Kura Oncology Reports Third Quarter 2022 Financial Results

November 3, 2022

– Abstract reporting updated data from KOMET-001 accepted for oral presentation at ASH –

– First demonstration of durable clinical response with tipifarnib plus alpelisib in HNSCC –

– AIM-HN trial of tipifarnib in HRAS mutant HNSCC closed to further enrollment –

– $25 million equity investment from Bristol Myers Squibb and $125 million term loan facility from Hercules Capital –

– $428 million in cash plus equity investment and term loan facility, if fully drawn, provide runway into 2026 –

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

SAN DIEGO, Nov. 03, 2022 (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 third quarter 2022 financial results and provided a corporate update.

“We are very proud to announce that our abstract reporting updated data from the KOMET-001 trial of ziftomenib has been accepted for oral presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We continue to have strong conviction in ziftomenib and its potential to be a best-in-class menin inhibitor. Our confidence is supported by a growing body of clinical data, and we look forward to sharing a comprehensive update on the program at ASH.”

“Earlier this morning, we also announced a $25 million equity investment from Bristol Myers Squibb and a $125 million term loan facility from Hercules Capital,” Dr. Wilson continued. “If the term loan facility is fully drawn, proceeds from these two transactions, together with our existing cash, are expected to fund our current operating plan into 2026, enabling us to advance ziftomenib as well as our farnesyl transferase inhibitor programs through important, clinical-stage inflection points that we believe will create meaningful value for patients and shareholders.”

Recent Highlights

- **Updated data from KOMET-001 accepted for oral presentation at ASH** – An abstract reporting updated data from the KOMET-001 trial of ziftomenib has been accepted for oral presentation at the ASH Annual Meeting on December 10, 2022. The abstract, which will be published on the ASH website later today, highlights the encouraging safety profile and clinical activity of ziftomenib in patients with relapsed/refractory acute myeloid leukemia (AML). It includes 30 all-comer AML patients from the Phase 1a dose-escalation portion of the trial and 24 NPM1-mutant or KMT2A-rearranged AML patients from the Phase 1b portion – 12 patients at 200 mg and 12 patients at 600 mg.

- **Additional 18 patients enrolled in KOMET-001 Phase 1b extension** – Kura enrolled an additional 18 patients with NPM1-mutant or KMT2A-rearranged relapsed/refractory AML in a Phase 1b extension as the Company prepares to transition into the Phase 2 registration-directed portion of the KOMET-001 trial and initiate a series of combination studies in the relapsed and frontline settings, pending FDA review of the recommended Phase 2 dose (RP2D) and protocols. Kura anticipates sharing a more mature dataset, including preliminary data from the additional 18 patients in the Phase 1b extension, during its oral presentation at ASH.

- **Preliminary proof of mechanism of tipifarnib plus alpelisib in HNSCC** – Last week, at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium, Kura reported the first demonstration that the combination of tipifarnib and alpelisib can induce a durable clinical response in PIK3CA-dependent head and neck squamous cell carcinoma (HNSCC). A patient with stage III squamous cell carcinoma of the tonsil with a PIK3CA mutation and HRAS overexpression has achieved a durable partial remission in KURRENT-HN. As of mid-September, the patient has experienced an 84% reduction in target lesions and continued on-study for more than 27 weeks. Treatment-related adverse events in KURRENT-HN have been consistent with the known safety profiles of each drug and are manageable, with no dose-limiting toxicities reported to date.

- **AIM-HN registration-directed trial closed to further enrollment** – Kura continues to observe evidence of meaningful clinical activity in its AIM-HN registration-directed trial of tipifarnib as a monotherapy in recurrent and metastatic HRAS mutant HNSCC but has elected to close the trial to further enrollment due to significant feasibility challenges. The Company is currently evaluating the best way to harvest and use the clinical data from AIM-HN, along the with the data from the RUN-HN trial, which formed the basis of the Breakthrough Therapy Designation for tipifarnib, to inform future development of the program. Given the significant overlap between patients with HRAS overexpression and mutation,

HRAS mutant HNSCC patients in the U.S. may be eligible to enroll in the KURRENT-HN study.

- **Initiation of KURRENT-LUNG trial of tipifarnib plus osimertinib** – Kura has initiated a Phase 1 KURRENT-LUNG trial of tipifarnib in combination with osimertinib in EGFR-mutated non-small cell lung cancer (NSCLC) and expects to dose the first patient this quarter. Preclinical data, generated through a collaboration with INSERM (the French National Institute of Health and Medical Research), support the potential of tipifarnib to prevent emergence of resistance to osimertinib in EGFR-mutant NSCLC. The Company intends to perform initial clinical evaluation with tipifarnib in combination with osimertinib while advancing its next-generation FTI, KO-2806, through investigational new drug (IND)-enabling studies.

