# Kura Oncology Announces First Patient Dosed in an Investigator-Sponsored Phase 2 Trial of Tipifarnib in Patients With HRAS Mutant Urothelial Cancer

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LA JOLLA, Calif., Nov. 30, 2015 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (NASDAQ:KURA), today announced that the first patient has been dosed in an investigator-sponsored Phase 2 trial of its lead drug candidate, tipifarnib, an inhibitor of protein farnesylation, in cancer patients with urothelial carcinoma tumors characterized by HRAS mutations. The study is being conducted under the direction of Se Hoon Park, M.D., Ph.D. in the Division of Hematology-Oncology at the Samsung Medical Center in Seoul, South Korea.

"This study, in combination with our ongoing Phase 2 study in HRAS mutant tumors, should provide further insight into tipifarnib's activity in HRAS mutant tumors and broaden our understanding of its mechanism of action," said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology. "We are pleased to support the efforts of Dr. Park and his colleagues at the Samsung Medical Center."

"The development of new drugs for patients with refractory urothelial cancer is an important unmet medical need," said Dr. Park, lead investigator of the study. "There is a compelling scientific rationale to evaluate the role of HRAS and the activity of tipifarnib in this setting."

The primary objective of the Phase 2 study is to investigate the antitumor activity, in terms of objective response rate, of tipifarnib in patients with locally advanced, unresectable or metastatic, relapsed and/or refractory urothelial cancer tumors that carry HRAS mutations. Secondary objectives include evaluation of progression-free survival, duration of response and safety. It is planned that the study will enroll up to 18 patients.

**About HRAS**

The HRAS protein is a GTPase involved in regulating cell division in response to growth factor stimulation. Growth factors act by binding cell surface receptors that span the cell's plasma membrane. Once activated, receptors stimulate signal transduction events in the cytoplasm, a process by which proteins and second messengers relay signals from outside the cell to the cell nucleus and instruct the cell to grow or divide. HRAS is an early player in many signal transduction pathways.

HRAS acts as a molecular on/off switch. Once it is turned on, it recruits and activates proteins necessary for the propagation of the receptor's signal. In certain tumors, mutations in HRAS or its upstream effectors cause it to be permanently on, resulting in persistent activation of downstream growth and proliferation signals that drive tumor cell growth. Farnesyl transferase inhibitors (FTIs), such as tipifarnib, work to prevent the aberrant growth and proliferation of cells that are dependent on these signaling pathways by switching HRAS off.

**Trial Rationale**

The development of new drugs for patients with refractory urothelial cancer represents an important unmet medical need. Although the expression of HRAS in bladder tumors has been reported to have an inverse correlation with recurrence and disease progression, no data are yet available on the prognostic value of HRAS mutation in this indication. However, the strong association between Costello syndrome and bladder cancer may implicate HRAS in bladder carcinogenesis.

**About Tipifarnib**

Kura Oncology's lead drug candidate, tipifarnib, inhibits farnesylation, a key cell signaling process implicated in cancer initiation and development. In extensive clinical trials, tipifarnib has shown compelling and durable anti-cancer activity in certain patient subsets and a well-established safety profile. Preclinical and clinical data suggest that, in the right genetic 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, Kura Oncology will seek to identify patients most likely to benefit from tipifarnib. In addition to the currently ongoing Phase 2 clinical trial of tipifarnib in patients with tumors characterized by HRAS mutations, the company initiated a Phase 2 clinical trial in patients with peripheral T-cell lymphomas in the third quarter of 2015. 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 that is currently in two Phase 2 clinical studies: the first study in patients with locally advanced solid tumors that carry HRAS mutations and the second study in patients with peripheral T-cell lymphoma. The company plans to initiate a third Phase 2 clinical study in patients with lower risk myelodysplastic syndromes in the first half of 2016. Kura's preclinical pipeline includes KO-947, an ERK inhibitor, and a menin-MLL inhibitor program.

**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 safety and utility of tipifarnib and Kura Oncology's other compounds, the conduct and

results 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 do not demonstrate safety and/or efficacy in later pre-clinical 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.

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