Kura Oncology Announces First Patients Dosed in Phase 2 Registration-Directed Trial of Ziftomenib in NPM1-Mutant Acute Myeloid Leukemia

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– Phase 1 trial showed 30% CR rate among 20 NPM1-mutant AML patients treated at recommended Phase 2 dose –

– Phase 2 registration-directed trial expected to enroll 85 patients in the U.S. and Europe –

SAN DIEGO, Feb. 09, 2023 (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 its KOMET-001 Phase 2 registration-directed trial of ziftomenib, the Company's novel menin inhibitor, in patients with NPM1-mutant relapsed or refractory acute myeloid leukemia (AML).

"Dosing the first patients in our registration-directed trial of ziftomenib marks a significant milestone for our menin inhibitor program," said Troy Wilson, Ph.D., J.D., President & Chief Executive Officer of Kura Oncology. "Building on the strength of our Phase 1 data, we remain committed to our mission to realize the full potential of ziftomenib as an important treatment option to patients with acute leukemia. The speed with which we have begun enrolling in this registration-enabling Phase 2 study speaks to the significant interest in ziftomenib among investigators."

In the Phase 1 clinical trial, ziftomenib showed as of the data cutoff on October 24, 2022, a 30% complete response (CR) rate among 20 NPM1-mutant AML patients treated at 600 mg. In addition, the favorable safety profile and encouraging tolerability at the 600 mg daily dose resulted in its designation as the recommended Phase 2 dose following a positive Type C meeting with the U.S. Food and Drug Administration (FDA).

The primary endpoint in the Phase 2 registration-directed trial in patients with NPM1-mutant relapsed or refractory AML, is CR or complete response with hematologic recovery (CRh), and key secondary endpoints include clinical benefit as well as safety and tolerability. In addition to continued evaluation of ziftomenib as a monotherapy in NPM1-mutant AML, Kura plans to initiate the KOMET-007 and KOMET-008 trials later this year to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML.

For more information regarding the KOMET-001 trial, please visit www.clinicaltrials.gov (identifier: NCT04067336).

About Acute Myeloid Leukemia

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. NPM1-mutations are among the most common genetic alterations, representing approximately 30% of AML cases. While patients with NPM1-mutant 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 relapsed or refractory 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. Median overall survival is only six months following relapse for NPM1-mutant patients. KMT2A-rearrangements are less frequent, representing approximately 5-10% of AML. No FDA-approved therapies targeting NPM1-mutant and KMT2A-rearranged AML currently exist.

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 preclinical models, ziftomenib inhibits the KMT2A/MLL protein complex and exhibits downstream effects on HOXA9/MEIS1 expression and potent anti-leukemic activity in genetically defined preclinical models of AML. Ziftomenib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML. Additional information about clinical trials for ziftomenib can be found at kuraoncology.com/clinical-trials/clinical-trials-komet-001/.

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 potent and selective menin inhibitor, is currently in development for patients with NPM1-mutant and KMT2A-rearranged acute myeloid leukemia. Tipifarnib, a potent, selective and orally bioavailable FTI, has received Breakthrough Therapy Designation for the treatment of patients with HRAS-mutant HNSCC. Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company has also initiated a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in EGFR-mutant non-small cell lung cancer. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through a Phase 1 first-in-human study. For additional information, please visit Kura's website at www.kuraoncology.com.

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 (SEC), including the Company's Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 3, 2022, 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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