Kura Oncology Announces Publication of Ziftomenib Phase 1 Results in The Lancet Oncology

September 30, 2024

SAN DIEGO, Sept. 30, 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 the publication of its KOMET-001 Phase 1 study manuscript in *The Lancet Oncology* journal. The paper, entitled "Ziftomenib in relapsed/refractory acute myeloid leukaemia (KOMET-001): results from an open-label, multi-cohort, phase 1a/1b trial," is now available on *The Lancet Oncology* website and in the Scientific Manuscripts section on Kura's website.

"The results from the KOMET-001 Phase 1 study are encouraging as they demonstrate meaningful benefit of ziftomenib in *NPM1*-mutant acute myeloid leukemia (AML), and publication of these data expands the growing evidence supporting the efficacy and safety of ziftomenib in a disease indication of unmet need," said Ghayas C. Issa, M.D., assistant professor of Leukemia at The University of Texas MD Anderson Cancer Center. "We are thankful for the patients and their families for their participation in the KOMET-001 trial and for the scientific community who have contributed to this research to advance more tolerable and effective treatment options for AML patients."

The KOMET-001 study is a Phase 1/2 global, open-label, multi-cohort clinical trial evaluating the safety, tolerability and clinical activity of ziftomenib in relapsed/refractory (R/R) AML. In the Phase 1a dose escalation portion, patients received ziftomenib once daily in 28-day cycles and in the Phase 1b dose validation/expansion portion, patients were randomized to two parallel cohorts at 200 mg and 600 mg. As of the data cutoff on August 30, 2023, 83 patients received one or more doses of ziftomenib and the primary objective of this study was to determine the recommended phase 2 dose (RP2D) based on safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary activity. The results demonstrated promising clinical activity with manageable toxicity in heavily pretreated patients including marrow blast reduction, neutrophil and platelet recovery, transfusion independence, and clearance of measurable residual disease.

"Our Phase 1 study provided the critical safety and clinical activity data in order to determine the RP2D and support our pivotal Phase 2 registration-directed trial in patients with *NPM1*-mutant AML," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology. "These data reinforce our commitment to developing novel investigational therapies, including menin inhibitors, to realize the transformative value for patients with acute leukemias. The clinical data generated to date, including the insights gained from this study, demonstrate the potential for ziftomenib to become a cornerstone of AML therapy through monotherapy and combination approaches."

In May 2024, Kura Oncology announced completion of enrollment in the Phase 2 portion of KOMET-001, a registration-directed trial of ziftomenib in patients with R/R NPM1-mutant AML. Enrollment of the 85 patients in Phase 2 was completed in fewer than 16 months and the Company expects to report topline data from the trial in early 2025.

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 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]. 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 encouraging safety and tolerability with reported events 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 (BTD) 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 BTD for the treatment of R/R *NPM1*-mutant AML. Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-mutant AML (KOMET-001). The Company is also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R *NPM1*-mutant and *KMT2A*-rearranged AML. Kura is evaluating KO-2806, a next-generation farnesyl transferase inhibitor (FTI), in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies (FIT-001). Tipifarnib, a potent and selective 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). 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.

Source: Kura Oncology, Inc.