Kura Oncology Doses First Patient in Phase 2 Study of Tipifarnib in Lower Risk Myelodysplastic Syndromes

June 16, 2016

LA JOLLA, Calif., June 16, 2016 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (NASDAQ:KURA), a clinical stage biopharmaceutical company, today announced the first patient has been dosed in a Phase 2 clinical trial of tipifarnib in patients with lower risk myelodysplastic syndromes (MDS).

“We believe there is a significant unmet need for therapies targeting MDS,” said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology. “We were encouraged by data from a previous Phase 2 trial of tipifarnib conducted by Johnson & Johnson that showed modest activity of this agent in the overall population of patients with intermediate to high risk MDS. Using translational medicine methodologies, we identified potential predictive biomarkers of this activity, and one key goal of this study is to validate the ability of those biomarkers to identify the patients most likely to benefit from tipifarnib.”

“Patients with MDS, a group of diverse bone marrow disorders, suffer from a dearth of treatment options and the development of new drugs is vital to combat the disease,” said Joseph G. Jurcic, M.D., Professor of Medicine and principal investigator at Columbia University Medical Center. “The analyses from previous studies provide a strong rationale for evaluating tipifarnib in this indication.”

MDS is a group of hematopoietic stem cell malignancies with significant morbidity and mortality. MDS is characterized by ineffective blood cell production, or hematopoiesis, leading to low blood cell counts, or cytopenias, and a high risk of progression to acute myeloid leukemia. MDS is estimated to have an annual incidence of approximately 13,000 patients in the United States. These patients generally have a poor prognosis due to the low response rate to available treatment options.

The trial is designed to enroll approximately 58 patients and will evaluate tipifarnib as a treatment for patients with lower risk myelodysplastic syndromes. 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: NCT02779777.

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 will seek to identify patients most likely to benefit from tipifarnib. Kura Oncology holds an exclusive license to develop and commercialize tipifarnib in the field of oncology, under an agreement with Janssen Pharmaceutica NV.

About Kura Oncology

Kura Oncology is a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines for the treatment of solid tumors and blood cancers. Kura's pipeline consists of small molecules 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. The company's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, which is currently being studied in four Phase 2 clinical studies: the first is in patients with locally advanced solid tumors that carry HRAS mutations; the second is in patients with peripheral T-cell lymphomas; the third in patients with lower risk myelodysplastic syndromes; and the fourth is an investigator sponsored Phase 2 trial, in patients with urothelial carcinoma tumors characterized by HRAS mutations. Kura’s preclinical pipeline includes KO-947, an ERK inhibitor, and a menin-MLL inhibitor program that is currently in lead optimization. For additional information about Kura Oncology, please visit 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 and Kura Oncology’s other compounds and product candidates, 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," "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.

CONTACT INFORMATION

INVESTOR CONTACT:
Robert H. Uhl
Managing Director
Westwicke Partners, LLC
(858) 356-5932
robert.uhl@westwicke.com

MEDIA CONTACT:
Mark Corbae
Vice President
Canale Communications
(619) 849-5375
mark@canalecomm.com

Kura Oncology, Inc.