Kura Oncology Announces First Patients Dosed in Phase 1 Combination Trial of Ziftomenib for the Treatment of Advanced GIST

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– Phase 1 dose-escalation study to evaluate ziftomenib in combination with imatinib in patients with advanced GIST after imatinib failure –

– Combination of ziftomenib and imatinib shows robust and durable antitumor activity in imatinib-sensitive and imatinib-resistant GIST preclinical models –

SAN DIEGO, April 28, 2025 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today announced that the first patients have been dosed in KOMET-015, a Phase 1 clinical trial of ziftomenib, the Company's potent and selective, oral investigational menin inhibitor, in patients with advanced gastrointestinal stromal tumors (GIST) after imatinib failure.

"Building on compelling clinical activity of ziftomenib in patients with *NPM1*-mutant and *KMT2A*-rearranged AML, we are committed to evaluating the full therapeutic potential of menin inhibitors for the treatment of cancer," said Mollie Leoni, M.D., Chief Medical Officer of Kura Oncology. "Approximately 4,000 to 6,000 new cases of GIST are diagnosed each year in the U.S., and advanced GIST patients have limited treatment options. Our preclinical data demonstrate the combination of ziftomenib and imatinib provides robust and durable antitumor activity in both imatinib-sensitive (1L) and imatinib-resistant (2L/3L) GIST patient-derived xenograft models, and we look forward to seeing whether the combination offers potential to transform the treatment paradigm."

In preclinical studies, the data demonstrates the combination exerts antitumor activity via a synthetic lethal mechanism through which ziftomenib epigenetically targets a vulnerability of GIST tumors actively induced by even ineffective tyrosine kinase inhibitor (TKI) treatments. Sixty percent of patients develop resistance to imatinib, the frontline standard of care for GIST, within two years, and ziftomenib has the potential to delay the onset of or overcome that resistance in these patients.

"This study is an important step in developing new combination treatments to potentially improve outcomes for patients with advanced gastrointestinal stromal tumors, a disease indication for which new therapeutic options are needed," said Mrinal Gounder, M.D., Sarcoma Oncologist & Early Phase Drug Development Specialist at Memorial Sloan Kettering Cancer Center. "KOMET-015 builds upon the promising preclinical data observed with ziftomenib in combination with imatinib in GIST models and we look forward to evaluating the investigational drug candidate and its potential to transform the treatment landscape."

"Until now, most approaches to treating gastrointestinal stromal tumors rely on targeted KIT inhibition via tyrosine kinase inhibitors such as imatinib, however most patients eventually progress due to acquired secondary KIT mutations highlighting the need for new treatment options," said Shreyaskumar Patel, M.D., Center Medical Director, Sarcoma Center, at The University of Texas MD Anderson Cancer Center. "We are highly encouraged by the substantial preclinical data generated to date supporting the combination for ziftomenib in combination with KIT inhibitors in advanced GIST, and the dosing of the first patients marks an important milestone to address the meaningful unmet need for these patients."

The KOMET-015 Phase 1a/1b, open-label, dose-escalation trial is designed to evaluate the safety, tolerability, and preliminary antitumor activity of ziftomenib in combination with imatinib in adults with GIST who have documented disease progression while currently on or previously treated with imatinib. Upon completion of the dose-escalation portion of the trial, expansion cohorts are planned to further assess the safety, tolerability, and clinical activity of ziftomenib. The primary objectives include evaluation of safety and tolerability and determination of the recommended Phase 2 dose, and key secondary endpoints include clinical benefit, overall response rate (ORR), progression free survival (PFS), duration of response, and overall survival (OS).

Currently, there are no other clinical trials evaluating the combination of a menin inhibitor with standards of care for the treatment of GIST. For more information regarding the KOMET-015 trial, please visit www.clinicaltrials.gov (identifier: NCT06655246).

About GIST

Gastrointestinal stromal tumors (GIST) are the most common form of sarcoma, and are characterized as KIT-dependent solid tumors, with an estimated 4,000 to 6,000 new cases diagnosed in the U.S. each year. Despite the successful disease control achieved with imatinib in advanced GIST patients, most patients eventually progress due to acquired secondary KIT mutations. TKIs such as sunitinib target imatinib-resistant genotypes and are approved in later lines, but response rates and long-term outcomes are modest, so new therapeutic options are needed.

About Ziftomenib

Ziftomenib is a once daily, oral investigational menin inhibitor currently in development for the treatment of genetically defined AML and GIST patients with high unmet need. In April 2024, ziftomenib received Breakthrough Therapy Designation (BTD) from the FDA for the treatment of relapsed/refractory (R/R) *NPM1*-mutant (*NPM1*-m) AML based on data from Kura's KOMET-001 clinical trial. Additional information about clinical trials for ziftomenib can be found at www.kuraoncology.com/clinical-trials/#ziftomenib.

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 entered into a global strategic collaboration agreement with Kyowa Kirin Co., Ltd. to develop and commercialize ziftomenib for AML and other hematologic malignancies. Enrollment in 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 submission of a New Drug Application for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML. 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. Kura has also initiated a Phase 1 trial (KOMET-015) of ziftomenib in combination with imatinib in 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.

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 Kura's product candidates, ziftomenib, tipifarnib and KO-2806; plans, trial designs and expected timing of clinical trials; the anticipated timing of submission of an NDA for ziftomenib; and the potential for menin inhibitors to shift the treatment paradigm for GIST. 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, applications 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, 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.

Dr. Gounder has financial interests related to Kura Oncology.

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