Kura Oncology Reports Fourth Quarter and Full Year 2023 Financial Results

February 27, 2024

– Positive preliminary combination data from KOMET-007 trial of ziftomenib in NPM1-m and KMT2A-r AML, including effective mitigation of differentiation syndrome –

– First patient dosed in KOMET-008 trial of ziftomenib in combination with additional standards of care, including gilteritinib, FLAG-IDA and LDAC, in AML –

– Completion of enrollment in registration-directed trial of ziftomenib in NPM1-m AML anticipated by mid-2024 –

– $570 million in pro forma cash provides runway into 2027 –

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

SAN DIEGO, Feb. 27, 2024 (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 2023 financial results and provided a corporate update.

“Given its best-in-class safety and efficacy profile as well as optimal pharmaceutical properties, we believe ziftomenib is well positioned to become a cornerstone of therapy for patients with acute leukemias,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “This belief is supported by strong enthusiasm among both physicians and patients, as evidenced by rapid enrollment across our ongoing ziftomenib studies. We continue to be encouraged by the rate of enrollment in KOMET-001, our Phase 2 registration-directed trial of ziftomenib in patients with relapsed/refractory NPM1-mutant AML, and we remain on pace to complete enrollment of all 85 patients in the trial by the middle of this year. We also are seeing robust enrollment in our ongoing KOMET-007 study, which is investigating ziftomenib in combination with current standards of care in the frontline and relapsed/refractory settings. And with our recent financing, we remain in a strong financial position, which enables us to invest aggressively in research, development and pre-commercial activities to maximize the value of ziftomenib and support our other pipeline assets.”

Recent Highlights

- **Encouraging safety and tolerability profile for ziftomenib in combination with 7+3 and ven/aza** – In January 2024, Kura reported preliminary clinical data from the first 20 patients in KOMET-007, a Phase 1 dose-escalation trial of ziftomenib in combination with standards of care, including cytarabine/daunorubicin (7+3) and venetoclax/azacitidine (ven/aza), in patients with NPM1-mutant (NPM1-m) and KMT2A-rearranged (KMT2A-r) AML. The first 20 patients were enrolled between July 2023 and November 2023 and included five newly diagnosed patients with adverse risk NPM1-m or KMT2A-r AML and 15 patients with refractory/relapsed (R/R) NPM1-m or KMT2A-r AML. Continuous daily dosing of ziftomenib at 200 mg was well tolerated, and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed.
- **Encouraging evidence of clinical activity for ziftomenib combinations in NPM1-m and KMT2A-r AML** – As of the data cutoff on January 11, 2024, all five newly diagnosed patients treated with ziftomenib and 7+3 achieved a complete remission with full count recovery, for a complete remission (CR) rate of 100%. The overall response rate (ORR) among the 15 R/R patients treated with ziftomenib and ven/aza was 53%, including a 40% ORR in the 10 patients who had received prior venetoclax. The CR/CRh (CR with partial hematologic recovery) rate among the nine R/R patients who were menin inhibitor naïve was 56%. As of the data cutoff, 16 of the first 20 patients remained on trial, including all 11 NPM1-mutant patients. To date, enrollment at the 400 mg dose of ziftomenib is ongoing in the R/R ven/aza cohorts and in the frontline NPM1-mutant 7+3 cohort.
- **First patient dosed in KOMET-008 trial of ziftomenib in combination with additional standards of care in AML** – Yesterday, Kura announced dosing of the first patient in its KOMET-008 trial of ziftomenib in combination with the FLT3 inhibitor gilteritinib, FLAG-IDA or LDAC for the treatment of relapsed/refractory NPM1-m or KMT2A-r AML. Roughly half of patients with relapsed or refractory hNPM1-mutant AML have co-occurring FLT3 mutations, and the prognosis for these patients is poor. Preclinical data for ziftomenib in combination with FLT3 inhibitors demonstrate strong synergistic effects compared to either single agent alone.
- **Completion of enrollment in registration-directed trial of ziftomenib in NPM1-m AML anticipated by mid-2024** – The KOMET-001 registration-directed trial of ziftomenib in NPM1-m R/R AML is expected to enroll a total of 85 patients in the U.S. and Europe. In the Phase 1 trial, ziftomenib demonstrated a 35% CR rate and 45% overall response rate in 20 patients with NPM1-mutant AML treated at the recommended Phase 2 dose (RP2D). 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.

