Kura Oncology Reports Fourth Quarter and Full Year 2022 Financial Results

February 23, 2023

– Phase 1 data for ziftomenib highlighted by 30% CR rate among 20 patients with NPM1-mutant AML treated at recommended Phase 2 dose –

– Multiple patients dosed in registration-directed trial of ziftomenib in NPM1-mutant AML –

– First combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML on track to initiate in first half of 2023 –

– IND for KO-2806, a next-generation farnesyl transferase inhibitor, cleared by FDA –

– $25 million strategic equity investment from Bristol Myers Squibb –

– $438 million in cash, equivalents and investments provide runway into fourth quarter of 2025 –

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

SAN DIEGO, Feb. 23, 2023 (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 2022 financial results and provided a corporate update.

“We continue to have strong conviction in ziftomenib and its potential to be the best-in-class menin inhibitor,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “The speed with which we have begun enrolling patients with NPM1-mutant acute myeloid leukemia (AML) in our registration-directed trial speaks to our impressive Phase 1 data in this population as well as the significant interest in ziftomenib among investigators. In addition, we believe ziftomenib is well positioned for future combination strategies, with no evidence of drug-induced QTc prolongation, no predicted adverse drug-drug interactions and oral daily dosing that should enable convenient administration with standards of care. We continue to prioritize investment in the program and look forward to sharing further updates as the year progresses, including the presentation of a more mature dataset from our Phase 1 trial of ziftomenib in NPM1-mutant AML patients at a medical meeting in mid-2023.”

“Meanwhile, clearance of the IND for KO-2806 marks an important next step for our next-generation farnesyl transferase inhibitor (FTI) program,” Dr. Wilson continued. “Our preclinical data is supportive of FTIs in combination with a growing number of targeted therapies, including EGFR inhibitors and PI3 kinase alpha inhibitors as well as tyrosine kinase inhibitors in renal cell carcinoma and KRAS G12C inhibitors in lung cancer, and we look forward to starting our first-in-human trial of KO-2806 in the coming months.”

Recent Highlights

- **Updated clinical data from Phase 1 trial of ziftomenib at ASH** – In December, Kura reported updated data from its Phase 1 trial of ziftomenib, the Company’s potent and selective menin inhibitor, in an oral presentation at the American Society of Hematology (ASH) Annual Meeting. The data highlighted the encouraging safety profile and clinical activity of ziftomenib in patients with relapsed/refractory AML, including a 30% complete response (CR) rate with full count recovery among 20 patients with NPM1-mutant AML treated at the 600 mg dose. Notably, two-thirds of NPM1-mutant AML patients who achieved a CR at 600 mg had IDH and/or FLT3 co-mutations, all of whom had failed prior treatment with IDH and/or FLT3 inhibitors. A median duration of response had not been reached as of the ASH data cutoff on October 24, 2022.

- **Recommended Phase 2 dose for ziftomenib in NPM1-mutant AML** – In December, Kura also announced that 600 mg once-daily dosing has been designated as the recommended Phase 2 dose and schedule for ziftomenib in NPM1-mutant AML following a positive Type C meeting with the U.S. Food and Drug Administration (FDA). Agreement was also reached on key elements of the Company’s Phase 2 registration-directed trial design.

- **First patients dosed in registration-directed trial of ziftomenib in NPM1-mutant AML** – Earlier this month, Kura announced that multiple patients had been dosed in its Phase 2 registration-directed trial (KOMET-001) of ziftomenib in NPM1-mutant relapsed or refractory AML. The Company expects to enroll a total of 85 patients in the U.S. and Europe. The primary endpoint is CR or CR with partial hematologic recovery (CRh), and key secondary endpoints include duration of response, transfusion independence, safety and tolerability. NPM1-mutant AML accounts for approximately 30% of new AML cases annually and represents a disease of significant unmet need for which no approved targeted therapy exists.

- **Combination trials to support commercial potential for ziftomenib** – Kura is preparing to initiate multiple Phase 1 trials to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The Company intends to establish a foundation where ziftomenib can be combined safely with various commonly used regimens, such as venetoclax plus azacitidine, FLT3

inhibitors and standard induction cytarabine plus daunorubicin (7+3) chemotherapy, then prioritize those combinations that represent the largest populations and greatest potential commercial value. Kura expects to initiate the first of these trials, KOMET-007, in the first half of 2023.

