensive chemotherapy-eligible and -ineligible patients –

– Kura Oncology to host a virtual investor event today, December 8, 2025, at 12:30 p.m. ET / 9:30 a.m. PT –

SAN DIEGO and TOKYO, Dec. 08, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced new data demonstrating a favorable safety profile and encouraging antileukemic activity for KOMZIFTI (ziftomenib) in combination with venetoclax and azacitidine (ven/aza) for the treatment of acute myeloid leukemia (AML) harboring *NPM1* mutations (*NPM1*-m) or *KMT2A* rearrangements (*KMT2A*-r). The ongoing KOMET-007 Phase 1a/1b trial evaluated patients in cohorts with newly diagnosed chemotherapy-ineligible AML and relapsed/refractory (R/R) AML. The new data are being reported today in two oral presentations at the 67th Annual Meeting of the American Society of Hematology (ASH 2025).

"The addition of ziftomenib to venetoclax and azacitidine has shown promising clinical activity, with 86% of newly diagnosed *NPM1*-mutated AML patients achieving composite complete remission and 68% attaining deep molecular MRD negativity, though median duration of response and overall survival remain immature," said Gail J. Roboz, M.D., the William S. Paley Professor in Clinical Medicine and Director of the Clinical and Translational Leukemia Program at Weill Cornell Medicine and a hematologist/oncologist at NewYork-Presbyterian/Weill Cornell Medical Center. "In relapsed/refractory *NPM1*-m and *KMT2A*-r AML, overall response rates of 65% and 41% were observed, rising to 83% and 70% in venetoclax-naïve patients, underscoring ziftomenib's potential benefit even in challenging settings. Importantly, inclusion of ziftomenib was generally well tolerated, paving the way for its integration into front-line and relapsed/refractory regimens through ongoing registrational trials."

KOMZIFTI (ziftomenib), the first and only once-daily oral menin inhibitor for adult patients with R/R AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options, has been approved by the U.S. Food and Drug Administration (FDA) and is commercially available in the United States.

Ziftomenib + Venetoclax/Azacitidine in Newly Diagnosed *NPM1*-m AML

The ongoing KOMET 007 Phase 1a/b trial (NCT05735184) evaluated 40 patients with newly diagnosed *NPM1*-m AML as of the September 24, 2025 data cutoff date. Of these, 58% (23/40) had an ECOG performance status of 2 and 37 were response evaluable.

Robust activity was observed in newly diagnosed *NPM1*-m AML, including high rates of durable morphologic complete responses (CRc 86%; CR 73%).

- 68% of CRc responders achieved molecular MRD negativity by central next-generation sequencing (NGS).
- Median duration of CR and OS were not reached at median follow-up of 26.1 weeks (range 1.6–54.1) as of the data cutoff.
- 68% of patients remained alive and on treatment or in long-term follow-up as of the data cutoff.
- Five chemotherapy-ineligible patients received HSCT; three received ziftomenib maintenance therapy thereafter.

The triplet combination was generally well tolerated in newly diagnosed *NPM1*-m AML, with a safety profile consistent with that reported for ven/aza alone. Rates of ziftomenib-related myelosuppression were low, and the median times to neutrophil and platelet recovery were also consistent with those expected for ven/aza alone. One case each of grade 2 differentiation syndrome and grade 3 investigator-assessed QTc prolongation were successfully managed without treatment discontinuation.

Ziftomenib + Venetoclax/Azacitidine in R/R AML

The ongoing KOMET 007 Phase 1a/b trial (NCT05735184) evaluated 83 patients with R/R *NPM1*-m or *KMT2A*-r AML as of the September 24, 2025 data cutoff date. Of these, 58% (48/83) had received prior venetoclax and 80 were response evaluable.

Robust activity was observed in patients with R/R *NPM1*-m AML, including among those previously treated with venetoclax.

- ORR was 65% and CRc rate was 48%, with CRc median duration of 39.9 weeks.
- In venetoclax-naïve patients, ORR was 83% and CRc rate was 70%, compared with 48% and 28%, respectively, in venetoclax-exposed patients.
- Median OS was 54.9 weeks (95% CI 32.0–NE).
- 14 patients received HSCT, five proceeded to ziftomenib maintenance therapy, and five were pending maintenance at time of data cutoff.

