Kura Oncology Announces Publication of Tipifarnib Phase 2 Data in Journal of Clinical Oncology

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– Phase 2 RUN-HN trial showed ORR of 55%, median PFS of 5.6 months and median OS of 15.4 months in recurrent/metastatic HRAS mutant HNSCC –

– Statistically significant improvement in median PFS compared with median PFS of 3.6 months on last prior therapy (p=0.0012) –

– Safety profile consistent with previously published data for tipifarnib –

– Results support continuation of AIM-HN registration-directed trial in HRAS mutant HNSCC –

SAN DIEGO, March 22, 2021 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today announced the publication of results from its RUN-HN study, a Phase 2 open-label, single-arm trial of tipifarnib in patients with HRAS mutant head and neck squamous cell carcinoma (HNSCC) whose disease had progressed after prior therapy. The paper, titled “Tipifarnib in Head and Neck Squamous Cell Carcinoma with HRAS Mutations,” was published online in the *Journal of Clinical Oncology* earlier today.

As of the April 10, 2020 data cutoff, a total of 22 HNSCC patients with high HRAS mutant variant allele frequency[1] were enrolled, of whom 20 were evaluable for response. Eleven of the 20 evaluable patients met RECIST v1.1 criteria for confirmed partial response (PR) and, for an objective response rate (ORR) of 55% (95% CI, 31.5 to 76.9).

Median progression-free survival (PFS) of 5.6 months (95% CI, 3.6 to 16.4) on tipifarnib was a statistically significant improvement over the median PFS of 3.6 months (95% CI, 1.3 to 5.2) on last prior therapy (p=0.0012). The median overall survival (OS) was 15.4 months (95% CI, 7.0 to 29.7). Robust activity was seen despite resistance to chemotherapy, immunotherapy and/or cetuximab.

The ORR for three FDA-approved therapies for treatment of HNSCC in the second line range from 13-16%, with median PFS of 2-3 months and median OS of 5-8 months.

“We are encouraged by the compelling efficacy and safety profile of tipifarnib in patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma,” said Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center and principal investigator of the trial. “Importantly, these patients experienced limited benefit on prior therapies, including immunotherapies, which demonstrates the high unmet need for this disease. These data also reinforce the relevance of genomic testing for HRAS mutations to identify patients who could potentially benefit from tipifarnib treatment.”

Tipifarnib was generally well-tolerated in the trial. The most common grade 3 or 4 adverse events (AEs) seen in at least 10% of patients, were anemias and lymphopenias. Patients had received a median of two prior lines of systemic therapy (range 0-6; one patient received prior radiotherapy only), with 64% receiving prior immunotherapy, 50% receiving prior cetuximab, and 23% receiving both.

"We are pleased to see our data from the Phase 2 RUN-HN trial of tipifarnib published in the *Journal of Clinical Oncology* for review by the broader clinical community,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "The highlighted data from the RUN-HN trial comes on the heels of our Breakthrough Therapy Designation from the FDA and we continue to advance the ongoing AIM-HN registration-directed trial in patients with HRAS mutant HNSCC, for whom there is an urgent unmet need.”

The AIM-HN registration-directed trial of tipifarnib, in patients with recurrent or metastatic HRAS mutant HNSCC, is currently recruiting at more than 100 clinical sites in the U.S., Europe, Russia/Ukraine and Asia/Pacific. Patients interested in participating in this trial may talk to their doctor to have their tumor tested for the HRAS mutation for eligibility to enroll in this trial. Further details regarding the trial are available at clinicaltrials.gov (NCT03719690).

HRAS mutations occur in 4%-8% of patients with recurrent and/or metastatic HNSCC. The HRAS biomarker can be found on most commercially available genomic panels. More information about HRAS and biomarker testing is available at uncoverhras.com

About HNSCC

Head and neck squamous cell carcinoma (HNSCC) is the seventh most common cancer worldwide, accounting for more than 500,000 new cases each year. Despite advances in immunotherapy, the prognosis for advanced HNSCC patients remains poor, with an estimated median overall survival of 13-15 months in patients when stratified by PD-L1 expression. Although the anti-epidermal growth factor receptor (EGFR) antibody, cetuximab, was approved more than a decade ago, development of biomarker-directed therapies in HNSCC has been stymied by the limited number of druggable targets in the genomic landscape and the challenge of managing drug refractory recurrent/metastatic HNSCC.

About Tipifarnib

Tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen. Previously, tipifarnib was studied in more than 5,000 cancer patients and showed compelling and durable anti-cancer activity in certain patient subsets; however, no molecular mechanism of action had been determined that could explain its clinical activity across a range of solid tumor and hematologic indications. 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 Breakthrough Therapy Designation, tipifarnib has been granted Fast Track designation by the FDA for the treatment of patients with HRAS mutant HNSCC. In addition to HNSCC, tipifarnib has demonstrated encouraging clinical activity in multiple additional genetically defined tumor types. 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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1/2 clinical trial (KOMET-001) and targeting patients with relapsed/refractory acute myeloid leukemia, including patients with NPM1 mutations. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura is also developing a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. For additional information about Kura, please visit the Company's website at www.kuraoncology.com.

Disclosures

Memorial Sloan Kettering (MSK) has institutional financial interests related to the research in this release in the form of intellectual property rights and associated interests by virtue of licensing agreements between MSK and Kura.

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's drug candidates, tipifarnib and KO-539, progress and expected timing of Kura's drug development programs and clinical trials and submission of regulatory filings, the presentation of data from clinical trials, plans regarding regulatory filings and future clinical trials, the regulatory approval path for tipifarnib, the strength of Kura's balance sheet and the adequacy of cash on hand. 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 may not obtain approval to market its drug candidates, uncertainties associated with performing clinical trials, regulatory filings, applications and other interactions with regulatory bodies, the risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with the COVID-19 global pandemic, 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 assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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

Source: Kura Oncology, Inc.