Kura Oncology Receives FDA Authorization to Proceed with Phase 1b Study of KO-539 in Acute Myeloid Leukemia

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– FDA lifts partial clinical hold following agreement on mitigation strategy for differentiation syndrome –

– KOMET-001 study to resume screening and enrollment of new patients –

– Encouraging safety, tolerability and clinical activity observed among patients on study –

SAN DIEGO, Jan. 20, 2022 (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 U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on the KOMET-001 Phase 1b study of KO-539 in patients with relapsed or refractory acute myeloid leukemia (AML). The partial clinical hold was lifted following agreement with the FDA on the Company's mitigation strategy for differentiation syndrome, a known adverse event related to differentiating agents in the treatment of AML.

"I am very proud of our team for working diligently with the FDA and site investigators to resolve the partial clinical hold in such a timely manner," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Activities to resume patient screening are underway, and we look forward to expediting enrollment of patients in the Phase 1b study and determining the recommended Phase 2 dose for KO-539 in the coming months. Meanwhile, we continue to be encouraged by the safety, tolerability and clinical activity observed among currently enrolled patients and look forward to sharing a comprehensive update on the Phase 1 study at a future medical meeting."

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. KO-539 demonstrated a wide therapeutic window in the Phase 1a dose-escalation portion of KOMET-001, with promising single-agent activity in an all-comer population of patients with relapsed or refractory AML, including patients with NPM1 mutations and KMT2A rearrangements. The Phase 1b portion includes two expansion cohorts – a lower dose of 200 mg and a higher dose of 600 mg. Kura expects to enroll 12 patients with NPM1-mutant or KMT2A-rearranged relapsed or refractory AML in each cohort and assess those patients for safety and tolerability, pharmacokinetics and efficacy to determine the recommended Phase 2 dose for KO-539.

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 1b clinical trial (KOMET-001) for patients with relapsed/refractory AML, 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 HNSCC and is currently in a registration-directed trial (AIM-HN) in patients with this devastating disease. In addition, Kura is conducting a Phase 1/2 trial (KURRENT) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those who whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company is also developing KO-2806, 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, Kura's ability to expedite enrollment of patients in the Phase 1b study and determine the recommended Phase 2 does for KO-539, expected timing of a comprehensive update on the Phase 1 study of KO-539, and the efficacy, safety and therapeutic potential of KO-539. 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, 2021 filed with the SEC on November 4, 2021, 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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