Kura Oncology Announces Clinical Collaboration to Evaluate Tipifarnib in Combination with Alpelisib in Head and Neck Squamous Cell Carcinoma

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– Combination of tipifarnib and alpelisib shows robust activity in preclinical PDX models of HRAS and PIK3CA pathway dependent tumors –

– HNSCC accounts for more than 500,000 new cancer cases each year worldwide, and up to 50% are estimated to be dependent on HRAS and/or PIK3CA pathways –

– Phase 1/2 KURRENT trial of tipifarnib plus alpelisib expected to initiate in 2H 2021 –

SAN DIEGO, July 06, 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 a clinical collaboration with Novartis to evaluate the combination of tipifarnib and alpelisib in patients with head and neck squamous cell carcinoma (HNSCC) whose tumors have HRAS overexpression or PIK3CA mutation and/or amplification. 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.

"Our preclinical data suggest that HRAS and PI3Kα are co-dependent pathways involved in the development and maintenance of HNSCC in certain patient populations. Combining tipifarnib with alpelisib has the potential to provide a clinically meaningful increase in anti-tumor activity compared to when inhibiting either pathway alone," said Stephen Dale, M.D., Chief Medical Officer of Kura Oncology. "We believe this clinical collaboration will enable us to potentially expand the use of tipifarnib to a significantly higher percentage of patients with advanced HNSCC. We look forward to initiating the combination trial in the second half of 2021."

The Phase 1/2 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, which is approximately 50% of HSNCC patients, according to The Cancer Genome Atlas (TCGA).

Under the collaboration, Kura maintains global development and commercial rights to tipifarnib.

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 1/2 clinical trial (KOMET-001) and targeting 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, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura is also developing 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 Kura's drug candidates, tipifarnib and KO-539, progress and expected timing of Kura's drug development programs and clinical trials and submission of regulatory filings, the presentation of data from clinical trials, plans regarding regulatory filings and future clinical trials, the regulatory approval path for tipifarnib, the strength of Kura's balance sheet and the adequacy of cash on hand. 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 drug candidates, uncertainties associated with performing clinical trials, regulatory filings, applications and other

interactions with regulatory bodies, the risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with the COVID-19 global pandemic, 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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