Kura Oncology Announces Data Presentation on Lead Product Candidate Tipifarnib at the Upcoming ASH Meeting

December 3, 2015

Tipifarnib as Maintenance Therapy in Acute Myeloid Leukemia (AML) Improves Survival in a Subgroup of Patients With High Risk Disease

LA JOLLA, Calif., Dec. 3, 2015 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (NASDAQ:KURA), a clinical stage biopharmaceutical company, today announced that new data from a Phase 3 trial of tipifarnib, the company's lead product candidate, will be presented at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition to be held in Orlando, December 5-8, 2015.

The accepted abstract is listed below and is available online on the ASH conference website: https://ash.confex.com/ash/2015/webprogram/Paper81390.html.

Tipifarnib As Maintenance Therapy in Acute Myeloid Leukemia (AML) Improves Survival in a Subgroup of Patients with High Risk Disease. Results of the Phase 3 Intergroup Trial E2902 (abstract # 1308)
Date & Time: Saturday, December 5, 2015 at 5:30 p.m. ET
Session: 613. Acute Myeloid Leukemia: Clinical Studies: Poster I

Location: Hall A, Level 2 (Orange County Convention Center)

The abstract describes results from the ECOG-ACRIN Cancer Research Group's (ECOG-ACRIN) Phase 3 trial E2902, which compared tipifarnib as maintenance therapy to observation only with respect to disease-free survival in patients with AML in second or subsequent complete remission, in complete remission following primary induction failure, or patients 60 years of age or older in first complete remission. See www.clinicaltrials.gov using identifier NCT00093470.

Between August 2004 and December 2009, 144 patients with AML were enrolled in the study at multiple medical facilities (sites) across the United States, as well as one site in Israel and one site in Peru, through ECOG-ACRIN, the Alliance for Clinical Trials in Oncology and SWOG. Researchers in these groups designed and conducted trial E2902 independent of Kura Oncology and with sole sponsorship from the National Cancer Institute, part of the National Institutes of Health.

The median age of patients was 69 years (range 28-86), 73 patients (51%) were male and 135 patients (94%) were white. Ninety-one percent of patients were 60 years of age or older. A majority of patients enrolled on the study (70%) were in first complete remission (CR). Eighty patients (56%) had post remission chemotherapy prior to randomization. A total of 73 patients were enrolled onto the treatment arm (Arm A), while 71 patients were enrolled onto the observation arm (Arm B).

The primary endpoint of the study was an analysis of disease-free survival (DFS) on an-intent-to-treat basis. The median DFS for arms A and B was 8.87 months and 5.26 months respectively (p=0.058, HR 0.760). When restricted to eligible patients only (n=134), the DFS for arms A and B was 10.81 versus 5.26 months, respectively (p=0.019, HR 0.690). An unplanned subgroup analysis was performed by gender. The median DFS for male patients (n=73) was 5.36 versus 5.91 months for arms A and B respectively (p=0.868, HR 1.320) and 12.09 versus 3.91 months for female patients (n=71) (p=0.0002, HR=0.408). Hematological toxicity was seen in both arms but was less frequent in the observation arm.

While the primary endpoint for improved disease-free survival was not reached when evaluating all randomized patients, when restricted to eligible patients only, a statistically significant improvement in DFS was observed. Moreover, an unplanned subgroup analysis by gender demonstrated an improvement in DFS and overall survival (OS) for females who were enrolled on the study, which persists on multivariate analysis. Possible explanations for the gender differences in DFS and OS include the use of flat dosing rather than body-surface area (BSA) based dosing. Given what appears to be a potentially clinically relevant benefit, the authors concluded that further evaluation of this agent is warranted.

"The results are exciting and suggest that tipifarnib, when administered in this fashion, provides a survival benefit to a significant group of patients with AML who otherwise have a high risk of relapse," said lead investigator Selina M. Luger, MD from the University of Pennsylvania. "Further studies should be done to better understand which patients can benefit or if alternate dosing would allow this benefit to extend to a larger population."

"We are encouraged by the outcomes of this study," said Antonio Gualberto, M.D., Ph.D., Chief Medical Officer of Kura Oncology. "We are in discussions with the study investigators and other key opinion leaders to determine the appropriate next steps for development of tipifarnib in this and other indications."

The ECOG-ACRIN Cancer Research Group is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. Its research is supported primarily by federal funding through the National Cancer Institute. www.ecog-acrin.org.

About Kura Oncology

Kura Oncology is a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines for the treatment of solid tumors and blood cancers. Kura's pipeline consists of small molecules 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. The company's lead drug candidate is

tipifarnib, a farnesyl transferase inhibitor that is currently in three Phase 2 clinical studies: the first study in patients with locally advanced solid tumors that carry HRAS mutations; the second study in patients with peripheral T-cell lymphomas; and the third study, an investigator-sponsored Phase 2 trial, in patients with urothelial carcinoma tumors characterized by HRAS mutations. The company plans to initiate a Phase 2 clinical study in patients with lower risk myelodysplastic syndromes in the first half of 2016. Kura's preclinical pipeline includes KO-947, an ERK inhibitor, and a menin-MLL inhibitor program. For additional information about Kura Oncology, please visit 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 potential safety and utility of tipifarnib and Kura Oncology's other compounds, the conduct and results of clinical trials, and plans regarding future research and development. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research do not demonstrate safety and/or efficacy in later pre-clinical studies or clinical trials, the risk that Kura Oncology may not obtain approval to market its product candidates, uncertainties associated with regulatory filings and applications, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further research, clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "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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