Kura Oncology and Kyowa Kirin Report Positive Updated Combination Data for Ziftomenib in Newly Diagnosed AML at 2025 European Hematology Association Congress

– Encouraging clinical activity with deep responses demonstrated in the KOMET-007 trial with the combination of 600 mg ziftomenib with 7+3 in newly diagnosed patients with *NPM1*-m and *KMT2A*-r AML –

– 93% (41/44) and 89% (24/27) CRc observed in *NPM1*-m and *KMT2A*-r AML response-evaluable patients, respectively –

– 71% (24/34) and 88% (14/16) CR measurable residual disease (MRD)-negativity observed among responding *NPM1*-m and *KMT2A*-r AML patients, respectively –

– 96% (47/49) of *NPM1*-m and 88% (29/33) *KMT2A*-r AML patients remain alive and continue on-study –

– Combination was well tolerated with no additive myelosuppression –

– KOMET-017-IC (intensive chemotherapy) and NIC (non-intensive chemotherapy) randomized phase 3 studies (NCT07007312) expected to start in 2H 2025 –

– Kura Oncology to host virtual investor event to discuss results and broader ziftomenib development plan on June 18, 2025 at 4:30pm ET / 1:30pm PT –

SAN DIEGO and TOKYO, June 12, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today provided positive updated clinical data from KOMET-007, a Phase 1a/1b trial of ziftomenib, a highly selective oral investigational menin inhibitor, in combination with standards of care in patients with newly diagnosed *NPM1*-mutant (*NPM1*-m) and *KMT2A*-rearranged (*KMT2A*-r) acute myeloid leukemia (AML). The data for the combination with cytarabine/daunorubicin (7+3) were presented as an oral presentation at the European Hematology Association 2025 Congress (EHA2025) being held in Milan, Italy from June 12-15, 2025.

"The findings presented at EHA2025 underscore the potential of ziftomenib in combination with 7+3 as an early intervention in the frontline setting of AML and could offer a meaningful opportunity to improve patient outcomes," said Harry Erba, M.D., Ph.D., Director of the Leukemia Program at the Duke Cancer Institute. "The high rates of complete remission and MRD negativity across the 7+3 cohorts are particularly encouraging. The continued rapid enrollment in the Phase 1b portion of this study underscores the urgency and enthusiasm for further evaluating this combination approach."

“We remain very encouraged by the updated clinical activity, safety and tolerability data from the KOMET-007 study evaluating ziftomenib with 7+3 in newly diagnosed AML patients with *NPM1* mutations or *KMT2A* rearrangements,” said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. “These updated data reinforce the combination potential of ziftomenib in the frontline setting, strengthening our confidence in its ability to provide a valuable treatment option for a significant portion of the AML population. We and our partners at Kyowa Kirin are working in earnest to prepare for the KOMET-017-IC and NIC pivotal Phase 3 studies, which will enable us to test ziftomenib-based combinations and their potential, if approved, to transform care for AML patients worldwide.”

In the ongoing study, ziftomenib dosed once daily at 600 mg in combination with 7+3 continued to demonstrate robust and evolving clinical activity in patients with newly diagnosed AML. Among 71 response-evaluable patients, 92% (65/71) achieved a composite complete remission (CRc) (93% for *NPM1*-m, 89% for *KMT2A*-r patients) and 80% (57/71) achieved a complete remission (CR) (84% for *NPM1*-m, 74% for *KMT2A*-r patients) at the time of data cutoff. A rate of CR minimal residual disease (CR-MRD) negativity of 71% for *NPM1*-m with a median time to MRD negativity of 4.7 weeks and a rate of CR-MRD negativity of 88% for *KMT2A*-r patients with a median time to MRD negativity of 4.4 weeks were observed. Ziftomenib did not delay time to neutrophil and platelet count recovery, which was comparable to intensive chemotherapy regimens.

Median follow-up times for the two populations were 24.9 weeks (range 4.3-47.1) in *NPM1*-m patients and 15.7 weeks (range 1.1-40.3) in *KMT2A*-r patients. Among response-evaluable *NPM1*-m patients, neither a median duration of CR nor a median overall survival (OS) had been reached. Among response-evaluable *KMT2A*-r patients, a median duration of CR was determined to be 25.6 weeks (95% CI, range 8.3-NE), and a median OS had not been reached. Notably, 96% (47/49) of *NPM1*-m patients and 88% (29/33) of *KMT2A*-r patients remained alive and on study.

The safety population included 82 newly diagnosed adult patients with *NPM1*-m or *KMT2A*-r AML from the pooled Phase 1a/1b portions of the trial at the 600 mg QD dose of ziftomenib. The safety profile observed with ziftomenib was consistent with previously reported data. Ziftomenib-related adverse events (TRAEs) of ≥ Grade 3 (Gr3), which occurred in more than 10% of patients were febrile neutropenia (15%), decreased platelet count (15%), anemia (11%) and decreased neutrophil count (11%). One case of differentiation syndrome (*KMT2A*-r, Gr3) was successfully managed by protocol-specified mitigation strategies. Two cases of investigator-assessed QTc prolongation (both *KMT2A*-r, Gr3) were reported; both patients were on other medications (posaconazole and/or piperacillin/tazobactam), which have been identified as potentially causing QT prolongation at the time of QT assessment. No dose-limiting toxicities, drug-drug interactions, clinically meaningful ziftomenib-associated QTc prolongation or additive myelosuppression were observed.

“Despite the availability of approved therapies for AML, up to 70% of patients who initially achieve a complete response relapse within three years – highlighting a substantial unmet need,” said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. “The data presented at EHA2025 suggest a favorable safety, tolerability, and efficacy profile for ziftomenib. We are encouraged by its potential as a future first-line treatment option and are committed to advancing the KOMET-017 Phase 3 trial, expected to begin later this year, to further evaluate its value in AML care.”

The EHA2025 oral presentation highlighting ziftomenib combined with 7+3 in newly diagnosed (1L) *NPM1*-m and *KMT2A*-r AML, and an encore presentation of results from the KOMET-001 registrational trial of ziftomenib in relapsed/refractory (R/R) *NPM1*-m AML (also presented during

EHA2025) are available in the Posters and Presentations section of the Kura website. The KOMET-017 protocol consists of 2 separate Phase 3 studies, which will investigate the benefits and risks of adding ziftomenib to standards of care treatments in patients newly diagnosed *NPM1*-m or *KMT2A*-r AML and which is registered at www.clinicaltrials.gov as NCT07007312.

Virtual Investor Event

Kura will host a virtual investor event featuring company management and investigators from the KOMET-007 trial of ziftomenib in combination with 7+3 in patients with *NPM1*-m and *KMT2A*-r AML at 4:30pm ET / 1:30pm PT on Wednesday, June 18, 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 (BTD) from the U.S. Food and Drug Administration (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 in the second quarter of 2025, the companies announced the FDA's acceptance of a New Drug Application for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML and assignment of a Prescription Drug User Fee Act target action date of November 30, 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 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.

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; potential benefits of combining ziftomenib with intensive chemotherapy and other standards of care for AML; progress of the ziftomenib program and clinical trials, including the KOMET-017-IC pivotal Phase 3 study; and the potential for ziftomenib to obtain regulatory approval. 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.