



Kura Oncology Reports Fourth Quarter and Full Year 2018 Financial Results

March 5, 2019

- Registration-directed trial of tipifarnib in HRAS mutant HNSCC underway –
- Data from three ongoing Phase 2 trials of tipifarnib anticipated this year –
- Third drug candidate menin-MLL inhibitor KO-539 poised to enter clinic next quarter –
- \$179 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, March 05, 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 fourth quarter and full year 2018 financial results and provided a corporate update.

"I am very pleased with the progress we have made over the past year, highlighted by the initiation of our registration-directed trial of tipifarnib in HRAS mutant head and neck squamous cell carcinoma (HNSCC)," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "In addition, we have made considerable strides toward broadening the clinical utility of tipifarnib, showing proof-of-concept in angioimmunoblastic T-cell lymphoma (AITL), validating CXCL12 as a therapeutic target in peripheral T-cell lymphoma (PTCL) and identifying a potential association between CXCL12 expression and clinical benefit in pancreatic cancer. Together, these efforts are helping us to expand the opportunity for tipifarnib beyond HRAS mutant solid tumors and into additional indications of high unmet need."

"As we begin 2019, we believe Kura is well positioned, with additional data from three ongoing Phase 2 trials of tipifarnib expected throughout the year and an emerging pipeline that includes KO-947, an ERK inhibitor with Phase 1 data expected later this year, and KO-539, a menin-MLL inhibitor that is anticipated to enter the clinic next quarter. We look forward to providing updates on each of our programs during the year as we continue to execute on our initial registration-directed trial."

Recent Highlights

- **New findings for tipifarnib in pancreatic cancer** – In January 2019, Kura presented new findings at the 2019 Gastrointestinal Cancers Symposium identifying a potential association between CXCL12 expression and clinical benefit in patients with pancreatic cancer treated with tipifarnib. Elevated CXCL12 expression is known to be a poor prognostic factor in patients with certain solid tumors, including pancreatic cancer. The Company is currently working with key opinion leaders and investigators on the design of a proof-of-concept trial in this indication.
- **Validation of CXCL12 as a therapeutic target of tipifarnib in PTCL** – In December 2018, Kura reported an association between CXCL12 expression and clinical benefit in the Phase 2 trial of tipifarnib in relapsed or refractory PTCL at the American Society of Hematology (ASH) Annual Meeting. Specifically, patients with a high ratio of expression of CXCL12 to its receptor CXCR4 experienced a 50% objective response rate (five of 10 with either complete response or partial response) and a 90% clinical benefit rate (nine of 10, including stable disease) with tipifarnib. Patients in the Phase 2 trial were heavily pretreated, with a median of three prior lines of therapy (range 1-7).
- **Proof-of-concept in AITL** – Kura also reported preliminary data from its Phase 2 clinical trial of tipifarnib in patients with relapsed or refractory PTCL at ASH. As of the November 21, 2018 data cutoff date, a total of 39 patients were enrolled in the trial, including 19 patients with AITL, an aggressive form of PTCL often characterized by high levels of CXCL12 expression. Of the 13 evaluable AITL patients, two achieved a complete response and four achieved a partial response, for an objective response rate of 46%, meeting the pre-specified primary efficacy endpoint for the AITL cohort.
- **New AITL patent strengthens intellectual property protection for tipifarnib** – In November 2018, Kura announced the issuance of U.S. Patent No. 10,137,121, which includes multiple claims directed to the use of tipifarnib as a method of treating patients with AITL. The patent has an expiration date of November 2037, excluding any possible patent term extension. The AITL patent was issued just six months after a U.S. patent was issued for the use of tipifarnib as method of treating patients with certain CXCL12-expressing cancers, namely PTCL and acute myeloid leukemia (AML). Kura continues to pursue U.S. and foreign patent protection in these and other indications.
- **Continued progress in dose-escalation trial of KO-947** – KO-947 is a potent and selective small molecule inhibitor of extracellular signal related kinase (ERK), which Kura is advancing as a potential treatment for patients with tumors that

have dysregulated activity due to mutations or other mechanisms in the mitogen-activated protein kinase (MAPK) pathway. The Company continues to evaluate a number of doses and schedules for KO-947 and anticipates having data from its Phase 1 clinical trial in 2019.

