Kura Oncology and Kyowa Kirin to Present First Ziftomenib-FLT3 Inhibitor Clinical Data at ASH 2026

November 4, 2026

– Two oral presentations to feature first ziftomenib combination data with quizartinib in newly diagnosed and gilteritinib in relapsed/refractory NPM1/FLT3 co-mutated AML –

– Longer-term Phase 1b data for ziftomenib plus venetoclax and azacitidine in frontline AML support the ongoing Phase 3 KOMET-017 registrational study –

– Exploratory analysis to evaluate ziftomenib clinical activity beyond NPM1-mutated and KMT2A-rearranged subtypes –

– A total of four oral presentations and four posters to highlight the expanding potential of menin inhibition with ziftomenib across AML treatment settings and combinations –

– Investor webcast on December 15, 2026, at 8:30 a.m. ET / 5:30 a.m. PT –

SAN DIEGO and TOKYO, Nov. 04, 2026 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd (TSE: 4151) today announced that eight abstracts related to ziftomenib, including four oral presentations and four posters, have been accepted for presentation at the 2026 American Society of Hematology (ASH) Annual Meeting, taking place December 12-15 in New Orleans. Kura and Kyowa Kirin are working together under a strategic collaboration and license agreement to develop and commercialize ziftomenib for the treatment of acute myeloid leukemia (AML) worldwide.

The presentations will include the first clinical results for ziftomenib in combination with the FLT3 inhibitors quizartinib and gilteritinib, longer-term frontline data for ziftomenib plus venetoclax and azacitidine, and an exploratory analysis of ziftomenib activity in molecularly defined AML subtypes beyond *NPM1*-mutated and *KMT2A*-rearranged disease.

“Our strategy is to establish ziftomenib as a preferred menin inhibitor for combination treatment, supported by clinical evidence across complementary therapeutic approaches,” said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. “Our first clinical results with quizartinib and gilteritinib extend this strategy into FLT3 inhibitor combinations. Together with longer-term venetoclax and azacitidine results and studies of additional combinations, these presentations will help define ziftomenib’s potential as a backbone therapy from initial diagnosis through relapsed or refractory disease.”

FLT3 mutations occur in nearly one third of patients with AML and approximately one half of those with an *NPM1* mutation. This overlap makes *NPM1/FLT3* co-mutated AML an important population for ziftomenib combination development.

Two oral presentations will report preliminary safety and clinical activity findings from ziftomenib combinations with FLT3 inhibitors:

- KOMET-007: Ziftomenib plus quizartinib and intensive chemotherapy (7+3) in newly diagnosed *NPM1/FLT3*-ITD co-mutated AML
- KOMET-008: Ziftomenib plus gilteritinib in relapsed or refractory (R/R) *NPM1/FLT3* co-mutated AML

A poster presentation from KOMET-007 will provide longer-term follow-up on response durability, overall survival, and safety with ziftomenib plus venetoclax and azacitidine in patients with newly diagnosed *NPM1*-mutated AML who are ineligible for intensive chemotherapy. These findings support the ongoing global, randomized Phase 3 KOMET-017 registrational study evaluating this combination.

An exploratory analysis from KOMET-001 will describe clinical activity with ziftomenib monotherapy in patients with R/R AML without *NPM1* mutations or *KMT2A* rearrangements whose disease harbors other genomic alterations associated with MEIS1 expression. The findings support further investigation of ziftomenib in additional molecularly defined AML populations.

Two additional oral presentations will feature ziftomenib. The first will report initial results from the PedAL Phase 1 ITCC-101/APAL2020K trial sponsored by Blood Cancer United and Princess Maxima Center evaluating ziftomenib with fludarabine and cytarabine in pediatric R/R acute leukemia. The second will present preclinical findings from additional subsets of menin-associated leukemias.

All eight abstracts related to ziftomenib, including those from investigator-sponsored trials, are available on the ASH website.

Select 2026 ASH Presentation Details

Abstract Title	Abstract Number	Presentation Details
Ziftomenib combined with gilteritinib for relapsed/refractory *NPM1* and *FLT3* co-mutated acute myeloid leukemia (AML): First results from the KOMET-008 phase 1 study	Oral Presentation #66	Session 617 December 12 10:45 a.m. CST Great Hall AD

Ziftomenib combined with intensive induction (7+3) and quizartinib for newly diagnosed*NPM1*-m and*FLT3*-ITD+ acute myeloid leukemia (AML): Preliminary results from KOMET-007	Oral Presentation #902	Session 617 December 14 3:00 p.m. CST Great Hall BC
Ziftomenib combined with venetoclax/azacitidine in newly diagnosed*NPM1*-m acute myeloid leukemia (AML): Long-term results from KOMET-007	Poster Presentation #5192	Session 617 December 14 6:00-8:00 p.m. CST Hall F
Clinical activity of ziftomenib extends beyond*NPM1*-mutated and*KMT2A*-rearranged acute myeloid leukemia (AML) into*MEIS1*-associated genomic subtypes	Poster Presentation #5190	Session 617 December 14 6:00-8:00 p.m. CST Hall F
Ziftomenib combined with fludarabine and cytarabine in pediatric relapsed/refractory acute leukemia with*KMT2A*rearrangements,*NUP98*rearrangements, or*NPM1*mutations: First results of the phase 1 ITCC-101/APAL2020K trial (NCT06376162)	Oral Presentation #666	Session 616 December 13 5:45 p.m. CST Hall B
SETBP1-mutant leukemias depend on MENIN-associated KMT2A chromatin complexes to maintain leukemogenic transcriptional programs	Oral Presentation #101	Session 636 December 12 10:30 a.m. CST Hall C

Conference Call and Webcast

Kura will host a webcast and conference call at 8:30 a.m. ET / 5:30 a.m. PT on December 15, 2026, featuring Kura management, Eunice Wang, M.D., Chief of Leukemia Service and Professor of Oncology at Roswell Park Comprehensive Cancer 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. A live webcast and archived replay of the event will be available in the Investors section of Kura's website at www.kuraoncology.com.

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 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 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 treatment of frontline and R/R 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.

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** for additional details.

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, Kura's plans and objectives for the clinical development of ziftomenib, including combination regimens and the ongoing Phase 3 KOMET-017 study; ziftomenib's potential to become a preferred menin inhibitor for combination treatment and a foundational component of AML treatment from initial diagnosis through relapsed or refractory disease; the potential therapeutic benefits of ziftomenib in combination with other agents; the potential for ziftomenib to address additional molecularly defined AML populations beyond *NPM1*-mutated and *KMT2A*-rearranged disease; and the development and commercialization of ziftomenib under Kura's collaboration agreement with Kyowa Kirin. Factors that may cause actual results to differ materially include the risk that preliminary, interim or exploratory clinical findings may change as additional patients are enrolled or longer-term follow-up becomes available; the risk that results from early-stage studies may not predict results in later-stage trials; the risk that additional studies may not confirm the safety, efficacy or durability of response suggested by earlier findings; risks associated with initiating, enrolling, conducting and completing clinical trials; unexpected adverse events or other safety findings; the risk that regulatory authorities may not permit planned studies to proceed or approve additional indications or combination regimens; the availability of sufficient funding to support development activities; 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," "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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