Kura Oncology Reports Fourth Quarter and Full Year 2020 Financial Results

February 24, 2021

– Preliminary clinical data for menin inhibitor KO-539 highlighted by single-agent activity in relapsed/refractory AML, including patients with NPM1 mutations –

– KO-539 continues to demonstrate a wide therapeutic window in dose escalation; protocol amendment to include genetically enriched Phase 1 expansion cohorts –

– Tipifarnib receives Breakthrough Therapy Designation from FDA –

– $633.3 million in cash, cash equivalents and investments provide runway into 2024 –

– Management to host webcast and conference call today at 8:00 a.m. ET –

SAN DIEGO, Feb. 24, 2021 (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 2020 financial results and provided a corporate update.

“Last year was a transformative one for Kura, and our team continues to make tremendous progress advancing our pipeline of anti-cancer therapeutics,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “In December, we reported encouraging first-in-human data for our menin inhibitor KO-539 in an all-comers population of patients with acute myeloid leukemia (AML). Now, we look forward to obtaining a larger clinical dataset as we move into genetically enriched Phase 1 expansion cohorts comprising NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients. KO-539 continues to demonstrate a clean safety and tolerability profile, compelling clinical activity and a wide therapeutic window, supporting a potentially best-in-class profile both as a monotherapy and in combination.”

“Meanwhile, we were very pleased to receive Breakthrough Therapy Designation from the FDA for tipifarnib,” continued Dr. Wilson. “We believe this designation acknowledges both the dire unmet need for patients with recurrent or metastatic HRAS mutant HNSCC and the promise of tipifarnib to provide clinical benefit to patients. Breakthrough Therapy Designation is the latest milestone in our effort to pioneer the use of farnesyl transferase inhibitors to treat patients with cancer. We are also developing a next-generation farnesyl transferase inhibitor, which we intend to direct at innovative biology and larger oncology indications through rational combinations. We have identified multiple advanced lead compounds with superior properties, and we expect to nominate a development candidate for IND-enabling studies in mid-2021. Finally, thanks to a successful public offering in December, we are in a stronger financial position than ever before, and we believe this provides us with sufficient resources to advance our pipeline programs through multiple value-inflection points.”

Recent Highlights

- **First clinical data for menin inhibitor KO-539 presented at ASH** – In December, Kura reported preliminary clinical data from a Phase 1/2 KOMET-001 clinical trial of KO-539 at the American Society of Hematology Annual Meeting. These data were highlighted by single-agent activity in an all-comer population of patients with relapsed or refractory AML, including patients with NPM1 mutations and KMT2A rearrangements. KO-539 also demonstrated a favorable safety and tolerability profile, with no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation.

- **KOMET-001 protocol amendment to include Phase 1 expansion cohorts** – Kura is currently evaluating KO-539 in an 800 mg dose cohort in Phase 1 dose escalation, and KO-539 continues to demonstrate compelling clinical activity, encouraging safety and tolerability and a wide therapeutic window. Based on recent feedback from the FDA regarding the registration-enabling design for the KOMET-001 study, the Company is amending the trial protocol to include two Phase 1 expansion cohorts while continuing to evaluate KO-539 in dose escalation. Kura plans to enrich these Phase 1 expansion cohorts with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients at doses that have already met the safety threshold to help determine a minimum safe and biologically effective dose. This will enable the Company to further characterize the efficacy of KO-539 in these target populations and better inform a recommended Phase 2 dose. Initiation of the genetically enriched Phase 1 expansion cohorts is expected in mid-2021.

- **Tipifarnib receives Breakthrough Therapy Designation from FDA** – Earlier today, Kura announced that tipifarnib has been granted Breakthrough Therapy Designation by the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC) with variant allele frequency ≥ 20% after disease progression on platinum-based chemotherapy. The Breakthrough Therapy Designation is based upon data from the Company’s Phase 2 clinical trial (RUN-HN), which was recently accepted for publication in an upcoming issue of the *Journal of Clinical Oncology*. Tipifarnib is currently being evaluated in an ongoing registration-directed clinical trial

(AIM-HN) in this indication of high unmet need.

