Kura Oncology and Kyowa Kirin Launch Clinical Trial Evaluating Dual Inhibition of NPM1 and FLT3 Mutations in Patients with Newly Diagnosed Acute Myeloid Leukemia (AML)

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– Expanding clinical experience and safety profile of ziftomenib support its evaluation in combination with approved FLT3 *inhibitors in frontline AML –*

– FLT3 mutations occur in approximately 30% of newly diagnosed adult patients with AML and up to 50% of adult patients with NPM1*-m AML, making* FLT3 *one of the most common genetic alterations in AML –*

– Ziftomenib clinical trials are now active in multiple frontline settings that include up to 50% of incident patients with AML in the U.S. –

SAN DIEGO and TOKYO, Oct. 01, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced dosing of the first patient in a cohort of the KOMET-007 clinical trial (NCT05735184). This cohort evaluates ziftomenib, a once-daily, investigational oral menin inhibitor, combined with cytarabine and daunorubicin (7+3) as well as quizartinib, for patients with newly diagnosed acute myeloid leukemia (AML). Despite recent advances, including regulatory approvals of *FLT3* inhibitors such as quizartinib, patients with *FLT3/NPM1* co-mutations face a high risk of relapse and limited durable treatment options. Ziftomenib is the only menin inhibitor to have received Breakthrough Therapy Designation by the Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory *NPM1*-mutated AML.

"Patients with *FLT3*/*NPM1* co-mutated AML, a significant subset of newly diagnosed cases, face high relapse rates and limited durable treatment options," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "Preclinical data demonstrate that ziftomenib synergizes with *FLT3* inhibitors such as quizartinib, potentially enhancing activity without increasing toxicity. The KOMET-007 trial, alongside our recently launched KOMET-017 registrational trial combining ziftomenib with intensive and non-intensive chemotherapy, reflects our commitment to integrating menin inhibition across AML treatment regimens to improve patient outcomes."

"Initiation of the *FLT3* inhibitor cohort in the KOMET-007 trial marks a pivotal advancement in addressing the urgent needs of patients with *FLT3/NPM1* co-mutated AML," said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. "*FLT3* mutations play a critical role in AML, driving aggressive leukemia cell proliferation, leading to poor prognosis, higher relapse rates, and shorter overall survival. Kyowa Kirin is proud to collaborate with Kura Oncology to advance this innovative menin inhibitor combination, aiming to improve outcomes for AML patients throughout the continuum of care."

The trial arm will evaluate safety, tolerability and activity of intensive chemotherapy and quizartinib in combination with ziftomenib in adult patients with newly diagnosed *FLT3*-ITD / *NPM1* co-mutated AML. Primary and secondary endpoints include complete remission (CR) and composite complete remission (CRc). More information regarding this trial arm and the KOMET-007 trial is available at www.clinicaltrials.gov (identifier: NCT05735184).

Ziftomenib is currently under clinical development, and its safety and efficacy have not been established by any regulatory authority.

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 of small molecule drug candidates is designed to target cancer signaling pathways and address high-need hematologic malignancies and solid tumors. Kura is developing ziftomenib, a menin inhibitor targeting certain genetic drivers of acute myeloid leukemias, and continues to pioneer advancements in both menin inhibition and farnesyl transferase inhibition to address mechanisms of adaptive and innate resistance in the treatment of solid tumors. 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, among other things, statements regarding the safety, tolerability, and therapeutic potential of ziftomenib, and expectations regarding trial enrollment. 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, 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 Kura faces, please refer to Kura'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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