Kura Oncology Reports Preliminary Proof of Mechanism in Phase 1/2 Clinical Trial of Tipifarnib Plus Alpelisib in Head and Neck Squamous Cell Carcinoma

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– First demonstration that precision combination therapies can achieve a durable clinical response in PIK3CA-dependent HNSCC –

– Preclinical data support potential to address ~45% of HNSCC tumors that harbor HRAS overexpression and/or PIK3CA mutation –

– Enrollment in the PIK3CA-dependent and HRAS-overexpression cohorts continues –

SAN DIEGO, Oct. 26, 2022 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today reported proof of mechanism in KURRENT-HN, the Company's Phase 1/2 clinical trial of tipifarnib in combination with alpelisib in patients with HRAS- and/or PIK3CA-dependent head and neck squamous cell carcinoma (HNSCC). The preliminary data are being presented at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium in Barcelona.

In a poster entitled, "HNSCCs overexpressing wild-type HRAS are sensitive to combined tipifarnib and alpelisib treatment," Kura highlights a patient with stage III squamous cell carcinoma of the tonsil, including a PIK3CA mutation and HRAS overexpression, who has achieved a durable partial remission on study. The 35-year-old patient enrolled in KURRENT-HN after failing two prior treatments, experienced an 81% reduction in target lesions after one cycle of tipifarnib and alpelisib and an 84% reduction after three cycles. As of September 14, 2022, the patient continued on study for more than 27 weeks. Treatment-related adverse events in the study have been consistent with the known safety profiles of each drug and are manageable, with no dose-limiting toxicities reported to date. A copy of the poster is available at www.kuraoncology.com.

Although tipifarnib has shown single-agent clinical activity in a highly selected population of HRAS mutant HNSCC[1], and alpelisib has shown single-agent clinical activity in patients with PIK3CA-mutant, ER-positive/HER2-negative breast cancer[2], no objective responses have been observed with either agent as a monotherapy in patients with PIK3CA-mutant HNSCC.

"These preliminary data from KURRENT-HN are encouraging, supporting the biologic rationale that combining a farnesyl transferase inhibitor with a PI3Kα inhibitor can achieve meaningful clinical responses in PIK3CA-dependent HNSCC," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology. "In addition, our new preclinical data support the potential of this combination to address approximately 45% of HNSCC tumors that harbor an actionable HRAS and/or PIK3CA mutation or overexpression. We are now working to identify a recommended Phase 2 dose and schedule for the combination and remain committed to bringing this important new treatment option to patients with recurrent or metastatic HNSCC who are in dire need of better therapies."

About KURRENT-HN

The KURRENT-HN trial is a biomarker-defined cohort study designed to evaluate the safety, determine the recommended combination dosing and assess early anti-tumor activity of tipifarnib and alpelisib for the treatment of HNSCC patients whose tumors are dependent on HRAS and/or PI3Kα pathways. The initial cohort in the trial is comprised of patients who have PIK3CA-dependent HNSCC. In August, Kura announced the first patient was dosed in a second cohort comprised of patients with HRAS overexpression. For more information about the trial, refer to www.kuraoncology.com/kurrent/.

About HNSCC

Head and neck squamous cell carcinoma (HNSCC) is the seventh most common cancer worldwide, accounting for more than 500,000 new cases each year. Despite advances in immunotherapy, the prognosis for advanced HNSCC patients remains poor, with an estimated median overall survival of 13-15 months in patients when stratified by PD-L1 expression. Although the anti-epidermal growth factor receptor (EGFR) antibody, cetuximab, was approved more than a decade ago, development of biomarker-directed therapies in HNSCC has been stymied by the limited number of druggable targets in the genomic landscape and the challenge of managing drug refractory, recurrent/metastatic HNSCC.

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. Ziftomenib (KO-539), a potent and selective menin inhibitor, is currently in a Phase 1b clinical trial (KOMET-001) for patients with relapsed/refractory acute myeloid leukemia, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor (FTI), has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC and is currently in a registration-directed trial (AIM-HN) in patients with this devastating disease. In addition, Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company is also preparing to initiate a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in treatment-naïve, locally advanced/metastatic, EGFR mutant non-small cell lung cancer. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through IND-enabling studies. For additional information, please visit Kura'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, the opportunity of the KURRENT-HN trial to significantly expand the potential patient population, and the potential that combining tipifarnib with a PI3Kα inhibitor has to provide meaningfully greater antitumor activity. 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, applications and other interactions with regulatory bodies, 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 (SEC), including the Company’s Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 3, 2022, 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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[1] J Clin Oncol. 2021 Jun 10;39(17):1856-1864
[2] J Clin Oncol. 2018 May 1;36(13):1291-1299

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