Kura Oncology Announces Positive Phase 2 Trial of Tipifarnib in HRAS Mutant Urothelial Carcinoma

September 3, 2019

– Confirmed objective responses achieved in five of 13 evaluable patients –

– Primary endpoint met prior to completion of enrollment with four patients experiencing progression-free survival greater than 6 months –

– Proof-of-concept trial sponsored by Samsung Medical Center in Seoul, Korea –

– Full data to be presented at a future medical meeting –

SAN DIEGO, Sept. 03, 2019 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today announced positive topline results from an investigator-sponsored Phase 2 trial of its lead drug candidate, tipifarnib, in patients with relapsed or refractory urothelial carcinomas that carry HRAS mutations.

The ongoing, single-agent, single-arm trial is designed to enroll at least 18 patients, with a primary endpoint of progression-free survival (PFS) rate at 6 months. Secondary endpoints include objective response rate, duration of response and safety. The trial is being conducted at the Samsung Medical Center in Korea.

To date, more than 200 patients with relapsed or refractory urothelial carcinoma have been screened for the presence of tumor HRAS mutations. A total of 15 patients were identified to carry tumors with HRAS mutations. Two patients withdrew from the trial prior to their first response assessment. Of the 13 evaluable patients, five experienced confirmed objective responses, according to RECIST 1.1 criteria, for an overall response rate of 38%. Notably, four patients have experienced PFS of greater than 6 months. According to the trial protocol, the primary endpoint is met when at least four patients achieve PFS at 6 months.

“Although the treatment paradigm for advanced urothelial carcinoma has evolved with the introduction of checkpoint inhibitors, there remains a need for more precise and effective treatment options for these patients,” said Se Hoon Park, M.D., Ph.D., Samsung Medical Center, principal investigator for the trial. “These biomarker-driven data in patients with relapsed or refractory urothelial carcinoma are promising and further underscore the potential for tipifarnib in HRAS mutant solid tumors.”

All patients joined the trial upon progression from at least one prior systemic chemotherapy cycle, with a median of one prior therapy. Tipifarnib has been generally well-tolerated in the trial; adverse events observed are consistent with the known safety profile of tipifarnib. Further analyses of the trial are ongoing, and detailed data are expected to be presented at a future medical meeting.

“We are very encouraged to see that this investigator-sponsored trial in HRAS mutant urothelial carcinoma met its primary endpoint prior to the completion of enrollment,” said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. “This study represents the fourth clinical proof-of-concept for tipifarnib and the second proof-of-concept in a HRAS mutant solid tumor indication. We believe that more than five percent of urothelial carcinoma patients carry the HRAS mutation, which represents a meaningful additional market opportunity for tipifarnib. Based on these results, we are currently evaluating next steps for tipifarnib in this indication and look forward to the presentation of the full data set at an upcoming medical meeting.”

About Urothelial Carcinoma

Urothelial carcinoma, also known as transitional cell carcinoma, develops from urothelial cells that line the inside of the bladder. Urothelial carcinoma accounts for 90 percent of all bladder cancers, and can also arise in the renal pelvis and ureters. The American Cancer Society estimates approximately 80,470 new cases of bladder cancer in the United States for 2019. Despite the approval of checkpoint inhibitors in recent years, the treatment of patients with advanced urothelial carcinoma in the second-line setting remains a significant unmet need.

About Tipifarnib

Kura Oncology’s lead drug candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen in December 2014. Previously, tipifarnib was studied in more than 5,000 cancer patients and showed compelling and durable anti-cancer activity in certain patient subsets; however, no molecular mechanism of action had been determined that could explain its clinical activity across a range of solid tumor and hematologic indications. Leveraging advances in next-generation sequencing as well as emerging information about cancer genetics and tumor biology, Kura is seeking to identify those patients most likely to benefit from tipifarnib. In November 2018, following an end of Phase 2 meeting with the U.S. Food and Drug Administration, Kura initiated its first registration-directed trial of tipifarnib in patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC). In addition to HRAS mutant HNSCC and HRAS mutant urothelial carcinoma, the Company has achieved clinical proof-of-concept with tipifarnib in angioimmunoblastic T-cell lymphoma and CXCL12-expressing peripheral T-cell lymphoma.

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’s lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company is conducting a registration-directed trial in recurrent or metastatic patients with HRAS mutant HNSCC. In

addition, tipifarnib is being evaluated in multiple other Phase 2 clinical trials in solid tumor and hematologic indications. Kura's pipeline also includes KO-947, an ERK inhibitor, currently in a Phase 1 dose-escalation trial, and KO-539, a menin-MLL inhibitor, which is entering a Phase 1 clinical trial. For additional information about Kura, 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 efficacy, safety and therapeutic potential of Kura's product candidate tipifarnib, the market potential for tipifarnib, and progress and expected timing of Kura's drug development programs 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 and applications, 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, 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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