Kura Oncology Provides Regulatory Update on Tipifarnib and Reports Fourth Quarter and Full Year 2017 Financial Results

March 12, 2018

– Company plans to initiate registration-directed trial of tipifarnib in second half of 2018 following recent end of Phase 2 meeting with the FDA –

– Single-arm trial to enroll at least 59 recurrent or metastatic HRAS mutant HNSCC patients with response rate as primary endpoint –

– Company expects cash, cash equivalents and short-term investments to be sufficient to fund current operations into first half of 2020 –

– Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, March 12, 2018 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq:KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today provided a regulatory update for its lead product candidate, tipifarnib, and reported fourth quarter and full year 2017 financial results.

“Following a successful end of Phase 2 meeting with the FDA, we plan to initiate a single-arm, registration-directed trial of tipifarnib in at least 59 recurrent or metastatic patients with HRAS mutant squamous cell head and neck cancer (HNSCC) with objective response rate (ORR) as the primary endpoint,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We expect to initiate this trial, which we are calling the AIM-HN trial, in the second half of 2018. We are encouraged by the feedback we received from the FDA regarding the development path for tipifarnib in HRAS mutant HNSCC, and we look forward to providing more specific information regarding the design and execution of the trial in the months ahead.”

Recent Operational Highlights

- Feedback from end of Phase 2 clinical meeting with the FDA – Based on feedback from the FDA, Kura is planning for the initiation of its AIM-HN trial of tipifarnib in HRAS mutant HNSCC patients, pending completion of site feasibility activities and submission of the final protocol to the FDA. The AIM-HN trial will be a global, multi-center, single-arm, study of at least 59 recurrent or metastatic patients with measurable disease as determined by RECIST version 1.1 criteria. The primary endpoint will be ORR, as determined by independent radiological review. The FDA indicated in the minutes from the meeting that the AIM-HN trial, as currently designed, may be adequate to support an NDA seeking accelerated approval.

- Update on Phase 2 trial of tipifarnib in HRAS mutant HNSCC – In February 2018, Kura reported updated preliminary results from its Phase 2 trial of tipifarnib in patients with HRAS mutant HNSCC at the 2018 Multidisciplinary Head and Neck Cancers Symposium. The update showed that five of the six evaluable patients achieved a confirmed, partial response. Two of these patients achieved durable responses beyond a year and a half. The one evaluable patient who did not achieve a response, based on standard RECIST criteria, experienced prolonged disease stabilization for more than six months. Tipifarnib has been generally well-tolerated with adverse events observed consistent with its known safety profile.

- Potential biomarkers identified for tipifarnib in hematologic malignancies – In December 2017, Kura presented new findings at the American Society of Hematology (ASH) Annual Meeting that identified activation of the CXCL12 pathway and bone marrow homing of myeloid cells as potential biomarkers of tipifarnib’s activity in certain hematologic malignancies, including peripheral T-cell lymphoma (PTCL), myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and acute myeloid leukemia (AML). Based on these observations, the company is now prospectively investigating these potential biomarkers in its ongoing Phase 2 trials in various hematologic malignancies.

Upcoming Potential Milestones and Expectations for Clinical Programs

- Preclinical data for tipifarnib in HRAS mutant squamous non-small cell lung tumor models at the American Association for Cancer Research (AACR) Annual Meeting in April 2018

- Preclinical biomarker data from KO-947 in squamous cell carcinomas at AACR in April 2018

- Initiation of the tipifarnib SEQ-HN trial, a screening and outcomes study in HRAS mutant HNSCC in the first half of 2018

- Initiation of the tipifarnib AIM-HN trial in HRAS mutant HNSCC in the second half of 2018

- Data from Phase 1 dose-escalation trial of KO-947 in the second half of 2018

- Additional updates from the ongoing Phase 2 study of tipifarnib in HRAS mutant HNSCC in the second half of 2018
- Initiation of a proof-of-concept study of tipifarnib in HRAS mutant squamous non-small cell lung cancer through the Spanish Lung Cancer Group in 2018
- Additional clinical data from tipifarnib in hematologic malignancies in the second half of 2018
- Submission of an investigational new drug (IND) application for KO-539 in late 2018 or early 2019

Financial Results for the Fourth Quarter and the Full Year 2017

- Research and development expenses for the fourth quarter of 2017 were $8.1 million, compared to $5.5 million for the fourth quarter of 2016. Research and development expenses for the full year 2017 were $26.4 million, compared to $20.4 million for the prior year.
- General and administrative expenses for the fourth quarter of 2017 were $2.9 million, compared to $2.0 million for the fourth quarter of 2016. General and administrative expenses for the full year 2017 were $9.7 million, compared to $8.0 million for the prior year.
- Net loss for the fourth quarter of 2017 was $10.7 million, compared to a net loss of $7.3 million for the fourth quarter of 2016. Net loss for the full year 2017 was $35.4 million, compared to a net loss of $27.6 million for the prior year.
- Cash, cash equivalents and short-term investments totaled $93.1 million as of December 31, 2017, compared with $100.8 million as of September 30, 2017 and $67.8 million as of December 31, 2016.
- Subsequently, in January 2018, Kura sold an aggregate of approximately 3.1 million shares of its common stock under an ATM facility for net proceeds of $57.4 million.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund its current operations into the first half of 2020.

Conference Call and Webcast

Kura's management will host a webcast and conference call today at 4:30 p.m. ET / 1:30 p.m. PT today, March 12, 2018, to discuss the regulatory update and financial results. The live call may be accessed by dialing (877) 516-3514 for domestic callers and (281) 973-6129 for international callers and using conference ID # 5196505. 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 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 Kura Oncology's lead product candidate, tipifarnib, progress and expected timing of Kura Oncology's drug development programs and clinical trials, including the timing of initiation of the AIM-HN trial, 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 Oncology'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 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.

KURA ONCOLOGY, INC.
Statements of Operations Data
(unaudited)
(in thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2017	**2016**	**2017**	**2016**
Operating Expenses:				
Research and development	$ 8,119	$ 5,503	$ 26,426	$ 20,404
General and administrative	2,876	1,975	9,651	7,963
Total operating expenses	10,995	7,478	36,077	28,367
Other income, net	247	131	643	807
Net loss	$ (10,748)	$ (7,347)	$ (35,434)	$ (27,560)
Net loss per share, basic and Diluted	$ (0.37)	$ (0.38)	$ (1.52)	$ (1.47)
Weighted average number of shares used in computing net loss per share, basic and diluted	29,234	19,153	23,237	18,701

KURA ONCOLOGY, INC.
Balance Sheet Data
(unaudited)
(in thousands)

	December 31, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	$ 93,145	$ 67,790
Working capital	84,610	63,359
Total assets	95,851	69,821
Long-term liabilities	5,955	7,494
Accumulated deficit	(89,290)	(53,856)
Stockholders' equity	79,865	56,876

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