Kura Oncology Doses First Patient in Phase 1b Expansion Cohorts with Menin Inhibitor KO-539

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– Phase 1b expansion cohorts designed to enable refinement of recommended Phase 2 dose –

– At least 12 patients to be enrolled in each of two Phase 1b expansion cohorts: a 200 mg dose cohort and a 600 mg dose cohort –

– Each cohort to be genetically enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients –

– Company anticipates that patient data from the recommended Phase 2 dose cohort will be included as part of the registration-directed portion of the trial –

SAN DIEGO, June 24, 2021 (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 the Phase 1b portion of KOMET-001, a Phase 1/2 clinical trial of the Company's oral, potent and selective menin inhibitor, KO-539, in patients with relapsed or refractory acute myeloid leukemia (AML).

KO-539 demonstrated a wide therapeutic window in the Phase 1a dose-escalation portion of KOMET-001, with promising single-agent activity from 50 mg to 800 mg in an all-comer population of patients with relapsed or refractory AML, including patients with NPM1 mutations and KMT2A rearrangements. The Phase 1b portion of the study is designed to determine the lowest dose of KO-539 that provides maximum biologic and clinical effect in two expansion cohorts – a low dose (200 mg) and a high dose (600 mg) – each enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients. Both doses have demonstrated preliminary evidence of biologic and clinical activity and were determined to be safe and well tolerated in the Phase 1a portion of the study.

Kura expects to enroll at least 12 patients in each of the Phase 1b expansion cohorts and assess those patients for safety and tolerability, pharmacokinetics, pharmacodynamics and efficacy in order to determine the recommended Phase 2 dose. In addition, the Phase 1b gives the Company flexibility to enroll up to 18 additional patients per cohort, as appropriate. Kura believes that data from patients enrolled in the cohort selected as the recommended Phase 2 dose can be included as part of the registration-directed portion of the KOMET-001 trial.

"We believe KO-539 has the potential to be both a first-in-class and a best-in-class menin inhibitor," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology. "We intend to conduct a comprehensive clinical development plan for KO-539, both as a monotherapy and in front-line combination studies. A critical component of this plan is the determination of an optimal dose, particularly given the compelling efficacy, safety and wide therapeutic window of KO-539. These Phase 1b expansion cohorts enable us to gather a more robust dataset in our targeted populations and help refine selection of a recommended dose for Phase 2 and beyond, while maintaining an aggressive development timeline for the program. We look forward to presenting data at a future medical meeting."

In December 2020, Kura reported preliminary clinical data from the KOMET-001 clinical trial of KO-539 at the American Society of Hematology Annual Meeting. These data were highlighted by single-agent activity in patients with relapsed or refractory AML, including patients with NPM1 mutations and KMT2A rearrangements. KO-539 also demonstrated a favorable safety and tolerability profile, with no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation.

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, especially in the relapsed/refractory setting. More than 50% of patients with AML who achieve a CR after induction therapy relapse within one to three years, and less than 10% of those with relapsed/refractory AML are alive at three years. Prognosis is poor in patients with KMT2A rearrangements and in those with co-mutations that may include NPM1.

About KOMET-001

KOMET-001 (Kura Oncology Menin Inhibitor Trial) is a Phase 1/2, first-in-human, open-label trial to determine the safety, tolerability and anti-tumor activity of KO-539 in patients with refractory or relapsed AML. The Phase 1b portion is currently open to enroll patients with NPM1 mutations or KMT2A-rearrangments. A Phase 2 registration-enabling expansion portion is planned following determination of the optimal Phase 2 dose. Additional information about KOMET-001 can be found at kuraoncology.com/clinical-trials-komet.

About KO-539

KO-539 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, KO-539 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. KO-539 has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML.

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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1/2 clinical trial (KOMET-001) and targeting patients with relapsed/refractory acute myeloid leukemia, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura is also developing a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. For additional information about Kura, please visit the Company'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 Kura's drug candidates, tipifarnib and KO-539, progress and expected timing of Kura's drug development programs and clinical trials and submission of regulatory filings, the presentation of data from clinical trials, plans regarding regulatory filings and future clinical trials, the regulatory approval path for tipifarnib, the strength of Kura's balance sheet and the adequacy of cash on hand. 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 drug candidates, uncertainties associated with performing clinical trials, regulatory filings, applications and other interactions with regulatory bodies, the risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with the COVID-19 global pandemic, 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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