Kura Oncology Presents Late-Breaking Clinical Data for Menin Inhibitor Ziftomenib at 2023 European Hematology Association (EHA) Congress

June 11, 2023

– 35% CR rate (7/20) among patients with relapsed/refractory NPM1-mutant AML treated at 600 mg dose (RP2D) –

– 33% (2/6) of patients with FLT3 co-mutations and 50% (4/8) of patients with IDH co-mutations achieved a CR on ziftomenib –

– Ziftomenib monotherapy drives durable remissions, with median DoR of 8.2 months –

– Data suggest ziftomenib is less likely to induce menin resistance mutations –

– Enrollment in Phase 2 registration-directed trial in NPM1-mutant AML continues to outperform projections –

– First combination study in NPM1-mutant and KMT2A-rearranged AML on track to dose first patients this quarter –

– Management to host virtual investor event at 8:00 a.m. ET on Monday, June 12 –

SAN DIEGO, June 11, 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 updated clinical data from KOMET-001, a Phase 1/2 clinical trial of the Company's potent and selective menin inhibitor, ziftomenib, including significant clinical activity in patients with heavily pretreated and co-mutated relapsed/refractory NPM1-mutant acute myeloid leukemia (AML).

The updated clinical data are being featured during a late-breaking oral session today at the 2023 European Hematology Association (EHA) Annual Congress in Frankfurt, Germany. A copy of the presentation is available in the Posters and Presentations section on Kura's website.

"Our goal with our ziftomenib program is to transform the standard of care for patients with acute leukemias," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology, "and we are delighted to share new clinical and preclinical data that we believe further demonstrate its potential best-in-class product profile. The emerging data for ziftomenib include: high clinical activity in relapsed/refractory NPM1-mutant AML patients, including 35% achieving durable complete remissions (CR) with maintained full count recovery on ziftomenib monotherapy; a lower frequency of *MEN1* resistance mutations; a favorable safety and tolerability profile; strong evidence of mechanistic synergy with standards of care such as venetoclax and FLT3 inhibitors; and convenient once-daily, oral dosing and optimal pharmaceutical properties for combination. We believe ziftomenib has the ideal properties to become a cornerstone of therapy across the continuum of treatment, and we intend to build on the growing momentum as we continue to execute on our registration-enabling study in *NPM1*-mutant AML and move rapidly into combinations."

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the recommended Phase 2 dose (RP2D) of 600 mg achieved a CR with full count recovery. Notably, 33% (2/6) of patients with FLT3 co-mutations and 50% (4/8) of patients with IDH co-mutations achieved a CR on ziftomenib. Two patients underwent a stem cell transplant (SCT) and remain in remission as of the data cutoff, including one on post-SCT ziftomenib maintenance therapy. An eighth patient who had a CR with incomplete recovery (CRi) at the time of transplant subsequently evolved to a CR and remains on study.

The median duration of response for all NPM1-mutant patients was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median duration of response for patients censored at SCT was 5.6 months (95% CI: 1.0 to NE). As of the cutoff date, three patients treated at 600 mg remain on study and in CR; an additional NPM1-mutant patient treated at 200 mg remained on ziftomenib for 36 cycles.

As part of an ongoing analysis, the resistance mutation *MEN1*-M327I has been detected in three patients treated with ziftomenib: in two patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations are less likely to evolve after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains full activity against the *MEN1*-T349M mutation, detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

"NPM1-mutant AML accounts for approximately 30% of AML cases annually and represents a disease of significant unmet need for which no approved targeted therapy exists," said Amir Fathi, M.D., Director of the Leukemia Program at the Massachusetts General Hospital. "The clinical data presented today continue to demonstrate the ability of ziftomenib to drive durable responses as a monotherapy in heavily pretreated patients with *NPM1*-mutant AML. In addition, data appears to suggest that ziftomenib is less likely to induce common *MEN1* resistance mutations, coupled with emerging data showing the retention of activity against other key resistance mutants, are exciting, as we look to advance ziftomenib into combinations and treat patients in earlier lines of therapy."

Continuous daily dosing of ziftomenib was well tolerated and the safety profile remains consistent with features of underlying disease. The on-target effect of differentiation syndrome was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

Enrollment in a Phase 2 registration-directed study of ziftomenib in patients with relapsed/refractory NPM1-mutant AML continues to outperform projections. The study is expected to enroll a total of 85 patients at 62 U.S. and European sites. Kura is also preparing to initiate a series of studies 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. The Company has begun site activation in the first of these studies, KOMET-007, and is on track to dose the first patients this quarter.

Virtual Investor Event

Management will host a virtual investor event featuring company management and investigators from the Phase 1 trial of ziftomenib at 8:00 a.m. ET on Monday, June 12, 2023. The event will be webcast live and can be accessed on the Investors section of Kura's website at www.kuraoncology.com. An archived replay will be available shortly after the conclusion of the live event.

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 approximately 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/#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. The Company is currently enrolling patients in a Phase 2 registration-directed trial (KOMET-001) of ziftomenib in NPM1-mutant relapsed or refractory AML. Kura is preparing to initiate multiple Phase 1 trials 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. Tipifarnib, a potent and selective farnesyl transferase inhibitor (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. Kura intends to evaluate KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with other targeted therapies in adult patients with advanced solid tumors. 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, progress and expected timing of the ziftomenib program, and plans regarding future 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 March 31, 2023 filed with the SEC on May 10, 2023, 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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