Kura Oncology Reports Positive Phase 2 Study of Tipifarnib in Chronic Myelomonocytic Leukemia

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– Primary objective met with three objective responses in nine patients with RAS wild-type tumor status (33%), two additional RAS wild-type patients pending best response evaluation –

– All nine evaluable patients with RAS wild-type achieved stable disease or better –

– Preliminary data presented today at American Society of Hematology Annual Meeting –

– More data, including progression-free survival in the RAS wild-type and RAS mutant subsets, expected in 2018 –

SAN DIEGO, Dec. 10, 2017 (GLOBE NEWSWIRE) -- Kura Oncology, Inc., (Nasdaq:KURA) a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today reported positive, preliminary results from a Phase 2 clinical study of its lead candidate tipifarnib in patients with chronic myelomonocytic leukemia (CMML). The data were presented today at the American Society of Hematology (ASH) Annual Meeting and Exposition in Atlanta. A copy of the poster is now available on the company's website at www.kuraoncology.com.

The CMML study is one of four ongoing company-sponsored Phase 2 studies of tipifarnib. The open-label study is evaluating the anti-tumor activity of tipifarnib as a single agent in patients with CMML, retrospectively stratified based on RAS mutational status. In addition, patient samples are analyzed for the presence or absence of various biomarkers potentially relevant to the activity of tipifarnib.

As of the data cutoff date of November 7, 2017, all nine evaluable patients in the study with RAS wild-type CMML had achieved stable disease or better, including three objective responses as assessed using the MDS/MPN International Working Group criteria. The primary objective of the study was met with an overall response rate of 33% in patients with RAS wild-type CMML. The study has enrolled 24 patients of whom 16 were evaluable for response as of the data cutoff date. Nine patients had tumors with RAS wild-type status and seven were RAS mutant.

"CMML is an aggressive malignancy with few therapeutic options, particularly for those patients who have been treated with hypomethylating agents," said Eric Padron, M.D., of the Department of Hematologic Malignancies at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida, a clinical investigator on this study. "These encouraging preliminary data indicate that tipifarnib has anti-tumor activity in a post-hypomethylating agent setting and support further study of tipifarnib for the treatment of CMML."

"Although the signal observed in RAS wild-type patients is encouraging, these data are still immature and time to event endpoints cannot be yet fully evaluated. We continue to follow these patients and evaluate biomarkers of activity, and look forward to reporting additional data from this study in the year ahead," said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology.

Patients receive tipifarnib administered at a starting dose of 900 mg, orally, twice a day for 7 days in alternating weeks in 28-day cycles. Tipifarnib was generally well-tolerated in the study, with adverse events consistent with its known safety profile.

In addition to the CMML study, Kura Oncology is also conducting Phase 2 clinical trials in HRAS mutant head and neck squamous cell carcinomas (HNSCC), peripheral T-cell lymphoma (PTCL) and myelodysplastic syndrome (MDS). In September 2017, Kura Oncology reported that its Phase 2 trial of tipifarnib in patients with HRAS mutant HNSCC achieved its primary efficacy endpoint prior to the completion of patient enrollment. The company is now planning to initiate a registration-enabling study of tipifarnib in HRAS mutant HNSCC in 2018.

About Chronic Myelomonocytic Leukemia

CMML is a clonal disorder of bone marrow stem cells that shares characteristics of both myeloproliferative and myelodysplastic diseases. CMML is characterized by increased monocytes and blasts in the peripheral blood and bone marrow, as well as dysplasia in at least one type of blood cell. The prognosis of CMML is poor, with a median survival of 2 to 3 years, due in part to limited therapeutic options. Hypomethylating agents are the most commonly used therapeutic intervention in CMML.

About Tipifarnib

Kura Oncology's lead candidate, tipifarnib, is a potent and selective inhibitor of farnesyl transferase, a key cell signaling process implicated in cancer initiation and development. In extensive clinical trials, tipifarnib has shown a well-established safety profile and 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 patients most likely to benefit from tipifarnib.

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 Oncology's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, which is currently being studied in multiple Phase 2 clinical trials. The company's pipeline also includes KO-947, an ERK inhibitor, currently in a Phase 1 trial, and KO-539, an inhibitor of the menin-MLL protein-protein interaction, currently in preclinical testing. 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 Kura Oncology's product candidate, tipifarnib, progress and expected timing of Kura Oncology's drug development programs and clinical trials, and plans regarding regulatory filings and future research and clinical trials. 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," "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 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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