Kura Oncology and Kyowa Kirin Report Positive Pivotal Ziftomenib Monotherapy Data at 2025 ASCO Annual Meeting

June 2, 2025

– CR/CRh rate of 23% in pivotal Ph 2 cohort of R/R *NPM1*-m AML patients –

– Consistent efficacy with comparable CR/CRh rates and clinically meaningful MRD-negative responses across pre-specified subgroups, regardless of prior HSCT, prior venetoclax, or *FLT3/IDH* co-mutations –

– Favorable safety and tolerability profile in heavily pre-treated patients: limited myelosuppression; no clinically meaningful QTc prolongation; 3% of patients discontinued due to treatment-related adverse events –

– Potential first approval of a once-daily, oral menin inhibitor for treatment of adult patients with relapsed or refractory *NPM1*-mutated AML with Priority Review and a PDUFA target action date of November 30, 2025 –

– Kura Oncology to host virtual investor event today at 7:30pm ET / 4:30pm PT –

SAN DIEGO and TOKYO, June 02, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, “Kura”) and Kyowa Kirin Co., Ltd. (TSE: 4151, “Kyowa Kirin”) announced the presentation of positive pivotal results from the KOMET-001 Phase 2 registration-directed trial of ziftomenib, a once-daily, oral investigational menin inhibitor, in patients with relapsed/refractory (R/R) *NPM1*-mutant (*NPM1*-m) acute myeloid leukemia (AML) in an oral session today at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago, IL from May 30 - June 3, 2025.

"We are delighted to announce positive pivotal data from the KOMET-001 trial in R/R *NPM1*-mutated AML patients treated with ziftomenib," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "*NPM1* mutations are among the most common in AML, representing approximately 30% of cases, and there are no FDA-approved therapies specifically for this patient population. With these encouraging results and a PDUFA target action date of November 30, 2025, we and our partners at Kyowa Kirin look forward to supporting FDA with its review of the ziftomenib New Drug Application (NDA) and are well-positioned to meaningfully impact relapsed or refractory patients with *NPM1* mutations.”

"Relapsed or refractory *NPM1*-mutated AML is a highly challenging disease with a poor prognosis and an urgent need for new treatments," said Eunice Wang, M.D., Chief of Leukemia Service, Professor of Oncology, Roswell Park Comprehensive Cancer Center, Buffalo, NY. "The promising results for ziftomenib in this heavily pretreated population are highly encouraging. Notably, the clinically meaningful minimal residual disease (MRD)-negative responses observed as well as the similar response rates seen regardless of prior therapies, including hematopoietic stem cell transplantation (HSCT) and venetoclax, hold great promise for the potential use of ziftomenib in patients with relapsed and refractory *NPM1*-mutated AML.”

The KOMET-001 Phase 2 population included 92 adult patients with R/R *NPM1*-m AML. The median age was 69 (range: 33 to 84). Patients were heavily pretreated, with 33% having received three or more prior lines of therapy (median prior lines: 2) and 59% having been previously treated with venetoclax.

A complete remission (CR) plus CR with partial hematological recovery (CRh) rate of 23% (21/92) was observed among patients with R/R *NPM1*-m AML in the Phase 2 portion of the KOMET-001 trial. Among those 21 patients who achieved CR/CRh, 13 had a CR and 8 had a CRh. The median duration of CR/CRh responses was 3.7 months (95% CI: 1.9, not estimable (NE)) and the restricted mean duration of response was 4.3 months (95% CI: 3.1, 5.6) at the time of the data cutoff. MRD status was assessed in 19 of 21 patients who achieved CR/CRh, and 63% (12/19) of these patients were MRD-negative.

Comparable CR/CRh rates were observed across pre-specified subgroups, regardless of prior HSCT, prior venetoclax or *FLT3/IDH* co-mutations. Additional patient benefit beyond CR/CRh was observed with a rate of transfusion conversion of 21% (17/82; 95% CI: 13-31) and a rate of maintenance of transfusion independence of 20% (2/10; 95% CI: 3-56). A median OS of 16.4 months (95% CI, 9.6–20.4) was observed for responders (patients who achieved CR, CRh, CRi/CRp, MLFS or PR) and a median overall survival (OS) of 3.5 months (95% CI, 2.5–4.0) was observed among non-responders.

The safety population included 112 adult patients with R/R *NPM1*-m AML from the pooled Phase 1b and Phase 2 portions of the KOMET-001 trial. The safety profile observed with ziftomenib in this population was consistent with previously reported data. Treatment-related adverse events (TRAEs) led to treatment discontinuations in 3% of patients. TRAEs of Grade ≥3 which occurred in more than 10% of patients were limited to differentiation syndrome (DS, 13%), which was well managed by protocol-specified mitigation strategies and no Grade 4/5 treatment-related DS was observed. Although QTc prolongation (1 Gr2; 2 Gr3) was reported in three patients per investigator assessment, all three patients were on concomitant medications associated with QTc prolongation, two had electrolyte abnormalities and one had a prior diagnosis of atrial fibrillation.

“Beyond ziftomenib’s clinical activity, we are highly encouraged by its consistent safety and tolerability profile,” said Mollie Leoni, MD, Chief Medical Officer of Kura Oncology. “Notably, the low rate of myelosuppression, low discontinuation rate, lack of clinically significant QTc prolongation, absence of drug-drug interactions, and effective management of differentiation syndrome underscore ziftomenib’s potentially favorable benefit-risk profile for patients with relapsed or refractory *NPM1*-mutated AML.”

“The data presented at ASCO strengthen our conviction that ziftomenib has potential to become a meaningful treatment option for patients with relapsed or refractory AML with *NPM1* mutations — patients who often face limited treatment options and significant uncertainty regarding their

prognosis," said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. "Encouraged by the favorable safety, tolerability, and promising clinical activity observed thus far, Kyowa Kirin, in collaboration with Kura, is working with urgency and purpose to bring ziftomenib monotherapy to patients as swiftly and responsibly as possible."

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. 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 Breakthrough Therapy Designation 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 announced submission of an NDA 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 Phase1 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.

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; interactions with the FDA relating to our NDA for ziftomenib; the anticipated timing of FDA approval of our NDA and the potential to benefit patients with R/R *NPM1*-m 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, 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. 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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