Kura Oncology Announces FDA Clearance of IND Application for KO-2806, a Next-Generation Farnesyl Transferase Inhibitor

January 24, 2023

SAN DIEGO, Jan. 24, 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 the clearance by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for KO-2806, the Company's next-generation farnesyl transferase inhibitor (FTI), for the treatment of advanced solid tumors. The Company intends to evaluate safety, tolerability and preliminary antitumor activity of KO-2806 in a Phase 1 first-in-human study as a monotherapy and in combination with other targeted therapies.

"Although we have seen significant advances in the development of targeted therapies for the treatment of various solid tumors, the reality is that most patients still eventually develop resistance and their cancer progresses on therapy," said Troy Wilson, Ph.D., J.D., President & Chief Executive Officer of Kura Oncology. "Over the past several years, we have pioneered the development of farnesyl transferase inhibitors as combination agents to prevent or delay emergence of resistance to certain classes of targeted therapy. Clearance of the IND for KO-2806 marks an important next step for this program, and we look forward to starting the Phase 1 study later this year."

The Phase 1 first-in-human study is designed to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of KO-2806 when administered as a monotherapy and in combination therapy in adult patients with advanced solid tumors. Following completion of the dose escalation as a monotherapy, Kura plans to evaluate KO-2806 in dose escalation combination cohorts in advanced solid tumors. The Company expects to initiate the Phase 1 study in the third quarter of 2023.

About KO-2806

KO-2806 is a potent next-generation inhibitor of farnesyl transferase designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. Kura has demonstrated encouraging clinical activity in HRAS-mutant head and neck squamous cell carcinoma (HNSCC) via farnesyl transferase inhibition with tipifarnib and is currently evaluating tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients. In addition, preclinical data is supportive of FTIs in combination with other targeted therapies to potentially overcome or prevent emergence of drug resistance to certain classes of drugs.

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 potent and selective menin inhibitor, is currently in development for patients with NPM1-mutant and KMT2A-rearranged acute myeloid leukemia. Tipifarnib, a potent, selective and orally bioavailable FTI, has received Breakthrough Therapy Designation for the treatment of patients with HRAS-mutant HNSCC. Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company has also initiated a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in EGFR-mutant non-small cell lung cancer. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through a Phase 1 first-in-human study. 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 KO-2806, potential benefits of combining KO-2806 with appropriate standards of care, and progress and expected timing of the KO-2806 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 (SEC), including the Company's Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 3, 2022, 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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Source: Kura Oncology, Inc.