Kura Oncology Initiates Registration-Directed Trial of Tipifarnib in HRAS Mutant Head and Neck Squamous Cell Carcinomas

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– AIM-HN designed to enroll at least 59 patients with HRAS mutant HNSCC –

– Full enrollment expected in two years with response rate as primary endpoint –

SAN DIEGO, Nov. 05, 2018 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today announced the initiation of its global, multi-center, registration-directed trial of tipifarnib in HRAS mutant head and neck squamous cell carcinomas (HNSCC).

"We are excited to announce that our first registration-directed trial is now underway," said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. "Prior to our experience, tipifarnib was studied in more than 5,000 patients and although it demonstrated compelling anti-cancer activity in some cases, no molecular target was identified that could explain such activity. This registration-directed trial implements the many learnings from our clinical experience in patients with HNSCC. We believe we can now identify those patients most likely to receive clinical benefit from tipifarnib. If successful, we believe this registration-directed trial could bring a much-needed treatment option to patients with HRAS mutant HNSCC."

About the Registration-Directed Trial

Kura's registration-directed clinical trial is a global, multi-center study of tipifarnib in HRAS mutant HNSCC. The open-label trial has two cohorts: AIM-HN, a treatment cohort, and SEQ-HN, a non-interventional screening and outcomes cohort.

AIM-HN is designed to enroll at least 59 patients with HRAS mutant HNSCC who have received prior platinum-based therapy, and is expected to take approximately two years to fully enroll. Based on observations from Kura's Phase 2 trial, patients in AIM-HN must have a tumor HRAS mutant allele frequency of at least 20%. Enrolled patients will receive a starting dose of 600 mg of oral tipifarnib, twice daily, on days 1-7 and 15-21 of 28-day treatment cycles. The trial's primary endpoint is objective response rate (ORR), as determined by independent radiological review. Secondary outcome measures will include overall survival, duration of response, progression free survival and time to response.

AIM-HN has approximately 80% power to detect a difference between a null hypothesis of 15%, which is the point estimate of the ORR of second-line therapy for recurrent and metastatic disease, and 30%, an ORR considered of interest. Based on feedback from the U.S. Food and Drug Administration (FDA), Kura believes that AIM-HN, if positive, may be adequate to support a new drug application (NDA) seeking accelerated approval.

SEQ-HN is an observational cohort and is designed as a case-control study, matching patients with recurrent or metastatic HNSCC with HRAS mutations against those who are HRAS wild type using factors such as age, line of therapy and type of treatment. SEQ-HN is expected to provide a better understanding of the natural history of patients with HRAS mutations while contributing to identify patients for potential enrollment into AIM-HN. HNSCC patients in whom HRAS mutations are identified and who meet eligibility criteria will be offered participation in AIM-HN. HNSCC patients in whom HRAS mutations are not identified may enroll into SEQ-HN.

Additional information about the trial can be found at clinicaltrials.gov using the identifier NCT03719690.

About Tipifarnib

Kura Oncology's lead candidate, tipifarnib, is an inhibitor of farnesylation, a key cell signaling process implicated in cancer initiation and development. In extensive clinical trials, tipifarnib has shown compelling and durable anti-cancer activity in certain patient subsets. 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 its development program in solid tumors with HRAS mutations, Kura has identified the CXCL12 pathway and bone marrow homing of myeloid cells as potential biomarkers of activity for tipifarnib in certain hematologic malignancies. The Company plans to present preliminary data from the angioimmunoblastic T-cell lymphoma (AITL) and CXCL12+ expansion cohorts in a Phase 2 trial of tipifarnib in peripheral T-cell lymphomas (PTCL) at the American Society of Hematology Annual Meeting in December 2018.

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 has initiated a registration-directed trial of tipifarnib in at least 59 recurrent or metastatic patients with HRAS mutant head and neck squamous cell carcinomas. In addition, tipifarnib is being evaluated in multiple other Phase 2 clinical trials in solid tumor and hematologic indications. Kura's pipeline also includes KO-947, an ERK inhibitor, currently in a Phase 1 dose-escalation trial, and KO-539, a menin-MLL inhibitor, currently in IND-enabling studies. For additional information about Kura Oncology, 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 conduct, results and timing of Kura Oncology's clinical trials including the Phase 2 HRAS mutant HNSCC and SCC trial and AIM-HN trial, the timing of release of clinical trial results, plans regarding future clinical trials and development activities and the regulatory approval path for tipifarnib. 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.

Contacts

Company:
Pete De Spain
Vice President, Investor Relations &
Corporate Communications
(858) 500-8803
pete@kuraoncology.com

Investors:
Robert H. Uhl
Managing Director
Westwicke Partners, LLC
(858) 356-5932
robert.uhl@westwicke.com

Media:
Jason Spark
Managing Director
Canale Communications
(619) 849-6005
jason@canalecomm.com

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