Kura Oncology and Kyowa Kirin Announce First Patient Dosed in Pivotal Phase 3 KOMET-017 Trial of Ziftomenib for Frontline Acute Myeloid Leukemia (AML)

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– KOMET-017-IC trial of intensive chemotherapy combination will assess MRD negative CR and EFS as dual-primary endpoints to support potential U.S. accelerated and full approval –

– KOMET-017-NIC trial of venetoclax / azacitidine combination will assess CR and OS as dual-primary endpoints to support potential U.S. accelerated and full approval –

SAN DIEGO and TOKYO, Sept. 29, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced that the first patient has been dosed under the KOMET-017 clinical trial protocol (NCT07007312), comprising two independent, global, randomized double-blind, placebo-controlled Phase 3 trials to evaluate ziftomenib, Kura Oncology's investigational menin inhibitor, in combination with both intensive and non-intensive combination regimens in patients with newly diagnosed *NPM1*-mutated (*NPM1*-m) or *KMT2A*-rearranged (*KMT2A*-r) acute myeloid leukemia (AML).

"The dosing of the first patient under the KOMET-017 protocol is a major milestone in the pursuit of improved treatments for patients with newly diagnosed AML," said Amer Zeidan, M.B.B.S., M.H.S., Chief of the Division of Hematologic Malignancies, Director of Hematology Early Therapeutics Research at Yale Cancer Center and lead investigator of KOMET-017. "AML remains one of the most aggressive and difficult-to-treat blood cancers, with many patients relapsing despite currently available therapies. Ziftomenib, which in my opinion has the potential to be the best-in-class menin inhibitor, has demonstrated promising safety and activity in early phase clinical trials of *NPM1*-m and *KMT2A*-r AML both as monotherapy and in combination with multiple standards of care. These two randomized Phase 3 trials offer the potential to confirm benefit across frontline populations that account for nearly half of newly diagnosed AML patients and where safe, tolerable and effective options are urgently needed."

"This is a pivotal moment for Kura, Kyowa Kirin, and patients with AML," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "To our knowledge, KOMET-017 is the only menin inhibitor program actively pursuing registrational trials across both intensive and non-intensive chemotherapy settings, underscoring the potential to address a broad spectrum of patients with AML. The opportunity to advance to the frontline AML setting offers the potential to reach patients earlier in their disease course, when the possibility to meaningfully change the trajectory of the disease is greatest. The willingness of the FDA to allow the trials to use MRD negative CR and CR as primary endpoints for accelerated approval is groundbreaking and could potentially enable us to deliver ziftomenib more quickly to patients in need. We are committed to driving the KOMET-017 program forward with the goal of transforming care for patients who continue to face a devastating prognosis."

"The initiation of the KOMET-017 trial represents a significant step forward in expanding treatment options for newly diagnosed AML patients with *NPM1*-m and *KMT2A*-r," said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. "AML remains a disease with poor prognosis, and developing safe and effective therapies is an urgent need. Ziftomenib's innovative mechanism of action, combined with its potential efficacy alongside both intensive and non-intensive therapies, holds promise to improve patients' quality of life and extend survival. Kyowa Kirin is committed to collaborating closely with Kura Oncology to bring life-changing value to patients living with AML."

Each frontline trial design includes dual-primary endpoints to support potential U.S. accelerated approval and full approval. The intensive chemotherapy Phase 3 trial of ziftomenib in combination with standard induction cytarabine / daunorubicin (7+3) will assess minimal residual disease (MRD) negative complete response (CR) and event-free survival (EFS) as dual-primary endpoints. The non-intensive chemotherapy Phase 3 trial of ziftomenib in combination with venetoclax / azacitidine will assess CR and overall survival (OS) as dual-primary endpoints. The trial is intended to serve as a registrational study and builds on encouraging clinical data previously reported with ziftomenib in genetically defined subsets of AML. The trial is expected to enroll patients at up to 200 sites worldwide, reflecting strong global interest in advancing ziftomenib for patients in need. More information regarding the KOMET-017 trial is available at www.clinicaltrials.gov (identifier: NCT07007312).

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.

Amer Zeidan, M.D., has consulted for and received honoraria from Kura Oncology and Kyowa Kirin. The opinions expressed represent his personal views and not necessarily those of his employer.

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 therapeutic potential of ziftomenib in combination with intensive and non-intensive combination regimens in patients in the frontline AML setting; the potential for U.S. accelerated approval and full approval; 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, 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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