Kura Oncology Doses First Patient in KOMET-008 Trial of Ziftomenib in Combination with Standards of Care, Including FLT3 Inhibitor, in Acute Myeloid Leukemia

February 26, 2024

– KOMET-008 is evaluating ziftomenib in combination with gilteritinib, FLAG-IDA or LDAC in patients with relapsed/refractory NPM1-mutant or KMT2A-rearranged AML –

SAN DIEGO, Feb. 26, 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 the first patient has been dosed in KOMET-008, the Company's Phase 1 trial of its menin inhibitor ziftomenib, in combination with gilteritinib, FLAG-IDA or LDAC for the treatment of NPM1-mutant or KMT2A-rearranged acute myeloid leukemia (AML).

"Roughly half of patients with relapsed or refractory NPM1-mutant AML have co-occurring FLT3 mutations, and the prognosis for these patients is particularly poor," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology. "Given the potential best-in-class safety and tolerability profile as well as the robust monotherapy activity observed in our Phase 1 study of ziftomenib, we believe an all-oral combination of ziftomenib and gilteritinib may provide an attractive treatment option for these patients."

KOMET-008 is a Phase 1 study designed to assess safety and tolerability, pharmacokinetics and evidence of clinical activity of ziftomenib in combination with gilteritinib, FLAG-IDA or LDAC for two genetically defined cohorts, NPM1-mutant AML and KMT2A-rearranged AML, in the relapsed/refractory setting. Trial participants will be enrolled in one of five dose escalation cohorts, including a cohort of NPM1-mutant AML patients with a documented FLT3 co-mutation, who will be treated in combination with the FLT3 inhibitor gilteritinib. For more information regarding KOMET-008, please visit www.clinicaltrials.gov (identifier: NCT06001788).

Kura is conducting a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations. In July, the Company began dosing patients in the first of these studies, KOMET-007, in combination with venetoclax and azacitidine in patients with relapsed/refractory NPM1-mutant and KMT2A-rearranged AML or in combination with standard induction cytarabine/daunorubicin chemotherapy (7+3) in patients with previously untreated NPM1-mutant and KMT2A-rearranged AML. Kura reported positive preliminary data from 20 patients in KOMET-007 on January 30, 2024.

Preclinical data for menin inhibitors in combination with multiple FLT3 inhibitors demonstrate strong synergistic effects compared to either single agent alone. Currently there are no other actively recruiting clinical trials evaluating the combination of a menin inhibitor with a FLT3 inhibitor for the treatment of AML.

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 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 and KMT2A rearrangements represent approximately 5-10% 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 presence 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]. Adult patients with KMT2A-r AML have a poor prognosis with high rates of resistance and relapse following standard of care, with median overall survival for this patient population of only 6 months following 2nd line and 2.4 months following 3rd line[2]. No FDA-approved therapies targeting NPM1-m and KMT2A-r 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. 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/#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 is a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction for the treatment of genetically defined AML patients with high unmet need. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with venetoclax and azacitidine and 7+3 in NPM1-mutant and KMT2A-rearranged newly diagnosed and relapsed/refractory AML (KOMET-007). 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 adagrasib in $KRAS^{G12C}$-mutated non-small cell lung cancer and cabozantinib in clear cell renal cell carcinoma (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, 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 GC, et al. Blood Adv. 2023;7(6):933-42.
[2] Issa GC, et al. Blood Cancer J. 2021;11(9):162.

Source: Kura Oncology, Inc.