Kura Oncology and Kyowa Kirin to Present Updated Frontline Ziftomenib / 7+3 Combination Data at EHA 2026 Congress

May 12, 2026

– Oral presentation to feature 99-patient dataset with extended follow-up in newly diagnosed NPM1-m or KMT2A-r AML –

– High CRc rates (90–96%) with deep MRD negativity (> 80%) across both subtypes –

– Durable responses with median duration of CRc not reached in NPM1-m patients at ~15 months median follow-up –

– Phase 3 KOMET-017 trial currently enrolling with potential for accelerated FDA review in 2028 –

– Virtual Kura investor call on June 12 at 8:00 a.m. ET –

SAN DIEGO, May 12, 2026 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced that updated results from the frontline arm of the Phase 1 KOMET-007 (NCT05735184) clinical trial evaluating ziftomenib in combination with cytarabine plus daunorubicin (7+3) in patients with newly diagnosed *NPM1*-mutant (*NPM1*-m) or *KMT2A*-rearranged (*KMT2A*-r) acute myeloid leukemia (AML) have been accepted for an oral presentation on Sunday, June 14, 2026, at the upcoming 2026 European Hematology Association (EHA) Congress in Stockholm, Sweden.

The oral presentation will highlight updated results in 99 patients with newly diagnosed *NPM1*-m or *KMT2A*-r AML treated with ziftomenib 600 mg once daily in combination with 7+3. These results represent one of the largest datasets reported to date for the evaluation of a menin inhibitor in combination with intensive chemotherapy in frontline AML.

As of the abstract data cut-off on January 16, 2026:

- **High response rates across both molecular subtypes**
  - Composite complete response (CRc) rates of 96% (47/49) for *NPM1*-m and 90% (45/50) for *KMT2A*-r AML
- **Deep molecular responses**
  - Measurable residual disease (MRD)-negativity rates among CRc responders of 83% (39/47) for *NPM1*-m and 82% (32/39) for *KMT2A*-r AML
- **Encouraging durability with extended follow-up**
  - Median follow-up of 14.9 months (*NPM1*-m) and 9.3 months (*KMT2A*-r)
  - Median duration of CRc not reached (*NPM1*-m) and 11.2 months (*KMT2A*-r)
- **Consistent and manageable safety profile**
  - Safety profile consistent across the *NPM1*-m and *KMT2A*-r groups with no new safety signals observed with long-term treatment
- Updated analyses with longer median follow-up, central MRD assessment, durability outcomes, and deeper characterization of safety and hematologic recovery will be included at the time of the oral presentation

"With nearly 100 patients treated as well as extended follow-up, ziftomenib in combination with 7+3 continues to demonstrate consistently high response rates, deep MRD negativity, and encouraging durability across genetically defined AML subsets," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "These data support our belief ziftomenib has potential to serve as a foundational backbone for frontline AML therapy, and we are advancing this regimen in our ongoing Phase 3 registrational program."

In addition to the oral presentation, abstracts for the KOMET-007 and KOMET-017 trials have been accepted for a poster presentation and online publication, respectively. Details are provided below and are available on the EHAweb.org website.

EHA 2026 Presentation Details

Title: Ziftomenib combined with intensive induction (7+3) for newly diagnosed *NPM1*-m or *KMT2A*-r acute myeloid leukemia (AML): Long-term results from the KOMET-007 trial
Session: s446 Novel treatments in AML
Date and Time: Sunday, June 14; 11:00-12:15 CEST
Location: Nobel Hall
Publication Number: S130

Title: Exposure-response analysis of ziftomenib combined with venetoclax/azacitidine or cytarabine/daunorubicin in newly diagnosed and relapsed/refractory *NPM1*-m or *KMT2A*-r acute myeloid leukemia
Session: Poster Session 1
Date and Time: Friday, June 12; 18:45-19:45 CEST
Location: Poster Hall
Publication Number: PF537

Title: Registrational Phase 3 studies of ziftomenib in combination with nonintensive or intensive chemotherapy for newly diagnosed *NPM1-m* or *KMT2A-r* acute myeloid leukemia (AML): The KOMET-017 trial
Location: Online Publication
Date and Time: Tuesday, May 12; 9:30 AM ET/15:30 CEST
Publication Number: PB2766

Copies of the presentations will be available on Kura's website at www.kuraoncology.com/pipeline/publications following presentation at the meeting.

Virtual Investor Event
Kura will host a webcast and conference call on June 12, 2026, at 8:00 am ET / 5:00 am PT, featuring management and a clinical investigator from the KOMET-007 study. The live webcast and replay will be available on the Company's website at www.kuraoncology.com under the Investors tab in the Events and Presentations section.

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.

About Ziftomenib
Ziftomenib (marketed as KOMZIFTI™ in theU.S.) is a once-daily, oral menin inhibitor approved by the U.S. Food and Drug Administration for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options. Ziftomenib is being studied across the AML treatment continuum, including in combination studies in newly diagnosed and relapsed/refractory *NPM1*-mutated AML, *KMT2A*-rearranged AML, and *FLT3*-mutated AML. Ziftomenib is also being explored in additional oncology indications, including advanced gastrointestinal stromal tumors.

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**.

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 of ziftomenib to serve as a foundational backbone for frontline AML therapy, the potential for accelerated FDA review of data from Kura's Phase 3 KOMET-017 trial, and the expected timing and presentation of results and data from clinical trials. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that Kura may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings, and other interactions with regulatory bodies, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, 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 the Company faces, please refer to the Company'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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