Kura Oncology Receives Fast Track Designation for Tipifarnib in HRAS Mutant HNSCC and Provides Enrollment Guidance for AIM-HN Trial

December 16, 2019

– Fast Track designation highlights potential for tipifarnib to address unmet need for patients with HRAS mutant HNSCC –

– Registration-directed AIM-HN trial expected to complete enrollment in first quarter of 2021 –

SAN DIEGO, Dec. 16, 2019 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company's lead drug candidate, tipifarnib, for the treatment of patients with HRAS mutant head and neck squamous cell carcinomas (HNSCC) after progression on platinum therapy.

"We are very encouraged by our growing body of clinical data for tipifarnib in HRAS mutant HNSCC and believe that the FDA's Fast Track designation puts us one step closer to delivering a precision medicine treatment for patients with this devastating disease," said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. "We continue to work with regulatory authorities in the U.S. and abroad in our effort to bring tipifarnib to patients as quickly as possible."

Fast Track designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening disease or conditions, which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of a New Drug Application.

AIM-HN Enrollment Guidance

The Company also provided enrollment guidance for AIM-HN, its ongoing registration-directed trial of tipifarnib in patients with recurrent or metastatic HRAS mutant HNSCC. The global, multi-center trial was initiated in November 2018 and was originally projected to take approximately two years to fully enroll. Based on a recent evaluation of current enrollment rates, the Company now expects the trial to complete enrollment in the first quarter of 2021. The slower pace of enrollment is primarily due to delays in site activation and a higher than anticipated screen failure rate. The trial is now open in more than 81 clinical sites in the U.S., Europe and Asia.

"Although we experienced some delays in site activation, we're encouraged to have the vast majority of the participating sites now open, with a corresponding increase in the rate of screening," said Kathleen Ford, Chief Operating Officer of Kura Oncology. "We recently presented impressive data from our Phase 2 trial in the same patient population and we believe that awareness of these data will continue to increase HRAS mutation testing and enrollment. Enrollment in AIM-HN remains our top priority and we remain steadfast in our commitment to bring tipifarnib to patients with HRAS mutant HNSCC for whom no treatment options are specifically indicated."

In addition, Kura plans to expand its targeted field-based medical science liaison team to help educate oncology practices on the importance of HRAS testing. The Company believes that this will provide HNSCC-treating physicians and their patients with more information about their diagnoses and enable them to make more educated decisions about their care, including potential clinical trial enrollment.

About Tipifarnib

Kura Oncology's lead drug candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen in December 2014. 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. 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 where there is a strong scientific and clinical rationale to improve outcomes by identifying those patients most likely to benefit from treatment. Kura's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company is conducting a registration-directed trial in patients with recurrent or metastatic HRAS mutant HNSCC and plans to conduct a second registration-directed trial in patients with relapsed or refractory AITL and related lymphomas. Kura's pipeline also includes KO-947, an ERK inhibitor, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 dose-escalation trials. 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 product candidate tipifarnib, Kura's potential for growth and the projected timing for full enrollment of the AIM-HN trial. 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," "anticipated," "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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Source: Kura Oncology, Inc.