

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

- 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 2 and 3, 2026 -- 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 *NPM1* 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 CRc of 3.9 weeks.

Venetoclax-Naïve Population (600 mg ziftomenib)

- 70% composite complete remission (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 venetoclax/azacitidine 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](https://clinicaltrials.gov/ct2/show/study/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.