- **Investigational new drug (IND) cleared for KO-539** – KO-539 is a potent and selective small molecule inhibitor of the menin-mixed lineage leukemia (menin-MLL) protein-protein interaction. Kura has generated preclinical data that support the potential anti-tumor activity of KO-539 in genetically defined subsets of acute leukemia. The U.S. Food and Drug Administration (FDA) has cleared Kura's IND application and the Company anticipates initiating a Phase 1 clinical trial of KO-539 in relapsed or refractory AML in the second quarter of 2019.

Financial Results

- Research and development expenses for the fourth quarter of 2018 were \$12.1 million, compared to \$8.1 million for the fourth quarter of 2017. Research and development expenses for the full year 2018 were \$46.8 million, compared to \$26.4 million for the prior year.
- General and administrative expenses for the fourth quarter of 2018 were \$4.6 million, compared to \$2.9 million for the fourth quarter of 2017. General and administrative expenses for the full year 2018 were \$16.1 million, compared to \$9.7 million for the prior year.
- Net loss for the fourth quarter of 2018 was \$16.1 million, compared to a net loss of \$10.7 million for the fourth quarter of 2017. Net loss for the full year 2018 was \$60.4 million, compared to a net loss of \$35.4 million for the prior year. Net loss for the fourth quarter and full year of 2018 included non-cash, share-based compensation expense of \$1.7 million and \$8.7 million, respectively, compared to \$1.4 million and \$4.5 million for the same periods in 2017, respectively.
- Cash, cash equivalents and short-term investments totaled \$179.0 million as of December 31, 2018, compared with \$93.1 million as of December 31, 2017.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund its 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-high PTCL cohort, in mid-2019
- Additional data from the ongoing Phase 2 trial of tipifarnib in HRAS mutant solid tumors, including HNSCC and other squamous cell carcinomas (SCCs), in the second half of 2019
- Additional data from the ongoing Phase 2 trial of tipifarnib in chronic myelomonocytic leukemia (CMML) in 2019
- Additional data on the molecular mechanisms of action of tipifarnib 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 the second quarter of 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, March 5, 2019, to discuss the financial results for the fourth quarter and full year 2018 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: 8996475. 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 is anticipated to enter into a Phase 1 clinical trial in the second quarter of 2019. 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 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		Year Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Operating Expenses:				
Research and development	\$ 12,084	\$ 8,119	\$ 46,787	\$ 26,426
General and administrative	4,550	2,876	16,096	9,651
Total operating expenses	16,634	10,995	62,883	36,077
Other income, net	537	247	2,436	643
Net loss	<u>\$ (16,097)</u>	<u>\$ (10,748)</u>	<u>\$ (60,447)</u>	<u>\$ (35,434)</u>
Net loss per share, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (0.37)</u>	<u>\$ (1.72)</u>	<u>\$ (1.52)</u>
Weighted average number of shares used in computing net loss per share, basic and diluted	<u>38,079</u>	<u>29,234</u>	<u>35,191</u>	<u>23,237</u>

KURA ONCOLOGY, INC.

Balance Sheet Data

(unaudited)

(in thousands)

	December 31,	December 31,
	2018	2017
Cash, cash equivalents and short-term investments	\$ 178,985	\$ 93,145
Working capital	167,582	84,610
Total assets	182,379	95,851
Long-term liabilities	7,779	5,955
Accumulated deficit	(149,737)	(89,290)
Stockholders' equity	160,985	79,865

Contacts

Company:
Pete De Spain
Vice President, Investor Relations &

Corporate Communications
(858) 500-8803
pete@kuraoncology.com

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

Media:
Jason Spark
Managing Director
Canale Communications
(619) 849-6005
jason@canalecomm.com



Source: Kura Oncology, Inc.