Kura Oncology Reports First Quarter 2019 Financial Results and Highlights Upcoming Milestones

May 7, 2019

– Registration-directed trial of tipifarnib in HRAS mutant HNSCC continues on track –

– Data from ongoing Phase 2 trial of tipifarnib in CXCL12-driven PTCL accepted for oral presentations at EHA and ICML next month –

– Data from ongoing Phase 2 trial of tipifarnib in HRAS mutant HNSCC and other SCCs anticipated in second half 2019 –

– $165.5 million in cash, cash equivalents and investments provide runway into 2021 –

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

SAN DIEGO, May 07, 2019 (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 reported first quarter 2019 financial results and highlighted upcoming milestones.

“We have made considerable progress over the past quarter, as we continue to execute against our first registration-directed trial for tipifarnib in patients with HRAS mutant squamous head and neck cancers,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “Meanwhile, our elucidation of the CXCL12 pathway as a therapeutic target of tipifarnib, coupled with identification of associated farnesylated proteins, offers the potential to significantly expand the population of patients who may benefit from treatment with tipifarnib. Ultimately, we believe that CXCL12 pathway biomarkers could enable registrational strategies for tipifarnib in multiple hematologic and solid tumor indications.”

“Now, we look forward to a series of important milestones,” continued Dr. Wilson, “beginning with an update from our ongoing Phase 2 trial of tipifarnib in angioimmunoblastic T-cell lymphoma (AITL) and CXCL12-positive peripheral T-cell lymphoma (PTCL), which was accepted for oral presentation at both the European Hematology Association (EHA) Annual Congress and the International Conference on Malignant Lymphoma (ICML) next month. This will be followed by additional data from our ongoing Phase 2 trial of tipifarnib in HRAS mutant solid tumors, including head and neck squamous cell carcinoma (HNSCC) and other squamous cell carcinomas (SCCs), as well as an update from our ongoing Phase 2 trial in chronic myelomonocytic leukemia (CMML) later in the year.”

Recent Highlights

- **Registration-directed trial of tipifarnib in HRAS mutant HNSCC –** Kura’s global, multi-center, open-label, non-comparative registration-directed trial of tipifarnib continues on track. 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. AIM-HN initiated in November 2018 and is expected to take approximately two years to fully enroll.

- **Farnesylated proteins associated with CXCL12 expression** – In April 2019, Kura reported new findings at the American Association for Cancer Research (AACR) Annual Meeting suggesting that gene expression of the exclusively farnesylated proteins RHOE and PRICKLE2 is strongly associated with CXCL12 expression in bone marrow stroma. These findings provide key evidence supporting the inhibition of the CXCL12 pathway as a mechanism of action mediating the activity of tipifarnib and other farnesyl transferase inhibitors.

- **Potential expansion to other CXCL12^{+} lymphoma indications** – Kura reported additional findings at AACR identifying CXCL12 expression as a potential biomarker of clinical benefit in patients with diffuse large B-cell lymphoma (DLBCL) as well as mycosis fungoides, the most common form of cutaneous T-cell lymphoma (CTCL). The results were obtained from an analysis of a subset of samples from a previously conducted Phase 2 trial of tipifarnib in patients with relapsed and refractory lymphomas and are consistent with similar findings from the Company in other indications such as PTCL, acute myeloid leukemia (AML) and pancreatic cancer.

- **Emerging pipeline of clinical-stage drug candidates** – Kura is advancing two additional pipeline programs: KO-947, a small molecule inhibitor of extracellular signal-related kinase (ERK), and KO-539, a potent and selective small molecule inhibitor of the menin-mixed lineage leukemia (menin-MLL) interaction. The Company continues to evaluate dosing regimens for KO-947 and anticipates having data from its Phase 1 clinical trial later this year. Meanwhile, the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for KO-539 and the Company is preparing to initiate a Phase 1 clinical trial in patients with relapsed or refractory AML in mid-2019.

Financial Results

- Research and development expenses for the first quarter of 2019 were $10.4 million, compared to $11.6 million for the first quarter of 2018.
- General and administrative expenses for the first quarter of 2019 were $4.6 million, compared to $3.4 million for the first quarter of 2018.
- Net loss for the first quarter of 2019 was $13.9 million, compared to $14.6 million for the first quarter of 2018.
- Cash, cash equivalents and short-term investments totaled $165.5 million as of March 31, 2019, compared with $179.0 million as of December 31, 2018.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2021.

Upcoming Milestones

- Additional data from the ongoing Phase 2 trial of tipifarnib in PTCL, including duration of response data from the AITL cohort and additional data from the CXCL12-positive PTCL cohort, at EHA and ICML in June 2019
- Additional data on biomarkers associated with elevated CXCL12 expression at EHA and ICML in June 2019
- Additional data from the ongoing Phase 2 trial of tipifarnib in HRAS mutant solid tumors, including HNSCC and other SCCs, in the second half of 2019
- Additional data from the ongoing Phase 2 trial of tipifarnib in CMML in 2019
- Data from the Phase 1 dose-escalation trial of KO-947 in 2019
- Initiation of the Phase 1 clinical trial of KO-539 in mid-2019

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, May 7, 2019, to discuss the financial results for the first quarter 2019 and provide a corporate update. The live call may be accessed by dialing (877) 516-3514 for domestic callers and (281) 973-6129 for international callers and entering the conference code: 4436235. A live webcast of the call will be available from the Investors and Media section of the Company's 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's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company has initiated a registration-directed trial of tipifarnib 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, currently in a Phase 1 dose-escalation trial, and KO-539, a menin-MLL inhibitor, which has been cleared to begin a Phase 1 clinical trial. 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 Kura's product candidates, tipifarnib, KO-947 and KO-539, progress and expected timing of Kura's drug development programs and clinical trials and submission of regulatory filings, the potential expansion of tipifarnib to additional indications, 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 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 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 March 31,	
	2019	**2018**
Operating Expenses:		
Research and development	$ 10,382	$ 11,566
General and administrative	4,569	3,425
Total operating expenses	14,951	14,991
Other income, net	1,011	387
Net loss	$ (13,940)	$ (14,604)
Net loss per share, basic and diluted	$ (0.37)	$ (0.46)
Weighted average number of shares used in computing net loss per share, basic and diluted	38,168	31,829

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

	March 31, 2019	**December 31, 2018**
Cash, cash equivalents and short-term investments	$ 165,525	$ 178,985
Working capital	155,443	167,582
Total assets	169,617	182,379
Long-term liabilities	7,909	7,779
Accumulated deficit	(163,677)	(149,737)
Stockholders' equity	149,565	160,985

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Source: Kura Oncology, Inc.