Kura Oncology Reports Second Quarter 2020 Financial Results

August 6, 2020

– Anticipate preliminary data presentation of menin inhibitor program, KO-539, at ASH –

– Continued progress in registration-directed trial of tipifarnib in HRAS mutant HNSCC –

– Opportunity to expand to HRAS and PI3K dependent tumors with potential to target up to 50% of HNSCC –

– $338.9 million in cash, cash equivalents and investments provide runway into 2023 –

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

SAN DIEGO, Aug. 06, 2020 (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 second quarter 2020 financial results and provided a corporate update.

“Last quarter we implemented a number of strategic measures to focus on our two major development pillars: tipifarnib in HRAS-dependent head and neck squamous cell carcinoma (HNSCC) and KO-539 in acute myeloid leukemia (AML),” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We believe tipifarnib and KO-539 provide opportunities to address large proportions of head and neck cancers and acute leukemias, respectively. Now, following a successful public offering this past quarter, we are well-positioned to advance each of these programs toward important upcoming catalysts.”

Corporate Update

- **Encouraging progress in Phase 1/2A trial of menin inhibitor, KO-539** – KO-539 is a potent and small molecule inhibitor of the menin-KMT2A(MLL) protein-protein interaction, with the potential to target at least 35% of patients with AML. A Phase 1/2A clinical trial of KO-539 in patients with relapsed/refractory AML (KOMET-001) continues in dose escalation. Kura remains focused on its goal of reaching a recommended Phase 2 dose and schedule, after which it intends to open expansion cohorts in NPM1-mutant and KMT2A(MLL)-rearranged AML – selected patient populations where KO-539 has the potential to demonstrate increased clinical benefit. The Company intends to submit an abstract for preliminary data presentation of the KO-539 program at the American Society of Hematology Annual Meeting in December 2020, and continues to add clinical sites to the trial in anticipation of moving into the expansion cohorts.

- **Updated data from Phase 2 trial of tipifarnib in HRAS mutant HNSCC** – Kura reported updated clinical outcome data from a Phase 2 clinical trial of tipifarnib in patients with recurrent or metastatic HRAS mutant HNSCC (RUN-HN) at the American Society of Clinical Oncology (ASCO) Virtual Scientific Program in May 2020. The data showed a median overall survival of 15.4 months, median progression-free survival of 5.9 months and an overall response rate of 50% among the 18 evaluable patients. Outcomes for three FDA-approved therapies for HNSCC are poor, with reported median OS of 5-8 months, PFS of 2-3 months and ORR of 13-16% in the second line. These data further support the Company’s efforts in HRAS mutant HNSCC, a disease of high unmet need.

- **Expanded enrollment in registration-directed trial of tipifarnib** – Kura has amended its ongoing registration-directed trial of tipifarnib (AIM-HN) to enroll all recurrent or metastatic HNSCC patients with HRAS mutations, regardless of variant allele frequency, expanding the proportion of patients who are being treated in the trial. The primary outcome measure for AIM-HN remains overall response rate in patients with high HRAS mutant variant allele frequency. The amendment enables the Company to assess the potential clinical benefit of tipifarnib in the overall HRAS mutant HNSCC population as well.

- **Expansion opportunity for tipifarnib in HRAS and PI3K dependent tumors** – Based upon the unmet need and encouraging preclinical data, Kura is prioritizing the clinical development of tipifarnib in combination with a PI3K alpha inhibitor as a strategy to treat HNSCC patients whose tumors overexpress the HRAS protein, as well as those with PI3K dependent tumors. These patients may represent significant subsets of HNSCC patients with distinct biology that may be targeted by tipifarnib, which is supported by observed activity in multiple models and in each of these subsets in preclinical studies. The Company believes that the total addressable population for tipifarnib may be as high as 50% of HNSCC.

Financial Results

- Research and development expenses for the second quarter of 2020 were $13.7 million, compared to $11.4 million for the second quarter of 2019.
- General and administrative expenses for the second quarter of 2020 were $7.5 million, compared to $4.5 million for the second quarter of 2019.
- Net loss for the second quarter of 2020 was $20.5 million, compared to a net loss of $14.9 million for the second quarter of 2019.
- Cash, cash equivalents and short-term investments totaled $338.9 million as of June 30, 2020, including net proceeds of approximately $134.9 million from a public offering completed in May 2020, compared with $236.9 million as of December 31, 2019.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2023.

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, August 6, 2020, to discuss the financial results for the second quarter 2020 and provide a corporate update. The live call may be accessed by dialing (866) 278-7953 for domestic callers and +1 (323) 347-3281 for international callers and entering the conference code: 1697775. 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 two wholly owned 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 most advanced drug candidate is tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor currently in a registration-directed trial (AIM-HN) in patients with recurrent or metastatic HRAS mutant HNSCC. The Company's pipeline is also highlighted by KO-539, a potent and selective inhibitor of the menin-KMT2A(MLL) protein-protein interaction currently in a Phase 1/2A clinical trial (KOMET-001) in patients with relapsed/refractory AML. 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 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, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating Expenses:				
Research and development	$ 13,697	$ 11,440	$ 26,272	$ 21,822
General and administrative	7,476	4,451	15,101	9,020

Total operating expenses	21,173	15,891	41,373	30,842
Other income, net	686	948	1,676	1,959
Net loss	$ (20,487)	$ (14,943)	$ (39,697)	$ (28,883)
Net loss per share, basic and diluted	$ (0.40)	$ (0.38)	$ (0.82)	$ (0.75)
Weighted average number of shares used in computing net loss per share, basic and diluted	51,633	38,928	48,522	38,550

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 338,869	$ 236,891
Working capital	323,635	224,039
Total assets	353,000	241,972
Long-term liabilities	12,075	7,627
Accumulated deficit	(252,574)	(212,877)
Stockholders' equity	322,374	218,781

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