Kura Oncology Reports Fourth Quarter and Full Year 2024 Financial Results

February 26, 2025

– KOMET-001 registrational trial in R/R *NPM1*-mutant AML achieved primary endpoint –

– Alignment reached with FDA and EMA on key aspects of the KOMET-017 protocol including use of MRD-negative CR endpoint for potential U.S. accelerated approval pathway in frontline intensive chemotherapy trial –

– Topline MRD-negative CR results from KOMET-017-IC Phase 3 trial anticipated in 2028 –

– Multiple data presentations for ziftomenib and pipeline programs expected throughout 2025 –

– $727.4 million in cash, together with anticipated collaboration agreement payments, to support ziftomenib commercialization through the frontline AML combination setting –

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

SAN DIEGO, Feb. 26, 2025 (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 2024 financial results and provided a corporate update.

"We are very pleased the KOMET-001 registrational trial achieved its primary endpoint. We look forward to sharing topline data at an upcoming medical conference and expect to submit a New Drug Application (NDA) in relapsed/refractory (R/R) *NPM1*-mutant acute myeloid leukemia (AML) next quarter," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "In parallel, we are advancing ziftomenib into registrational studies in the frontline (1L) setting. Approximately half of patients with newly diagnosed *NPM1*-mutated (*NPM1*-m) AML and 80% of patients with *KMT2A*-rearranged (*KMT2A*-r) AML will die from the disease within five years. Given this unmet need, we are pleased to have reached alignment with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) on key aspects of our Phase 3 trials, including the use of minimum residual disease (MRD)-negative complete response (CR) as a primary endpoint for potential accelerated approval in the U.S., with topline results anticipated in 2028. Our KOMET-017 trial is breaking new ground, and we and our partners at Kyowa Kirin are working as rapidly as possible to bring ziftomenib to AML patients worldwide."

Recent Highlights

- **Positive topline results from registration-directed trial of ziftomenib in R/R *NPM1*-m AML** – Kura and Kyowa Kirin announced positive topline results from KOMET-001, the Phase 2 registration-directed trial of ziftomenib in patients with R/R *NPM1*-m AML. The KOMET-001 trial achieved its primary endpoint, consistent with the targeted 20-30% CR/CR with partial hematological recovery (CRh) rate, and data have been submitted for presentation at ASCO. The benefit-risk profile for ziftomenib is highly encouraging, and safety and tolerability were consistent with previous reports. Facilitated by the Breakthrough Therapy Designation status of ziftomenib in R/R *NPM1*-m AML, the Company completed its pre-NDA meeting with FDA and anticipates submitting an NDA in the second quarter of 2025.

- **Positive feedback from FDA for 1L combination trial designs** – Earlier this month, Kura and Kyowa Kirin announced alignment with FDA on the KOMET-017 global trial protocol evaluating ziftomenib in combination with both intensive and non-intensive combination regimens in patients with newly diagnosed *NPM1*-m and/or *KMT2A*-r AML. This includes alignment on potential pathways for accelerated approval in the U.S. in both the KOMET-017-IC (intensive chemotherapy) and KOMET-017-NIC (non-intensive chemotherapy) trials by allowing the trials to use MRD-negative CR and CR, as primary endpoints, respectively. The companies also gained alignment with the EMA on the KOMET-017 protocol, and expect to initiate the KOMET-017 Phase 3 trials in the second half of 2025.

- **Positive clinical data for Phase 1 trial of ziftomenib in combination with standards of care** – In December 2024, Kura Oncology and Kyowa Kirin announced encouraging clinical data from KOMET-007, a Phase 1 trial of ziftomenib in combination with standards of care, including cytarabine/daunorubicin (7+3) and venetoclax/azacitidine in patients with *NPM1*-m and *KMT2A*-r AML. Among response-evaluable patients enrolled in the 7+3 combination cohort for patients with 1L *NPM1*-m or *KMT2A*-r adverse risk AML, 91% achieved a CR (100% for *NPM1*-m, 83% for *KMT2A*-r patients). Ziftomenib was generally well tolerated in combination at all dose levels evaluated across all cohorts in the Phase 1a dose-escalation portion of the trial. The positive results from KOMET-007 reported at ASH reinforce the companies' commitment to evaluating ziftomenib across the continuum of 1L AML treatment options.