- **Addressing the continuum of care for patients with acute leukemias**– Kura remains committed to developing new treatment options across the continuum of care for patients with acute leukemias, where poor outcomes and significant unmet medical need remain. In December 2023, the Company announced that ziftomenib was selected by the Leukemia & Lymphoma Society for the Pediatric Acute Leukemia (PedAL) Master Clinical Trial. As part of the study, ziftomenib will be evaluated in combination with chemotherapy in pediatric patients with R/R KMT2A-r, NPM1-m or NUP98-rearranged acute leukemia. In addition, Kura recently began dosing with ziftomenib in patients with R/R KMT2A-r acute lymphoblastic leukemia, a relatively small population with a large unmet medical need.
- **Positive results from registration-directed trial of tipifarnib in HRAS-mutant HNSCC** – In October 2023, Kura presented positive results from its AIM-HN registration-directed trial of tipifarnib as a monotherapy in patients with HRAS-mutant head and neck squamous cell carcinoma (HNSCC). The Company continues to evaluate tipifarnib in combination with alpelisib in patients with PIK3CA-dependent HNSCC as part of its ongoing KURRENT-HN dose-escalation trial.
- **Dose escalation continues in first-in-human trial of KO-2806** – In October 2023, Kura announced that the first patient was dosed in its FIT-001 Phase 1 dose-escalation trial of its next-generation FTI, KO-2806. Concurrent with dose escalation as a monotherapy in the FIT-001 trial, the Company also plans to evaluate KO-2806 in dose-escalation combination cohorts with cabozantinib in clear cell renal cell carcinoma (ccRCC) and with adagrasib in $KRAS^{G12C}$-mutated non-small cell lung cancer (NSCLC).
- **Preclinical data support clinical combinations of KO-2806 with targeted therapies** – In October 2023, Kura presented preclinical data supporting its rationale to combine KO-2806 with cabozantinib in ccRCC and with adagrasib in $KRAS^{G12C}$-mutated NSCLC. The new findings illustrate the potential for FTIs to drive enhanced antitumor activity and address mechanisms of innate and adaptive resistance to targeted therapies such as tyrosine kinase inhibitors and KRAS inhibitors.
- **Clinical collaboration with Mirati to evaluate KO-2806 and adagrasib in $KRAS^{G12C}$-mutated NSCLC** – In November 2023, Kura announced a clinical collaboration and supply agreement with Mirati Therapeutics to evaluate the combination of KO-2806 and adagrasib in patients with $KRAS^{G12C}$-mutated NSCLC. Kura anticipates dosing the first patients with KO-2806 and adagrasib in $KRAS^{G12C}$-mutated NSCLC by mid-2024.

Financial Results

- Research and development (R&D) expenses for the fourth quarter of 2023 were $32.5 million, compared to $22.7 million for the fourth quarter of 2022. R&D expenses for the full year 2023 were $115.2 million, compared to $92.8 million for the prior year.
- General and administrative (G&A) expenses for the fourth quarter of 2023 were $14.2 million, compared to $12.5 million for the fourth quarter of 2022. G&A expenses for the full year 2023 were $50.6 million, compared to $47.1 million for the prior year.
- Net loss for the fourth quarter of 2023 was $42.8 million, compared to a net loss of $33.1 million for the fourth quarter of 2022. Net loss for the full year 2023 was $152.6 million, compared to a net loss of $135.8 million for the prior year.
- Net loss for the fourth quarter and full year 2023 included non-cash, share-based compensation expense of $7.2 million and $28.1 million, respectively. This compares to $6.8 million and $26.3 million for the same periods in 2022.
- As of December 31, 2023, Kura had cash, cash equivalents and short-term investments of $424.0 million, compared to $438.0 million as of December 31, 2022.
- Pro forma for $146 million in approximate net proceeds from the company's private placement completed in January 2024, Kura had $570 million in cash, cash equivalents and short-term investments at December 31, 2023.
- Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations into 2027.

Forecasted Milestones

- Initiate the post-transplant maintenance program for ziftomenib in the first quarter of 2024.
- Complete enrollment of 85 patients in the KOMET-001 registration-directed trial of ziftomenib in NPM1-m AML by mid-2024.
- Initiate an expansion cohort evaluating ziftomenib as a monotherapy in patients who have neither NPM1-mutant nor KMT2A-rearranged AML by mid-2024.
- Determine the RP2D for ziftomenib in combination with ven/aza and initiate dose validation/expansion in frontline AML by mid-2024.

- Determine the RP2D for ziftomenib in combination with 7+3 by mid-2024.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with cabozantinib in ccRCC by mid-2024.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with adagrasib in $KRAS^{G12C}$-mutated NSCLC by mid-2024.
- Complete enrollment of two expansion cohorts to support determination of the optimal biologically active dose for tipifarnib in combination with alpelisib by the end of 2024.

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 27, 2024, to discuss the financial results for the fourth quarter and full year 2023 and to provide a corporate update. The live call may be accessed by dialing (888) 886-7786 for domestic callers and (416) 764-8658 for international callers and entering the conference ID: 02911668. 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. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-m R/R AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with ven/aza and 7+3 in NPM1-m and KMT2A-r newly diagnosed and R/R AML (KOMET-007). Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial in combination with alpelisib for patients with PIK3CA-dependent HNSCC (KURRENT-HN). Kura is also evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with cabozantinib in ccRCC and with adagrasib in $KRAS^{G12C}$-mutated NSCLC (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on X and LinkedIn.

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 to 2027. 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,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development	$ 32,533	$ 22,668	$ 115,235	$ 92,812
General and administrative	14,229	12,488	50,569	47,053
Total operating expenses	46,762	35,156	165,804	139,865
Other income, net	3,976	2,042	13,173	4,025
Net loss	$ (42,786)	$ (33,114)	$ (152,631)	$ (135,840)
Net loss per share, basic and diluted	$ (0.55)	$ (0.49)	$ (2.08)	$ (2.03)
Weighted average number of shares used in computing net loss per share, basic and diluted	77,337	67,781	73,229	66,990

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 423,957	$ 437,985
Working capital	397,218	422,369
Total assets	448,935	456,306
Long-term liabilities	16,399	11,971
Accumulated deficit	(721,439)	(568,808)
Stockholders' equity	397,273	420,278

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