Kura Oncology Reports Durable Anti-Tumor Activity in Phase 2 Trial of Tipifarnib in HRAS Mutant Head and Neck Cancer

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– 56% confirmed ORR in 18 efficacy-evaluable HNSCC patients with HRAS mutant variant allele frequency ≥ 20% –

– Median progression-free survival of 6.1 months vs. 2.8 months on last prior therapy –

– 8 efficacy-evaluable patients enrolled since last update include 3 confirmed PRs, 2 unconfirmed PRs –

– Data support enrichment strategy in ongoing registration-directed trial –

BOSTON and SAN DIEGO, Oct. 29, 2019 (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 reported updated data from a Phase 2 clinical trial of its lead drug candidate, tipifarnib, that show durable anti-tumor activity as a single agent in heavily pretreated patients with HRAS mutant head and neck squamous cell carcinomas (HNSCC). The results are being presented today at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston. Copies of the oral and poster presentations are available online at www.kuraoncology.com.

As of the October 17, 2019 data cutoff date, a total of 21 HNSCC patients with high HRAS mutant variant allele frequency[1] were enrolled in this Phase 2 trial (RUN-HN), of whom 18 were evaluable for efficacy. Ten of the 18 evaluable patients achieved a confirmed partial response (PR), as defined by standard RECIST criteria, for an objective response rate (ORR) of 56% (95% CI 0.31, 0.78). In addition, eight patients experienced disease stabilization, including two who achieved an unconfirmed PR, one of whom is awaiting a confirmatory response assessment. Of the three non-evaluable patients, two discontinued prior to an initial response assessment and one was awaiting an initial response assessment as of the data cutoff date.

The median progression-free survival (PFS) of the 18 evaluable patients treated with tipifarnib was 6.1 months, compared to 2.8 months on their last prior therapy, including 8.3 months among patients who achieved a PR on tipifarnib and 4.5 months for those with stable disease. Patients had a median of two prior lines of therapy (range 0-6), with no responses observed on their last prior therapy.

Overall 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.

“Tipifarnib is a targeted therapy that has demonstrated rapid and durable anti-tumor activity as a single agent in patients with head and neck squamous cell carcinomas that carry HRAS mutations, a disease that can be resistant to current standards of care, including immunotherapy,” said Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center and principal investigator of the study.

An analysis of preliminary data from the RUN-HN trial performed in October 2018 showed a significant association between tumor HRAS mutant allele frequency and clinical benefit from tipifarnib. Based upon these observations, Kura introduced a minimum HRAS mutant variant allele frequency as an entry criterion prior to the initiation of its registration-directed trial of tipifarnib in HRAS mutant HNSCC (AIM-HN) in November 2018. Concurrently, Kura also incorporated the HRAS mutant variant allele frequency entry criterion into the ongoing RUN-HN trial, which continued to enroll patients at clinical sites that had yet to open in the AIM-HN trial.

As of the October 17, 2019 data cutoff date, 10 new patients with high HRAS mutant variant allele frequency were prospectively enrolled in the RUN-HN trial. Of the eight evaluable patients, three achieved a confirmed PR and five had stable disease, including two who achieved an unconfirmed PR, one of whom is awaiting a confirmatory response assessment. Of the two non-evaluable patients, one discontinued prior to an initial tumor response assessment and one was awaiting an initial response assessment as of the data cutoff date.

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.

Treatment-emergent adverse events in the trial were consistent with the known safety profile of tipifarnib. The most frequently observed adverse events were hematological-related and were managed with best supportive care and/or dose interruption.

Notably, a total of five evaluable HNSCC patients started at the 600 mg dose in the RUN-HN trial, all of whom achieved an objective clinical response. Patients in the RUN-HN trial received oral doses ranging from 600 mg to 900 mg twice daily, however improved tolerability was observed with the 600 mg bid dose administered days 1-7 and 15-21 every 28-days, which is the recommended starting dose in the ongoing AIM-HN registration-directed trial.

“These results increase our confidence in the probability of success of our registration strategy in HRAS mutant HNSCC,” said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. “In addition to confirming the association between high HRAS mutant variant allele frequency and anti-tumor activity, these data show that the tipifarnib 600 mg bid dose is well tolerated and sufficient to drive clinical activity. Of note, this multi-center study included a number of clinical sites around the world, providing a real-world experience that further increases our confidence in the outcome of our AIM-HN registration-directed trial.”

[1] HRAS variant allele frequency >35%, or ≥ 20% if serum albumin ≥ 3.5 g/dL

About Tipifarnib

Kura Oncology's lead drug candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen in December 2014. In November 2018, following an end of Phase 2 meeting with the U.S. Food and Drug Administration, Kura initiated its first registration-directed trial of tipifarnib in patients with recurrent or metastatic HRAS mutant HNSCC. The clinical trial has two cohorts: A non-interventional screening and outcomes cohort (SEQ-HN) and a treatment cohort (AIM-HN). AIM-HN is designed to enroll at least 59 evaluable patients with HRAS mutant HNSCC who have received prior platinum-based therapy, and is expected to take approximately two years to fully enroll. Kura has received multiple issued patents for tipifarnib, providing patent exclusivity in the U.S. and foreign countries.

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 is conducting a registration-directed trial in recurrent or metastatic patients with HRAS mutant HNSCC. 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, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 dose-escalation 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 tipifarnib, the conduct, results and timing of Kura Oncology's clinical trials including the RUN-HN trial and the 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," "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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