



Kura Oncology Provides Update on Phase 1b Study of KO-539 in Acute Myeloid Leukemia

November 24, 2021

Management to host webcast and conference call today at 8:30 a.m. ET

SAN DIEGO, Nov. 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 U.S. Food and Drug Administration (FDA) has placed the KOMET-001 Phase 1b study of KO-539 in patients with relapsed or refractory acute myeloid leukemia (AML) on a partial clinical hold. The partial clinical hold was initiated following the Company's recent report to the FDA of a Grade 5 serious adverse event (patient death) potentially associated with differentiation syndrome, a known adverse event related to differentiating agents in the treatment of AML.

Patients currently enrolled in the Phase 1b study may continue to receive KO-539, although no additional patients may be enrolled until the partial clinical hold is resolved. Kura is working closely with the FDA and the site investigators to resolve the partial clinical hold as quickly as possible.

"We share the FDA's commitment to patient safety, and we appreciate our ongoing dialogue as we work diligently to address their questions," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Differentiation syndrome is known to be an on-target effect associated with therapeutic agents that induce differentiation, and we want to ensure physicians are fully informed and prepared to address these events if they occur. Based on the totality of preclinical and clinical data, we continue to believe that KO-539 has the potential to address the significant unmet medical need of AML patients, including those with NPM1 mutations and KMT2A rearrangements."

Until the partial clinical hold is resolved, and the Company has more clarity regarding the impact on timing, Kura is suspending guidance on the completion of enrollment in the KOMET-001 Phase 1b study and determination of the recommended Phase 2 dose of KO-539.

Conference Call and Webcast

Kura's management will host a webcast and conference call at 8:30 a.m. ET / 5:30 a.m. PT today, November 24, 2021. The live call may be accessed by dialing (877) 516-3514 for domestic callers and (281) 973-6129 for international callers and entering the conference code: 2452338. A live webcast and archive of the call will be available online from the investor relations section of the company website at www.kuraoncology.com.

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 study (AIM-HN) in patients with this devastating disease. In addition, Kura is pursuing the use of tipifarnib in combination with other oncology therapeutics to address larger genetic subsets of patients, including those who have HRAS- and/or PIK3CA-dependent HNSCC. 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 resolve the partial clinical hold, including the timing of any such resolution, the efficacy, safety and therapeutic potential of KO-539, and progress and expected timing of the KO-539 development program and clinical trial. 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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