Kura Oncology Receives FDA Breakthrough Therapy Designation for Tipifarnib in Head and Neck Squamous Cell Carcinoma

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SAN DIEGO, Feb. 24, 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 that its investigational drug, tipifarnib, has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC) with variant allele frequency ≥ 20% after disease progression on platinum-based chemotherapy. Tipifarnib is currently being evaluated in an ongoing registration-directed clinical trial (AIM-HN) in this indication of high unmet need.

HNSCC is the seventh most common cancer worldwide, accounting for more than 885,000 new cases each year. Despite recent treatment advances, prognosis remains poor, with a 5-year survival rate of less than 40%. Second-line treatments provide limited clinical benefit for many patients, with objective response rates (ORR) of 6-16%, median progression-free survival (PFS) of 2-3 months and median overall survival (OS) of 5-8 months.

Tipifarnib's Breakthrough Therapy Designation is based on data from RUN-HN, a Phase 2 clinical trial evaluating tipifarnib in patients with recurrent or metastatic HRAS mutant HNSCC. Data from this trial, presented at the American Society of Clinical Oncology Virtual Scientific Program in May 2020, showed an ORR of 50%, median PFS of 5.9 months and a median OS of 15.4 months among the 18 evaluable patients. HRAS represents approximately 4-8% of HNSCC patients. The HRAS biomarker can be found on most commercially available genomic panels.

"We are very pleased that the FDA has awarded Breakthrough Therapy Designation to tipifarnib, and we appreciate the agency's affirmation of its potential to treat this devastating disease," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "We remain focused on conducting our AIM-HN registration-directed trial and look forward to working closely with the FDA to bring this therapy to patients as soon as possible."

The granting of FDA's Breakthrough Therapy Designation is based on preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies. The designation enables expedited development and review of a drug candidate for the treatment of a serious or life-threatening disease. The benefits of a Breakthrough Therapy Designation include the eligibility for priority review, rolling submission of portions of the application and FDA's organizational commitment involving senior management to provide guidance to the company to help determine the most efficient route to approval.

About Tipifarnib

Tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen. Previously, tipifarnib was studied in more than 5,000 cancer patients and showed compelling and durable anti-cancer activity in certain patient subsets; however, no molecular mechanism of action had been determined that could explain its clinical activity across a range of solid tumor and hematologic indications. Leveraging advances in next generation sequencing as well as emerging information about cancer genetics and tumor biology, the Company is seeking to identify those patients most likely to benefit from tipifarnib. In addition to Breakthrough Therapy Designation, tipifarnib has been granted Fast Track designation by the FDA for the treatment of patients with HRAS mutant HNSCC. In addition to HNSCC, tipifarnib has demonstrated encouraging clinical activity in a number of 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 two clinical-stage small molecule drug candidates for which we own global commercial rights 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's most advanced drug candidate is tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor currently in a registration-directed trial (AIM-HN) in patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma. The Company's pipeline is also highlighted by KO-539, a potent and selective menin inhibitor currently in a Phase 1/2 clinical trial (KOMET-001) in patients with relapsed/refractory acute myeloid leukemia. 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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