- **Diagnostic development collaboration with Illumina** – Kura recently entered into a strategic collaboration with Illumina to develop a diagnostic in support of Kura's tipifarnib program. The partnership with Illumina is focused on the development of a next-generation sequencing-based companion diagnostic leveraging the content of TruSight Oncology 500 to detect HRAS mutations in HNSCC.

- **Initiation of Phase 1/2 study of tipifarnib plus PI3Kα inhibitor in 2H 2021** – In October, Kura reported preclinical data showing compelling activity of tipifarnib when combined with a PI3Kα inhibitor in models of HRAS-dependent and/or PI3K dependent HNSCC. The data, presented at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, support the Company's upcoming Phase 1/2 proof-of-concept study of tipifarnib in combination with a PI3Kα inhibitor in advanced or unresectable relapsed/refractory HNSCC harboring PIK3CA mutations or amplifications and/or HRAS overexpression. Kura believes that the total addressable population for tipifarnib may be as high as 50% of HNSCC.

Financial Results

- Research and development expenses for the fourth quarter of 2020 were $17.5 million, compared to $13.5 million for the fourth quarter of 2019. Research and development expenses for the full year 2020 were $60.4 million, compared to $47.8 million for the prior year.

- General and administrative expenses for the fourth quarter of 2020 were $8.8 million, compared to $5.5 million for the fourth quarter of 2019. General and administrative expenses for the full year 2020 were $31.5 million, compared to $19.7 million for the prior year.

- Net loss for the fourth quarter of 2020 was $26.2 million, compared to a net loss of $17.9 million for the fourth quarter of 2019. Net loss for the full year 2020 was $89.6 million, compared to a net loss of $63.1 million for the prior year. Net loss for the fourth quarter and full year of 2020 included non-cash share-based compensation expense of $3.7 million and $12.8 million, respectively, compared to $2.4 million and $9.4 million for the same periods in 2019, respectively.

- Cash, cash equivalents and short-term investments totaled $633.3 million as of December 31, 2020, compared with $236.9 million as of December 31, 2019. This includes net proceeds of approximately $324.1 million from a public offering completed in December 2020. Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2024.

Upcoming Milestones

- Initiation of genetically enriched Phase 1 expansion cohorts in KOMET-001 in mid-2021

- Additional Phase 1 data from KOMET-001 in the second half of 2021

- Initiation of a Phase 1/2 proof-of-concept study of tipifarnib in combination with a PI3Kα inhibitor in the second half of 2021

- Nomination of a next-generation farnesyl transferase inhibitor Development Candidate in mid-2021

Conference Call and Webcast

Kura's management will host a webcast and conference call at 8:00 a.m. ET / 5:00 a.m. PT today, February 24, 2021, to discuss the financial results for the fourth quarter and full year 2020 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: 8581798. 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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1/2 clinical trial (KOMET-001) and targeting patients with relapsed/refractory acute myeloid leukemia, including patients with NPM1 mutations. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura is also developing a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. 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, 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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating Expenses:				
Research and development	$ 17,524	$ 13,464	$ 60,397	$ 47,826
General and administrative	8,808	5,499	31,502	19,653
Total operating expenses	26,332	18,963	91,899	67,479
Other income, net	173	1,098	2,274	4,339
Net loss	$ (26,159)	$ (17,865)	$ (89,625)	$ (63,140)
Net loss per share, basic and diluted	$ (0.45)	$ (0.39)	$ (1.69)	$ (1.51)
Weighted average number of shares used in computing net loss per share, basic and diluted	58,760	45,333	53,077	41,946

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 633,320	$ 236,891
Working capital	611,268	224,039
Total assets	647,212	241,972
Long-term liabilities	10,283	7,627
Accumulated deficit	(302,502)	(212,877)
Stockholders' equity	610,905	218,781

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