In patients with R/R *KMT2A*-r AML, encouraging activity was also observed.

- ORR was 41% and CRc rate was 28%, with CRc median duration of 12.4 weeks.
- In venetoclax-naïve patients, ORR was 70% and CRc rate was 60%.
- Median OS was 21.1 weeks (95% CI 12.4–64.9).
- Two patients received HSCT and both proceeded to ziftomenib maintenance therapy.

The combination was generally well tolerated in both R/R *NPM1*-m and R/R *KMT2A*-r AML. Rates of ziftomenib-related myelosuppression were low, with neutrophil and platelet recovery consistent with expectations for ven/aza alone. No ziftomenib-related QTc prolongation was reported. One grade 3 differentiation syndrome case (in an *NPM1*-m patient) was successfully resolved with protocol-specified measures, and the patient resumed treatment with ziftomenib.

"We're truly encouraged by the consistent safety profile and the depth of responses observed with ziftomenib in combination with venetoclax and azacitidine across both newly diagnosed and relapsed/refractory *NPM1*-mutated and *KMT2A*-rearranged AML patients," said Mollie Leoni, M.D., Chief Medical Officer at Kura Oncology. "These compelling data reinforce our conviction that ziftomenib has the potential to become a foundational, best-in-class menin inhibitor for patients with AML. Importantly, we continue to activate sites in our pivotal KOMET-017 trials. The combination of a well-considered trial design and a compelling benefit-risk profile for ziftomenib gives us confidence in the pace and quality of enrollment of newly diagnosed and relapsed/refractory patients."

Presentations
Slides from the oral presentations will be available on Kura's website at www.kuraoncology.com under the Posters and Presentations tab in the Ziftomenib section, and in the ASH 2025 online program.

Virtual Investor Event
Kura will host a webcast and conference call today, December 8, 2025, at 12:30 p.m. ET / 9:30 a.m. PT featuring Kura management, Eunice Wang, M.D., Chief of Leukemia Service and Professor of Oncology at Roswell Park Comprehensive Center, and Amer Zeidan, M.B.B.S., M.H.S., Chief, Division of Hematologic Malignancies and Professor of Medicine at Yale School of Medicine. The live webcast and replay will be available on the on the Company's website at www.kuraoncology.com under the Investors tab in the Events and Presentations section.

About KOMZIFTI™ (ziftomenib)
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.

Ziftomenib 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 x 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™ (ziftomenib), 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 therapeutic potential of KOMZIFTI in combination with venetoclax and azacitidine for the treatment of newly diagnosed and relapsed/refractory *NPM1*-m or *KMT2A*-r AML; KOMZIFTI's potential benefit in challenging settings; the potential for KOMZIFTI to be integrated into front-line and relapsed/refractory regimens through ongoing registrational trials; the potential of KOMZIFTI to become a foundational, best-in-class menin inhibitor for patients with AML; the potential of KOMZIFTI in combination with venetoclax and azacitidine to have a favorable safety profile; the pace and quality of enrollment of patients in Kura's KOMET-017 trials; and the potential of KOMZIFTI to be combined with approved therapies and benefit a broad spectrum of patients earlier in their disease course. Factors that may cause actual results to differ materially include the risk that KOMZIFTI does not demonstrate safety and/or efficacy when used in combination with venetoclax and azacitidine in Kura's registrational KOMET-017 trials; the risk that Kura may not obtain approval to market KOMZIFTI in combination with venetoclax and azacitidine; uncertainties associated with performing clinical trials, regulatory filings, and other interactions with regulatory bodies; 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.

CR, complete response; CRc, composite complete response; *FLT3*, Fms-like tyrosine kinase 3; HSCT, hematopoietic stem cell transplant; *KMT2A*, lysine methyltransferase 2A; MRD, minimal residual disease; NE, not evaluable; *NPM1*, nucleophosmin 1; ORR, objective response rate; OS, overall survival.

Kura Contacts

Investors and Media:
Greg Mann
858-987-4046
gmann@kuraoncology.com

Kyowa Kirin Contacts

Investors:
Ryohei Kawai
ir@kyowakirin.com

Media, Global:
Nobuyuki Manita
media@kyowakirin.com

Source: Kura Oncology, Inc.