Kura Oncology Doses First Patient in Phase 1/2 Clinical Trial of Tipifarnib in Combination with Alpelisib in Head and Neck Squamous Cell Carcinoma

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– Preclinical data suggest HRAS and PI3Kα are co-dependent oncogenes in HNSCC –

– Combination has potential to address up to 50% of patients with HNSCC –

– Initial cohort comprised of patients with PIK3CA-dependent HNSCC –

SAN DIEGO, Dec. 16, 2021 (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 announced dose administration for the first patient in KURRENT, 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).

"Despite the approval of immunotherapy, the treatment of recurrent and metastatic HNSCC remains a significant unmet need," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "The KURRENT trial builds on the impressive clinical activity reported for tipifarnib as a monotherapy in HRAS mutant HNSCC and represents an opportunity to significantly expand the potential patient population and target mechanisms of drug resistance."

Tipifarnib is Kura's farnesyl transferase inhibitor drug candidate currently in a registration-directed trial as a monotherapy in patients with HRAS mutant HNSCC. Novartis' alpelisib is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against the PI3Kα isoform. Preclinical data suggests that HRAS and PI3kα are co-dependent oncogenes in HNSCC, and that combining tipifarnib with a PI3Kα inhibitor has the potential to provide meaningfully greater antitumor activity, relative to inhibiting either target alone.

Earlier this year, Kura announced a clinical collaboration with Novartis to evaluate the combination of tipifarnib and alpelisib in patients with HNSCC whose tumors have HRAS overexpression or PIK3CA mutation and/or amplification. Under the collaboration, Kura maintains global development and commercial rights to tipifarnib.

About KURRENT

The KURRENT 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. These patients account for approximately 50% of HNSCC, according to The Cancer Genome Atlas (TCGA). The initial cohort in the trial is comprised of patients who have PIK3CA-dependent HNSCC. 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 Tipifarnib

Tipifarnib is a potent, selective and orally bioavailable inhibitor of farnesyl transferase, which has been granted Breakthrough Therapy and Fast Track Designations by the FDA for the treatment of patients with HRAS mutant HNSCC. In addition to HNSCC, tipifarnib has demonstrated encouraging clinical activity in multiple additional genetically defined tumor types. Kura has received multiple issued patents for tipifarnib, providing patent exclusivity in the U.S. and foreign countries.

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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1b clinical trial (KOMET-001) for patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, 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) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those who whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company is also developing KO-2806, a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. 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 tipifarnib, the opportunity of the KURRENT trial to significantly expand the potential patient population and target mechanisms of drug resistance, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 filed with the SEC on November 4, 2021, 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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