Kura Oncology Lead Candidate Tipifarnib Shows Durable Anti-Tumor Activity in HRAS Mutant Head and Neck Cancer in AACR-NCI-EORTC Update

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- Confirmed partial responses observed in four out of six patients with HRAS mutant HNSCC
- Tipifarnib demonstrates rapid and durable responses, with partial responses observed beyond one year
- Registration-enabling study of tipifarnib in HRAS mutant HNSCC planned for 2018

SAN DIEGO, Oct. 27, 2017 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq:KURA), a clinical stage biopharmaceutical company focused on the development of precision medicines for oncology, today presented updated preliminary results from its Phase 2 open-label trial of tipifarnib, a farnesyltransferase inhibitor, in patients with head and neck squamous cell carcinomas (HNSCC) with HRAS mutations.

The results were featured in a late-breaking, oral presentation by Dr. Alan Ho of Memorial Sloan Kettering Cancer Center at the Spotlight on Proffered Papers Session 1 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place today in Philadelphia.

Four out of six evaluable HRAS mutant HNSCC patients enrolled in the study achieved a confirmed partial response, as defined by standard RECIST criteria. In addition, as of the data cutoff date of October 4, 2017, four HRAS mutant HNSCC patients remained on study in cycles 21, 7, 5 and 3. The patients in cycles 21, 7 and 5 had all experienced partial responses while the patient in cycle 3 experienced stable disease as of the first response assessment in cycle 2. One HRAS mutant HNSCC patient with a confirmed partial response remained on study through cycle 20 and withdrew in cycle 21 with progressive disease. Another HRAS mutant HNSCC patient experienced a best response assessment of stable disease and withdrew from the study in cycle 8.

Tipifarnib has demonstrated clinical activity in previously treated patients, including those who have progressed on chemotherapy with or without cetuximab or immune therapy. The majority of adverse events reported by the investigators have been mild to moderate and are consistent with the adverse event profile previously reported for tipifarnib.

“The responses, durability and safety data with tipifarnib clearly suggest this is an important drug candidate for patients with HRAS mutant head and neck cancers,” said Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center and presenter of the tipifarnib oral presentation. “We are excited to continue to follow these patients and treat additional HRAS mutant patients in the ongoing Phase 2 trial.”

“The consistent clinical activity of tipifarnib in HNSCC patients with HRAS mutations is very encouraging,” said Antonio Gualberto, M.D., Ph.D., chief medical officer of Kura Oncology. “Based on these positive results, we continue to explore available options to rapidly advance the development of tipifarnib and subject to input from regulatory authorities, we plan to initiate a registration-enabling study in HRAS mutant HNSCC in 2018.”

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 drug development programs 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.

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