



Kura Oncology Presents Update on Positive Phase 2 Trial of Tipifarnib in HRAS Mutant HNSCC and Preliminary Results in HRAS Mutant SCC

October 22, 2018

- Nine patients with HRAS mutant HNSCC experienced tumor size reductions, including six confirmed PRs and two patients with disease stabilization greater than six months –
 - One additional HNSCC patient dosed outside protocol with an unconfirmed PR –
 - Six patients enrolled in additional cohort of other SCCs, one PR in two evaluable patients –
- Significant association observed between HRAS mutant allele frequency and clinical benefit –
 - Management to host conference call today at 17:00 CET / 11:00 a.m. ET –

MUNICH, Germany and SAN DIEGO, Oct. 22, 2018 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today reported updated preliminary results from a Phase 2 clinical trial of its lead product candidate, tipifarnib, in squamous cell carcinomas with HRAS mutations. The results are being presented today at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich. A copy of the presentation is available online at www.kuraoncology.com.

As of the September 7, 2018 clinical data cutoff date, 17 patients with HRAS mutant head and neck squamous cell carcinomas (HNSCC) were enrolled in the ongoing Phase 2 trial. Tumor size reductions were observed in nine of 11 evaluable patients, with five confirmed partial responses (PRs) as defined by standard RECIST criteria, including three patients with durable responses lasting more than 17 months. A sixth patient achieved a confirmed PR after the data cutoff. Four patients had stable disease, including two patients who experienced prolonged disease stabilization lasting more than six months. Only one patient experienced progressive disease as best response.

Another patient with HRAS mutant HNSCC, who is currently being treated off-protocol, has been reported as an unconfirmed PR with a 40% tumor size reduction.

In addition, the ongoing Phase 2 trial enrolled six patients in an additional cohort of other HRAS mutant squamous cell carcinomas (SCCs). One of the two evaluable patients in this cohort achieved a confirmed PR. Four patients were not evaluable as of the data cutoff date, including two patients who were pending initial efficacy assessments.

An analysis of available tumor biopsy samples (n=20) indicated a significant association between the allele frequency of HRAS mutations and a patient's best response to tipifarnib. Patients with HRAS mutant allele frequencies as low as 1% were treated with tipifarnib. Of the 13 HNSCC/SCC patients with a tumor HRAS mutant allele frequency greater than 20%, six achieved PRs, one achieved an unconfirmed PR and is ongoing, and two experienced disease stabilization greater than six months. No meaningful clinical benefit was observed in the seven patients with an allele frequency less than 20%. Data from The Cancer Genome Atlas (TCGA HNSCC, provisional) indicate that patients with an HRAS mutant allele frequency greater than 20% represent approximately 5% of the overall HNSCC population.

"The results from this study indicate that tipifarnib is active in this difficult-to-treat population, with rapid and durable responses independent of prior therapy," said Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center and principal investigator of the study. "These data are particularly encouraging when we consider the high unmet need for patients with recurrent, metastatic head and neck squamous cell carcinomas, despite the introduction of immunotherapy into the treatment paradigm."

Response rates for the three therapies approved for treatment of HNSCC in the second line, Keytruda[®] (pembrolizumab), Opdivo[®] (nivolumab) and Erbitux[®] (cetuximab), range from 13-16%, with progression-free survival of approximately two months.

Patients in the Phase 2 trial of tipifarnib in HRAS mutant HNSCC had a median of two prior lines of therapy (range 1-5), with confirmed responses observed in patients who had progressed on cetuximab regimens, immunotherapy or both.

Dose-limiting, treatment-emergent adverse events in the trial included hematological events and gastrointestinal disturbances, which were managed by dose interruption and/or dose reduction. When dose interruption/delay is taken into account, the median dose received by trial patients across all three cohorts was determined to be 600 mg twice daily by Cycle 2. Four of the responses in the trial were achieved at the 600 mg dose, including one patient who started dosing at 600 mg due to frailty and experienced a PR, and three patients who were dose-reduced to 600 mg and experienced a confirmed PR. Two additional patients achieved disease stabilization greater than six months.

Based on the observations from this Phase 2 trial, Kura intends to introduce a minimum tumor HRAS mutant allele frequency, anticipated to be no lower than 20%, as an entry criterion and use 600 mg orally twice daily as the starting dose in its upcoming AIM-HN registration-directed study of tipifarnib in HRAS mutant HNSCC. Kura also intends to implement these modifications in its ongoing Phase 2 trial and anticipates being able to provide additional data in 2019.

"We are very encouraged by the progress reported today in the treatment of patients with HRAS mutant squamous cell carcinomas," said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. "These data provide preliminary clinical evidence of

successful targeting of RAS-driven tumors. Notably, we observed a significant association between HRAS mutant allele frequency and objective response. We believe this finding represents a meaningful advancement in the field of precision medicine that will help our efforts to deliver on the promise of tipifarnib as a therapy for the treatment of HNSCC. We are applying these learnings to our upcoming registration-directed trial, which remains on track to initiate by year end."

Conference Call and Webcast

Kura's management will host a webcast and conference call at 17:00 CET / 11:00 a.m. ET today, October 22, 2018, following the conclusion of Dr. Ho's presentation at the ESMO 2018 Congress. The live call may be accessed by dialing (877) 516-3514 for domestic callers or (281) 973-6129 for international callers and using conference ID #6045389. A live webcast of the call will be available from the Investors and Media section of the company website at www.kuraoncology.com, and will be archived there for 30 days.

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 expects to present biomarker-enriched data from 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 that is currently being studied in multiple Phase 2 clinical trials in solid tumor and hematologic indications. Kura is preparing to initiate a registration-directed trial of tipifarnib in HRAS mutant HNSCC later this year. 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 and plans regarding future clinical trials and development activities. 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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