- **$25 million equity investment from Bristol Myers Squibb** – Kura has agreed to sell 1,370,171 shares to Bristol Myers Squibb at a price of $18.25 per share for gross proceeds of $25 million. In connection with the equity investment, Bristol Myers Squibb will appoint a member to Kura's Global Steering Committee. The equity investment further strengthens the relationship between the two organizations and enables Bristol Myers Squibb, a leader in the discovery and development of transformational cancer treatments, to provide valuable strategic input into Kura's global development strategy.

- **$125 million term loan facility from Hercules Capital** – Under the terms of the loan agreement, $10 million will be drawn immediately after closing and an additional $15 million is immediately available to Kura at its sole discretion. Kura may draw an additional $75 million in two separate tranches upon achievement of near-term clinical milestones. An additional $25 million may be drawn in a fourth tranche, subject to the approval of Hercules Capital. The term loan facility augments Kura's already strong balance sheet and gives the Company significant financial strength and flexibility to invest across its three programs to drive meaningful value for both patients and shareholders.

Financial Results

- Research and development expenses for the third quarter of 2022 were $25.0 million, compared to $22.4 million for the third quarter of 2021. The increase in R&D expenses was primarily due to increases in personnel costs and discovery stage programs.

- General and administrative expenses for the third quarter of 2022 were $11.6 million, compared to $11.3 million for the third quarter of 2021. The increase in G&A expenses was primarily due to increases in personnel costs.

- Net loss for the third quarter of 2022 was $35.5 million, compared to a net loss of $33.4 million for the third quarter of 2021. This included non-cash share-based compensation expense of $6.4 million, compared to $6.1 million for the same period in 2021.

- Cash, cash equivalents and short-term investments totaled $427.8 million as of September 30, 2022, compared with $518.0 million as of December 31, 2021.

- As adjusted for the $25 million equity investment from Bristol Myers Squibb and the $10 million initial draw from the Hercules term loan facility, Kura had, on a pro forma basis, $462.8 million in cash, cash equivalents and short-term investments at September 30, 2022.

- Management believes that cash, cash equivalents and short-term investments, plus cash from the term loan facility from Hercules, if fully drawn, will be sufficient to fund its current operating plan into 2026.

Forecasted Milestones

- Oral presentation of the Phase 1 data from KOMET-001, including preliminary data from additional 18 patients in the Phase 1b extension, at ASH in December

- Initiation of the Phase 2 registration-directed portion of KOMET-001 in the first half of 2023, pending FDA review of the RP2D and protocol

- Initiation of a Phase 1 combination study of ziftomenib in front line and relapsed/refractory AML in the first half of 2023, pending FDA review of the RP2D and protocol

- First patient dosed in the Phase 1 KURRENT-LUNG study of tipifarnib plus osimertinib in the fourth quarter of 2022

- Determination of the optimal biologically active dose (OBAD) for the PIK3CA cohort in the Phase 1 KURRENT-HN study of tipifarnib plus alpelisib in mid-2023

- Submission of the IND application for KO-2806 in the fourth quarter of 2022

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, November 3, 2022, to discuss the financial results for the third quarter 2022 and to provide a corporate update. The live call may be accessed by dialing (888) 394-8218 for domestic callers and (323) 994-2093 for international callers and entering the conference ID: 2251807. A live webcast and archive of the call will be available online from the investor relations section of the company website at www.kuraoncology.com.

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. Ziftomenib (KO-539), a potent and selective menin inhibitor, is currently in a Phase 1b clinical trial (KOMET-001) for patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable FTI, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC. Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company has also initiated a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in treatment-naïve locally advanced/metastatic EGFR mutant NSCLC. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through IND-enabling studies. For additional information, please visit Kura'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, ziftomenib, tipifarnib and KO-2806, 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 sufficiency of cash, cash equivalents and short-term investments, plus cash from the term loan facility from Hercules, if fully drawn, to fund its current operating plan into 2026. 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, including the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2022, 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating Expenses:				
Research and development	$ 24,973	$ 22,367	$ 70,144	$ 63,765
General and administrative	11,621	11,310	34,565	34,455
Total operating expenses	36,594	33,677	104,709	98,220
Other income (expense), net	1,090	311	1,983	497
Net loss	$ (35,504)	$ (33,366)	$ (102,726)	$ (97,723)
Net loss per share, basic and diluted	$ (0.53)	$ (0.50)	$ (1.54)	$ (1.47)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,889	66,353	66,723	66,285

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

	September 30, 2022	**December 31, 2021**
Cash, cash equivalents and short-term investments	$ 427,775	$ 517,960

Working capital	411,646	499,834
Total assets	447,988	534,051
Long-term liabilities	3,622	4,987
Accumulated deficit	(535,694)	(432,968)
Stockholders' equity	419,621	506,609

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