Kura Oncology Provides Update on Phase 2 Trial of Tipifarnib in HRAS Mutant Head and Neck Cancer

February 15, 2018

– Confirmed partial responses observed in five of six evaluable patients with HRAS mutant HNSCC –

– Rate of enrollment increasing with three additional patients enrolled in four months –

– Initiation of registrational trial in HRAS mutant HNSCC anticipated this year –

SAN DIEGO, Feb. 15, 2018 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq:KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today announced the presentation of updated preliminary results from its Phase 2 clinical trial of its lead product candidate, tipifarnib, in patients with head and neck squamous cell carcinomas (HNSCC) with HRAS mutations.

The results are being presented by Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center at the 2018 Multidisciplinary Head and Neck Cancers Symposium, taking place today in Scottsdale, Arizona. A copy of the poster is available online at www.kuraoncology.com.

Nine patients with HRAS mutant HNSCC had been enrolled in the Phase 2 trial as of the February 8, 2018 data cutoff date. Five out of the six evaluable patients achieved a confirmed, partial response as defined by standard RECIST criteria for an overall response rate of 83% (36-99.6%, 95%CI), including durable responses of more than 18 months in two patients. The sixth evaluable patient experienced tumor shrinkage and prolonged disease stabilization. Three additional patients were enrolled since the last update in October 2017, however, none of the three additional patients was evaluable as of the February 8th data cutoff date; two are off study and one was still too early for disease assessment.

“We continue to be very encouraged by the high level of clinical activity of tipifarnib observed in patients with HRAS mutant HNSCC,” said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. “In addition to rapid responses in patients who do not appear to benefit from current standards-of-care, we are also seeing dramatic resolution of disfiguring and often painful lesions. We are continuing to enroll patients in the ongoing Phase 2 trial while we gather input from regulatory agencies on the design of a potential registrational trial of tipifarnib in HRAS mutant HNSCC anticipated to be initiated later this year.”

All patients joined the trial upon progression from at least one line of therapy, including chemotherapy, cetuximab or immune therapy, with patients having experienced a median of two prior therapies (range, 1-4). Response rates for the three agents approved for treatment of HNSCC in the second line are in the range of 13-16%, with a median progression-free survival of approximately 2 months and a median overall survival of up to 7.5 months.

Tipifarnib was generally well-tolerated in the trial. Adverse events observed are consistent with the known safety profile of tipifarnib.

In September 2017, Kura announced that the Phase 2 trial in HRAS mutant HNSCC had achieved its primary efficacy endpoint prior to the completion of enrollment. The trial protocol required four confirmed, partial responses, per RECIST 1.1 criteria, out of 18 patients to meet its primary endpoint.

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 a well-established safety profile and compelling and durable anti-cancer activity in certain patient subsets. Preclinical and clinical data suggest that, in the appropriate context, tipifarnib has the potential to provide significant benefit to cancer patients with limited treatment options. Leveraging advances in next-generation sequencing as well as emerging information about cancer genetics and tumor biology, Kura Oncology is seeking to identify patients most likely to benefit from tipifarnib. In addition to its development program in solid tumors with HRAS mutations, Kura has identified potential biomarkers of activity for tipifarnib in hematologic malignancies, including peripheral T-cell lymphomas (PTCL), myelodysplastic syndromes (MDS), acute myeloid leukemia (AML) and chronic myelomonocytic leukemia (CMML).

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. Kura’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 tipifarnib, progress and expected timing of Kura Oncology’s drug development programs and clinical trials 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.

Contacts for Kura Oncology

Company:
Pete De Spain
Vice President, Investor Relations &
Corporate Communications
(858) 500-8803
pete@kuraoncology.com

Investors:
Robert Uhl
Managing Director
Westwicke Partners, LLC
(858) 356-5932
robert.uhl@westwicke.com

Media:
Mark Corbae
Vice President
Canale Communications
(619) 849-5375
mark@canalecomm.com

Source: Kura Oncology, Inc.