Kura Oncology Completes Enrollment in Registration-Directed Trial of Ziftomenib in NPM1-Mutant AML

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– Company enrolls 85 patients with R/R NPM1-mutant AML in fewer than 16 months –

– Topline data expected in early 2025 –

– Breakthrough Therapy Designation to enable expedited review by FDA –

SAN DIEGO, May 14, 2024 (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 it has completed enrollment of 85 patients in the Phase 2 portion of KOMET-001, a registration-directed clinical trial of the Company's menin inhibitor, ziftomenib (KO-539), in patients with relapsed or refractory (R/R) NPM1-mutant acute myeloid leukemia (AML). The Company expects to report topline data from the trial in early 2025.

"We are thrilled to announce this critical milestone, which brings us one step closer to delivering ziftomenib as a potentially best-in-class treatment for patients with genetically defined acute leukemias," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Our confidence is supported by our recently announced Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA), which recognizes ziftomenib's potential as an innovative medicine for patients with R/R NPM1-mutant AML and is intended to expedite review as we prepare for submission of a New Drug Application. We are grateful for the KOMET-001 investigators, patients and their families, and we look forward to sharing topline data from this pivotal study early next year."

Kura announced the first patients dosed in the Phase 2 portion of KOMET-001 in February 2023. The registration-directed study is designed to assess evidence of clinical activity, safety and tolerability of ziftomenib in patients with R/R NPM1-mutant AML, with a primary endpoint of complete response. The study has completed enrollment of the 85 patients necessary to support the primary endpoint analysis.

"The rapid enrollment of this study reflects the urgent need for more effective treatment options in AML as well as the potential for ziftomenib to address this need," said Eunice Wang, M.D., Chief of the Leukemia Service at Roswell Park Comprehensive Cancer Center and principal investigator of the trial. "NPM1-mutant AML represents approximately 30% of new AML cases annually and is a disease of significant unmet need for which there is no approved targeted therapy. The favorable safety profile and encouraging clinical activity demonstrated by ziftomenib to date offer the potential to transform the standard of care for these AML patients."

About NPM1-mutant AML

AML is the most common acute leukemia in adults and begins when the bone marrow makes abnormal myeloblasts (white blood cells), red blood cells or platelets. Despite the many available treatments for AML, prognosis for patients remains poor and a high unmet need remains. The menin pathway is considered a driver for multiple genetic alterations of the disease, of which NPM1 mutations are among the most common, representing approximately 30% of AML cases. While patients with NPM1-m AML have high response rates to frontline therapy, relapse rates are high and survival outcomes are poor, with only 30% overall survival at 12 months in the R/R setting. Additionally, NPM1 mutations frequently occur with co-mutations in other disease-associated genes, including FLT3, DNMT3A and IDH1/2, with prognosis heavily influenced by the occurrence of co-occurring mutations. Adult patients with NPM1-m AML and select co-mutations and/or R/R disease have a poor prognosis, with median overall survival of only approximately 7.8 months in 2nd line, 5.3 months in 3rd line and 3.5 months following the 4th line.[1] There are currently no FDA-approved therapies targeting NPM1-m AML.

About Ziftomenib

Ziftomenib is a novel, once-daily, oral investigational drug candidate targeting the menin-KMT2A/MLL protein-protein interaction for treatment of genetically defined AML patients with high unmet need. In the KOMET-001 Phase 1 study, ziftomenib demonstrated an encouraging safety profile and tolerability with reported events most often consistent with features and manifestations of underlying disease. Clinical activity of ziftomenib as a monotherapy was optimal at the 600 mg daily dose and a 35% complete remission rate was observed in 20 patients with NPM1-mutant AML treated at the recommended Phase 2 dose (600 mg). Ziftomenib has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the treatment of R/R NPM1-mutant AML. Additional information about clinical trials for ziftomenib can be found at 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 that target cancer signaling pathways. Ziftomenib, a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction, has received Breakthrough Therapy Designation for the treatment of R/R NPM1-mutant AML. Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant R/R AML (KOMET-001) and expects to report topline data in early 2025. The Company is also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in NPM1-mutant and KMT2A-rearranged newly diagnosed and R/R AML. Tipifarnib, a potent and selective farnesyl transferase inhibitor (FTI), is currently in a Phase 1/2 trial in combination with alpelisib for patients with PIK3CA-dependent head and neck squamous cell carcinoma (KURRENT-HN). Kura is also evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in

combination with targeted therapies (FIT-001). For additional information, please visit Kura's website at www.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 ziftomenib, potential benefits of combining ziftomenib with appropriate standards of care, and progress and expected timing of the ziftomenib program and clinical trials. 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.

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[1] Issa G, et al. Blood Adv 2023;7(6):933-42.

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