- **Preliminary proof of mechanism of tipifarnib plus alpelisib in HNSCC** – In October, 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) at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium. A patient with stage III squamous cell carcinoma of the tonsil with a PIK3CA mutation achieved a durable partial response in the Company's KURRENT-HN trial and continued on-study for more than 27 weeks as of the data cutoff on September 14, 2022. Treatment-related adverse events in KURRENT-HN are consistent with the known safety profiles of each drug and are manageable, with no dose-limiting toxicities reported to date.

- **IND for KO-2806, a next-generation farnesyl transferase inhibitor** – Last month, Kura announced FDA clearance of its Investigational New Drug (IND) application for KO-2806 for the treatment of advanced solid tumors. KO-2806 is a potent inhibitor of farnesyl transferase designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. The Company intends to evaluate safety, tolerability and preliminary antitumor activity of KO-2806 in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with other targeted therapies in adult patients with advanced solid tumors.

- **$25 million equity investment from Bristol Myers Squibb** – In November, Kura sold 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 has appointed 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.

Financial Results

- Research and development expenses for the fourth quarter of 2022 were $22.7 million, compared to $21.0 million for the fourth quarter of 2021. R&D expenses for the full year 2022 were $92.8 million, compared to $84.7 million for the prior year.

- General and administrative expenses for the fourth quarter of 2022 were $12.5 million, compared to $12.1 million for the fourth quarter of 2021. G&A expenses for the full year 2022 were $47.1 million, compared to $46.5 million for the prior year.

- Net loss for the fourth quarter of 2022 was $33.1 million, compared to a net loss of $32.7 million for the fourth quarter of 2021. Net loss for the full year 2022 was $135.8 million, compared to a net loss of $130.5 million for the prior year. Net loss for the fourth quarter and full year 2022 included non-cash, share-based compensation expense of $6.8 million and $26.3 million, respectively, compared to $6.4 million and $23.6 million for the same periods in 2021.

- Cash, cash equivalents and short-term investments totaled $438.0 million as of December 31, 2022, including the $25 million equity investment from Bristol Myers Squibb and a one-time $10 million draw from a term loan facility with Hercules Capital, compared with $518.0 million as of December 31, 2021. Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations into the fourth quarter of 2025.

Forecasted Milestones

- Dose the first patients in the KOMET-007 combination trial of ziftomenib in the first half of 2023.

- Present updated data from the KOMET-001 trial of ziftomenib in NPM1-mutant AML at a medical meeting in mid-2023.

- Dose the first patients in the KOMET-008 combination trial of ziftomenib in the second half of 2023.

- Determine the optimal biologically active dose in the KURRENT-HN trial of tipifarnib in combination with alpelisib in mid-2023.

- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in the third quarter of 2023.

Conference Call and Webcast

Kura's management will host a webcast and conference call at 4:30 p.m. ET / 1:30 p.m. PT today, February 23, 2023, to discuss the financial results

for the fourth quarter and full year 2022 and to provide a corporate update. The live call may be accessed by dialing (877) 407-4018 for domestic callers and (201) 689-8471 for international callers and entering the conference ID: 13735896. 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 is a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction for the treatment of genetically defined AML patients with high unmet need. Ziftomenib is currently enrolling patients in a Phase 2 registration-directed trial (KOMET-001) in NPM1-mutant relapsed or refractory AML. Kura is preparing to initiate multiple Phase 1 trials to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial (KURRENT-HN) in combination with alpelisib for patients with PIK3CA-dependent HNSCC. Kura intends to evaluate KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with other targeted therapies in adult patients with advanced solid tumors. 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 to fund its current operating plan into fourth quarter of 2025. 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,	
	2022	**2021**	**2022**	**2021**
Operating Expenses:				
Research and development	$ 22,668	$ 20,956	$ 92,812	$ 84,721
General and administrative	12,488	12,082	47,053	46,537
Total operating expenses	35,156	33,038	139,865	131,258
Other income, net	2,042	295	4,025	792
Net loss	$ (33,114)	$ (32,743)	$ (135,840)	$ (130,466)
Net loss per share, basic and diluted	$ (0.49)	$ (0.49)	$ (2.03)	$ (1.97)
Weighted average number of shares used in computing net loss per share, basic and diluted	67,781	66,550	66,990	66,352

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 437,985	$ 517,960
Working capital	422,369	499,834

Total assets	456,306	534,051
Long-term liabilities	11,971	4,987
Accumulated deficit	(568,808)	(432,968)
Stockholders' equity	420,278	506,609

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