Kura Oncology Announces Positive Phase 2 Study for Tipifarnib in HRAS Mutant Head and Neck Cancer

September 7, 2017

Four of the first six HRAS mutant HNSCC patients enrolled on study achieve confirmed RECIST partial responses

Durable responses greater than one year observed

SAN DIEGO, Sept. 07, 2017 (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 a Phase 2 trial for its lead product candidate, tipifarnib, in patients with HRAS mutant relapsed or refractory squamous cell carcinomas of the head and neck (HNSCC). The Phase 2 trial achieved its primary endpoint prior to the completion of enrollment.

The trial protocol requires four confirmed, partial responses, per RECIST 1.1 criteria, out of 18 patients to meet its primary endpoint. Four confirmed, partial responses and two patients with disease stabilization have been observed among the first six evaluable HNSCC patients enrolled in the trial. In addition, objective responses greater than one year in duration have already been observed in two patients. All patients joined the study upon progression on prior therapy, including chemotherapy, cetuximab or immune therapy. Kura will continue to enroll HRAS mutant HNSCC patients and plans to present data from the study at an upcoming scientific or medical conference.

“We have observed rapid and, in some cases, dramatic responses in patients with relapsed and/or refractory HNSCC who do not appear to benefit from other therapies,” said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology. “Based on these very encouraging results, we are exploring available options to advance the development of tipifarnib in this patient population as quickly as possible.”

About HRAS Mutant HNSCC

Head and neck cancer is one of the leading causes of cancer-related deaths worldwide, with squamous cell carcinomas accounting for most head and neck cancers. Response rates for the three agents approved for treatment of HNSCC in the second line, including cetuximab and immune therapy agents, are in the range of 13-16%, and median overall survival is up to 7.5 months. HRAS is a proto-oncogene that has been implicated in the development and progression of HNSCC and has been established to be uniquely farnesylated.

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. Kura’s pipeline also includes KO-947, an ERK inhibitor, currently in a Phase 1 trial, and KO-539, an inhibitor of the menin-MLL protein-protein interaction, currently in preclinical testing. 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 efficacy, safety and therapeutic potential of tipifarnib, progress and expected timing of Kura Oncology’s tipifarnib drug development program and clinical trials and plans regarding future clinical trials and development activities. 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 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 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

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

Kura Oncology, Inc.