Kura Oncology and Kyowa Kirin Announce Publication in Blood of Ziftomenib plus Venetoclax / Azacitidine Combination in Patients with R/R NPM1-m AML

June 2, 2026

– 87% ORR and 70% CRc in venetoclax-naïve and 48% ORR and 24% CRc in venetoclax-experienced patients at the recommended 600 mg once-daily dose –

– Central MRD negativity in 75% of CRc responders with no prior venetoclax exposure; median CRc duration was 9.2 months –

– Median OS not reached after median follow up of 10.7 months in patients with no prior venetoclax exposure –

– Combination was well tolerated, with low rates of differentiation syndrome and QTc prolongation observed –

SAN DIEGO and TOKYO, June 02, 2026 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced the publication in *Blood* of updated results from the relapsed/refractory (R/R) *NPM1*-mutated acute myeloid leukemia (*NPM1*-m AML) cohort of KOMET-007, a Phase 1a/b trial evaluating ziftomenib in combination with venetoclax and azacitidine (ven/aza). The publication reports nearly two-thirds of patients experienced clinically meaningful, deep and durable responses with a well-tolerated safety profile in adults with R/R *NPM1*-m AML.

KOMZIFTI™ (ziftomenib) is approved by the U.S. Food and Drug Administration as monotherapy for adult patients with relapsed or refractory AML with a susceptible *NPM*1 mutation who have no satisfactory alternative treatment options. Ziftomenib in combination with ven/aza is investigational and has not been approved by the FDA.

"This analysis provides a more mature evaluation of ziftomenib in combination with venetoclax and azacitidine in patients with *NPM1*-mutated AML," said Eunice S. Wang, M.D., Chief of Leukemia, Roswell Park Comprehensive Cancer Center, and co-first senior author of the publication. "In the relapsed/refractory setting, outcomes with venetoclax-based regimens in patients with *NPM1*-mutant AML remain suboptimal, highlighting the substantial need for more effective therapies. These KOMET-007 results are notable for the depth and durability of response observed with the investigational three-drug combination. The favorable safety profile also supports the continued evaluation of this combination in a setting where better treatment options are urgently needed."

"As combination approaches become increasingly important in this setting, the data highlighted in this publication strengthen the case for ziftomenib as a backbone in *NPM1*-mutant AML," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "Ziftomenib combined with ven/aza demonstrated deep molecular responses, durable remissions, and a generally manageable safety profile in R/R *NPM1*-m AML. These findings support our ongoing efforts to evaluate ziftomenib-based combinations across the treatment continuum, including in randomized studies designed to define the potential of ziftomenib in newly diagnosed disease."

KOMET-007 Results in R/R *NPM1*-m AML

The data include 64 response-evaluable patients with R/R *NPM1*-m AML from the ongoing KOMET-007 Phase 1a/b trial (NCT05735184), 27 of whom were treated in phase 1a dose escalation and 37 of whom were treated in phase 1b expansion, as of the January 16, 2026 data cutoff date. Patients had received 1 to 8 prior lines of therapy (median of 1), and 37 patients (55%) had prior venetoclax exposure.

Robust clinical activity was observed in patients with R/R *NPM1*-m AML across all ziftomenib dose levels, with nearly two-thirds of all patients experiencing clinically meaningful, deep, and durable responses. In addition, rapid responses were observed, with a median time to composite complete remission (CRc) of 3.9 weeks.

Venetoclax-Naïve Population (600 mg ziftomenib)

- 70% CRc rate (16/23) with 75% (9/12) central measurable residual disease (MRD) negativity (<0.01% threshold), demonstrating deep molecular responses
- 87% objective response rate (ORR) (20/23)
- Median duration of CRc response of 9.2 months (95% CI, 5.8-NE)
- Median overall survival (OS) not reached after median follow-up of 10.7 months (N=25)

Venetoclax-Experienced Population (600 mg ziftomenib)

- 24% CRc rate (6/25) with 50% (3/6) central MRD negativity (<0.01% threshold)
- 48% ORR (12/25)
- Median duration of CRc response of 8.6 months (95% CI, 1.6-NE)
- Median OS of 7.4 months after median follow-up of 9.9 months (N=26)

Safety in Both Populations at All Dose Levels (N=67)

- The triplet combination was well tolerated, with a safety profile consistent with that reported for ven/aza alone
- Low rates of differentiation syndrome (3%, 2/67) observed with the protocol-specified staggered dosing schedule of ven/aza before menin inhibition; both events resolved with protocol-specified mitigation
- One case of ziftomenib-related QTc; the event resolved without dose interruption or dose change
- Median time to neutrophil and platelet recovery were similar to ven-based regimens alone, supporting feasibility in combination regimens

"For people living with relapsed or refractory *NPM1*-mutated AML, the need for new treatment regimens remains significant," said Yoshifumi Torii, Ph.D., Chief Medical Officer of Kyowa Kirin. "These published findings in the journal *Blood* add to our understanding of ziftomenib in combination with venetoclax and azacitidine and reinforce our shared commitment with Kura Oncology to advancing this program with urgency and rigor for patients who may benefit."

The ongoing KOMET-007 Phase 1a/1b trial (NCT05735184) is evaluating ziftomenib in combination with ven/aza in multiple cohorts of newly diagnosed chemotherapy-ineligible AML and relapsed/refractory AML. The trial is also evaluating ziftomenib in combination with cytarabine plus daunorubicin (7+3) in patients with newly diagnosed *NPM1*-m or *KMT2A*-rearranged (*KMT2A*-r) AML, as well as ziftomenib combined with quizartinib plus 7+3 intensive chemotherapy in patients with newly diagnosed AML harboring *FLT3*-ITD/*NPM1*-m co-mutations.

Kura and Kyowa Kirin are continuing to evaluate ziftomenib across multiple combination regimens and treatment settings, including in the ongoing pivotal KOMET-017 Phase 3 trials in newly diagnosed *NPM1*-m and *KMT2A*-r AML.

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 in the United States as KOMZIFTI™, is a once-daily, oral menin inhibitor approved by the U.S. Food and Drug Administration as monotherapy 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 evaluated in clinical trials across the AML treatment continuum, including in combination with established treatment backbones, 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**.

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, among other things, statements regarding the potential of ziftomenib to serve as a combination backbone in *NPM1*-mutant AML. 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, 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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