Kura Oncology Doses First Patient in Phase 2 Study of Tipifarnib in Chronic Myelomonocytic Leukemia

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LA JOLLA, Calif., Jan. 17, 2017 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq:KURA), a clinical stage biopharmaceutical company, today announced that the first patient has been dosed in its Phase 2 clinical trial of tipifarnib in patients with chronic myelomonocytic leukemia (CMML).

“Objective responses, including complete responses, have been previously observed with tipifarnib in CMML. Our goals with this Phase 2 study are to confirm the level of activity of tipifarnib in this patient population as well as to validate biomarker hypotheses that may allow us to identify those patients most likely to experience durable responses,” said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology.

“New pharmaceutical treatments are urgently needed to combat this rare disease,” said Eric Padron, M.D., of the Department of Hematologic Malignancies at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida, a clinical investigator on this study. “Given the previous results obtained with tipifarnib in this setting and the potential to identify genetic biomarkers to prospectively select patients in future studies, we are excited to evaluate tipifarnib as a potential therapeutic for CMML.”

This Phase 2 clinical trial is designed to enroll approximately 20 patients with CMML and will evaluate the antitumor activity of tipifarnib in terms of overall response rate. Patients will receive tipifarnib administered orally, twice a day for 7 days in alternating weeks in 28 day cycles. Patient samples will be analyzed for the presence or absence of various biomarkers potentially relevant to the activity of tipifarnib. Additional information about this clinical trial is available at clinicaltrials.gov using the identifier: NCT02807272.

About Chronic Myelomonocytic Leukemia

CMML is a clonal disorder of bone marrow stem cells that shares characteristics of both myeloproliferative and myelodysplastic diseases. CMML is characterized by increased monocytes and blasts in the peripheral blood and bone marrow, as well as dysplasia in at least one type of blood cell. CMML is estimated to have an annual incidence of approximately 1,400 patients in the United States. These patients generally have a poor prognosis due to limited therapeutic options with only a 29% survival rate three years after diagnosis.

About Tipifarnib

Kura Oncology’s lead program, tipifarnib, is an inhibitor of farnesylation, a key cell signaling process implicated in cancer initiation and development. In extensive clinical trials, tipifarnib has shown a well-established safety profile and compelling and durable anti-cancer activity in certain patient subsets. Preclinical and clinical data suggest that, in the appropriate context, tipifarnib has the potential to provide significant benefit to cancer patients with limited treatment options. Leveraging advances in next-generation sequencing as well as emerging information about cancer genetics and tumor biology, Kura Oncology is seeking to identify patients most likely to benefit from tipifarnib.

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 includes KO-947, an ERK inhibitor, and KO-539, an inhibitor of the menin-MLL protein-protein interactions. 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 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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