Kura Oncology Receives Fast Track Designation for Tipifarnib in T-Cell Lymphomas

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– Second Fast Track designation for tipifarnib further highlights potential for tipifarnib to address unmet need for patients –

– Company plans to initiate a registration-directed trial of tipifarnib in advanced nodal lymphomas of TFH phenotype, including AITL, in second half of 2020 –

SAN DIEGO, March 03, 2020 (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 adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma (AITL), follicular T-cell lymphoma (FTCL) and nodal peripheral T-cell lymphoma with T follicular helper (TFH) phenotype.

"This important designation from the FDA comes just two months after tipifarnib was awarded Fast Track for the treatment of patients with HRAS mutant head and neck squamous cell carcinomas (HNSCC)," said Bridget Martell, M.A., M.D., Acting Chief Medical Officer of Kura Oncology. "We believe that this designation reflects tipifarnib's significant potential in these devastating disease settings, and we are now actively preparing to initiate a second registration-directed trial of tipifarnib in advanced nodal lymphomas of TFH phenotype, including AITL."

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.

In December 2019, Kura reported updated clinical data at the American Society of Hematology Annual Meeting showing robust and durable activity from tipifarnib as a monotherapy in relapsed or refractory AITL. The data demonstrated an objective response rate (ORR) of approximately 50% in a heavily pre-treated patient population, with a median of three prior regimens. Additionally, enhanced anti-tumor activity was observed in patients who carried mutations in the killer-cell immunoglobulin-like receptor, or KIR, a CXCL pathway-associated biomarker. These patients had an ORR of 70% and a complete response rate of 40%.

About T-Cell Lymphomas

Peripheral T-cell lymphomas compromise up to 20% of all aggressive non-Hodgkin lymphomas and consist of many different subtypes of fast-growing lymphomas, representing approximately 20,000 incident cases per year worldwide. Outcomes for these patients are poor, with 5-year survival of approximately 30%. Although several drugs have been approved in the relapsed and/or refractory setting, none has led to a survival benefit. In addition, the National Comprehensive Cancer Network guidelines currently recommend clinical trials for these patients. Significant advances in the genetic landscape of T-cell lymphomas have led to revisions to the World Health Organization classification and the introduction of new entities. As a result, cases of AITL, an aggressive form of T-cell lymphoma frequently characterized by high levels of CXCL12 expression, are now unified with FTCL under the classification of nodal lymphomas of TFH phenotype.

About Tipifarnib

Kura Oncology's lead drug candidate, tipifarnib, is a potent, selective farnesyl transferase inhibitor in-licensed from Janssen in December 2014. Previously, tipifarnib was studied in more than 5,000 cancer patients, showing compelling and durable anti-cancer activity in certain patient subsets. However, no molecular mechanism of action was determined that could explain its clinical activity across a range of solid tumor and hematologic indications. Leveraging advances in next-generation sequencing and emerging information about cancer genetics and tumor biology, Kura is seeking to identify those patients most likely to benefit from tipifarnib. The Company has received multiple issued patents for tipifarnib in the U.S. and foreign countries, including one issued by the U.S. Patent and Trademark Office in September 2019 that further extends Kura's exclusivity to the use of any farnesyl transferase inhibitor for the treatment of CXCL12-expressing peripheral T-cell lymphoma and acute myeloid leukemia.

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 three clinical-stage, 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. The Company plans to conduct a second registration-directed trial in patients with advanced nodal lymphomas of TFH phenotype, including AITL. Kura's pipeline also includes KO-947, an ERK inhibitor, and KO-539, a menin-MLL inhibitor, both of which are in early-stage clinical 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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