Kura Oncology Receives FDA Clearance to Proceed with Clinical Trial for ERK Inhibitor KO-947 and Nominates KO-539 as Development Candidate for Menin-MLL Inhibitor Program

January 4, 2017

LA JOLLA, Calif., Jan. 04, 2017 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (NASDAQ:KURA), a clinical stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) accepted the company's Investigational New Drug (IND) application to begin Phase 1 clinical testing of KO-947, its small molecule inhibitor of extracellular-signal-regulated kinases 1 and 2 (ERK1/2) as a treatment for cancers in which the mitogen activated protein kinase (MAPK) pathway is dysregulated. Additionally, Kura announced nomination of KO-539, an orally-available small molecule inhibitor of the menin-MLL interaction, as a development candidate for the treatment of mixed lineage leukemias, a genetically-defined subset of the two most common forms of acute leukemia, acute myeloid leukemia and acute lymphoblastic leukemia.

"We are delighted to reach these important milestones in the development of our pipeline programs. KO-947, our ERK inhibitor, has shown compelling and differentiated anti-tumor activity in preclinical models of cancers in which the MAPK pathway is dysregulated, and we look forward to advancing it into human clinical testing," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "We are also pleased to nominate KO-539, an inhibitor of the menin-MLL interaction, as a development candidate, which we are advancing as a potential treatment for patients with particularly aggressive forms of leukemia. Along with the progress we have made on tipifarnib, our lead program, these achievements are a testament to our team's ability to execute on our stated goal of simultaneously advancing multiple programs aimed at addressing the urgent needs of cancer patients facing a poor prognosis and limited treatment options."

Kura expects to initiate a Phase 1 clinical trial of KO-947 in patients with a variety of solid tumors with dysregulation of the MAPK pathway in the first half of 2017. The company's goal for its menin-MLL inhibitor program is to initiate a Phase 1 clinical trial in 2018.

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 where there is a strong scientific and clinical rationale to improve outcomes by identifying those patients most likely to benefit from treatment. Kura Oncology's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, which is currently being studied in multiple Phase 2 clinical trials. The pipeline also includes KO-947, an ERK inhibitor, and KO-539, an inhibitor of the menin-MLL protein-protein interaction. For additional information about Kura Oncology, 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 potential utility of tipifarnib, KO-947 and KO-539, the conduct, results and timing of preclinical studies and clinical trials and plans regarding future research and development. 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 Oncology may not obtain approval to market its product candidates, uncertainties associated with regulatory filings and applications, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further research, clinical trials, development and commercialization of product candidates. 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 Oncology assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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