



## Kura Oncology and Kyowa Kirin Announce Pivotal Monotherapy Data for Ziftomenib in Oral Presentation at the 2025 ASCO Annual Meeting

May 22, 2025

- Results from KOMET-001 registration-directed trial of ziftomenib in R/R *NPM1*-m AML patients selected for oral presentation on Monday, June 2nd –
- Encore presentation planned at EHA 2025 Congress –
- Kura Oncology to host virtual investor event at 7:30pm ET / 4:30pm PT on June 2nd to discuss the trial results –

SAN DIEGO and TOKYO, May 22, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced that an abstract highlighting the full data analyses from the KOMET-001 registration-directed trial of ziftomenib, a once-daily, oral investigational menin inhibitor, has been accepted for oral presentation at the upcoming 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, to be held in Chicago, IL from May 30 - June 3, 2025.

The KOMET-001 registration-directed trial (NCT #04067336) is designed to assess evidence of clinical activity, safety and tolerability of ziftomenib, the only investigational therapy to receive Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA) for treatment of relapsed/refractory (R/R) *NPM1*-mutant (*NPM1*-m) acute myeloid leukemia (AML). *NPM1* mutations are among the most common, representing approximately 30% of AML cases, and there are no FDA approved therapies for *NPM1*-m AML. Kura and Kyowa Kirin previously announced positive topline results from the KOMET-001 trial, which achieved its primary endpoint of complete remission (CR) plus CR with partial hematological recovery (CRh) and the primary endpoint was statistically significant. Ziftomenib was well-tolerated with limited myelosuppression and 3% ziftomenib-related discontinuations. The benefit-risk profile for ziftomenib is highly encouraging, and safety and tolerability were consistent with previous reports.

"These data highlight ziftomenib's potential use as a treatment option for R/R *NPM1*-mutant AML," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "We are encouraged by the safety and tolerability profile as well as the clinical efficacy observed for this subset of AML patients, and together, Kura and Kyowa Kirin are committed to advancing ziftomenib toward commercialization. We look forward to sharing a more comprehensive dataset at the ASCO Annual Meeting in the coming weeks."

In addition to the oral presentation, a trial-in-progress abstract for the KOMET-015 trial has been accepted for poster presentation on May 31, 2025. Session titles and information for both abstracts are listed below and are now available on the [ASCO.org](https://www.asco.org) website. Updated data from the published abstract for KOMET-001 will be disclosed during the oral presentation.

### **Ziftomenib in Relapsed/Refractory (R/R) *NPM1*-Mutant Acute Myeloid Leukemia (AML): Phase 1b/2 Clinical Activity and Safety Results from the Pivotal KOMET-001 Study (#6506)**

Session: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allogeneic Transplant  
Session Date and Time: Monday, June 2, 2025; 3:00PM - 6:00PM CDT  
Presentation Time: 4:36PM - 4:48PM CDT  
Location: McCormick Place, S100a

### **Phase 1a/1b Study of the Safety, Pharmacokinetics, and Antitumor Activity of Ziftomenib in Combination with Imatinib in Patients with Advanced Gastrointestinal Stromal Tumors (GIST) After Imatinib Failure**

Session: Poster Session – Sarcoma  
Session Date and Time: Saturday, May 31, 2025; 9:00AM - 12:00PM CDT  
Location: McCormick Place, Hall A – Posters and Exhibits

Copies of the presentations will be available on Kura's website at [www.kuraoncology.com/pipeline/publications/](https://www.kuraoncology.com/pipeline/publications/) following presentation at the meeting.

### **Virtual Investor Event**

Kura will host a virtual investor event featuring company management and investigators from the KOMET-001 trial of ziftomenib in R/R *NPM1*-m AML at 7:30pm ET / 4:30pm PT on Monday, June 2, 2025. Those who would like to participate may access the live webcast [here](#), or register in advance for the teleconference [here](#). The event can also be accessed on the Investors section of Kura's website at [www.kuraoncology.com](https://www.kuraoncology.com). An archived replay will be available shortly after the conclusion of the live event.

### **About Kura Oncology**

Kura Oncology is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. The Company's pipeline consists of small molecule drug candidates designed to target cancer signaling pathways. Ziftomenib, a once-daily, oral menin inhibitor, is the first and only investigational therapy to receive BTD from the FDA for the treatment of R/R *NPM1*-m AML. In November 2024, Kura Oncology entered into a global strategic collaboration agreement with Kyowa Kirin to develop and commercialize ziftomenib for AML and other hematologic malignancies. Enrollment in KOMET-001, a Phase 2 registration-directed trial of ziftomenib in R/R *NPM1*-m AML, has been completed, and the companies submitted a New Drug Application for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML in the first quarter of 2025. Kura and Kyowa Kirin are conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R *NPM1*-m and *KMT2A*-rearranged AML. Ziftomenib is also being evaluated in a Phase 1 dose-escalation trial (KOMET-015) in combination with imatinib for treatment of patients with advanced GIST. KO-2806, a next-generation farnesyl transferase inhibitor (FTI), is being

evaluated in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with targeted therapies for patients with various solid tumors. Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial (KURRENT-HN) in combination with alpelisib for patients with *PIK3CA*-dependent head and neck squamous cell carcinoma. For additional information, please visit Kura's 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](http://www.kyowakirin.com).

### **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 efficacy, safety and therapeutic potential of ziftomenib; the advancement of ziftomenib toward commercialization as a monotherapy and expansion of its development across diverse settings; potential benefits of combining ziftomenib with intensive chemotherapy 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](http://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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