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

– 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 –

SAN DIEGO and TOKYO, December 8 and 9, 2025 -- 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.

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.

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.