- **Global strategic collaboration with Kyowa Kirin to develop and commercialize ziftomenib in acute leukemias** – In

November 2024, Kura Oncology and Kyowa Kirin announced they entered into a global strategic collaboration to develop and commercialize ziftomenib (Kyowa Agreement), funding the expansive AML development program through U.S. commercialization in 1L combinations. Under the partnership, Kura retains leadership and key strategic rights to ziftomenib in the U.S. and preserves strategic flexibility, while enabling development and commercialization of ziftomenib across the continuum of care in acute leukemias, including both fit and unfit 1L indications, post-transplant maintenance setting and combinations with targeted therapies.

- **Preclinical data supporting opportunity for ziftomenib in treatment of gastrointestinal stromal tumors (GIST)** – In October 2024, Kura reported preclinical data presented at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, supporting the potential for ziftomenib in combination with KIT inhibitors for GIST patients. The combination of ziftomenib and imatinib demonstrated robust and durable antitumor activity in imatinib-sensitive (1L) and imatinib-resistant (2L/3L) GIST patient-derived xenograft models. Sixty percent of patients develop resistance to imatinib within two years and ziftomenib has the potential to delay the onset of resistance to, or overcome resistance in patients pre-treated with, imatinib. In August 2024, Kura announced clearance by the FDA of an IND application and the Company remains on track to initiate the KOMET-015 trial evaluating ziftomenib plus imatinib in patients with advanced GIST, in the first half of 2025.

- **Clinical and preclinical data support combinations of farnesyl transferase inhibitors with targeted therapies** – Despite multiple advances, innate and adaptive resistance remain a challenge for many classes of targeted therapies in cancer. A growing body of clinical and preclinical data demonstrates the potential of farnesyl transferase inhibitors as companion therapeutic agents to augment the antitumor activities of various targeted therapies and overcome resistance in combination. Enrollment in the FIT-001 trial evaluating our next-generation farnesyl transferase inhibitor KO-2806 continues to progress and the dose-escalation portion of the KURRENT-HN trial with tipifarnib is now complete. Kura expects to present the first clinical data for KO-2806 as a monotherapy and in combination, as well as clinical data from the KURRENT-HN trial, in the second half of 2025.

Financial Results

- Collaboration revenue from our Kyowa Kirin partnership for the fourth quarter and full year 2024 was $53.9 million, compared to no revenue in 2023.

- Research and development (R&D) expenses for the fourth quarter of 2024 were $52.3 million, compared to $32.5 million for the fourth quarter of 2023. R&D expenses for the full year 2024 were $170.0 million, compared to $115.2 million for the prior year.

- General and administrative (G&A) expenses for the fourth quarter of 2024 were $24.1 million, compared to $14.2 million for the fourth quarter of 2023. G&A expenses for the full year 2024 were $77.1 million, compared to $50.6 million for the prior year.

- Net loss for the fourth quarter of 2024 was $19.2 million, compared to a net loss of $42.8 million for the fourth quarter of 2023. Net loss for the full year 2024 was $174.0 million, compared to a net loss of $152.6 million for the prior year.

- Net loss for the fourth quarter and full year 2024 included non-cash, share-based compensation expense of $8.6 million and $33.9 million, respectively. This compares to $7.2 million and $28.1 million for the same periods in 2023.

- As of December 31, 2024, Kura had cash, cash equivalents and short-term investments of $727.4 million, including the upfront payment of $330.0 million from Kyowa Kirin, compared to $424.0 million as of December 31, 2023.

- Based on our current plans, we believe our cash, cash equivalents and short-term investments as of December 31, 2024 will be sufficient to enable us to fund our current operating expenses into 2027, and combined with anticipated collaboration funding under the Kyowa Agreement, should support our ziftomenib AML program through commercialization in the 1L combination setting.

Forecasted Milestones

- Submit an NDA for ziftomenib in R/R *NPM1*-m AML in the second quarter of 2025.

- Present topline data from KOMET-001 Phase 2 registration-directed trial in R/R *NPM1*-m AML in the second quarter of 2025.

- Present preliminary clinical data from the KOMET-007 Phase 1b expansion cohort evaluating ziftomenib with intensive

chemotherapy (7+3) at a medical meeting in the second quarter of 2025.

- Initiate the KOMET-015 trial evaluating ziftomenib and imatinib in patients with advanced GIST in the first half of 2025.
- Initiate two independent Phase 3 registration-enabling trials in 1L intensive (KOMET-017-IC) and non-intensive (KOMET-017-NIC) AML in the second half of 2025.
- Present preliminary clinical data from the KOMET-007 Phase 1b expansion cohort evaluating ziftomenib with venetoclax and azacitidine at a medical meeting in the second half of 2025.
- Nominate a development candidate for next-generation menin inhibitor program in diabetes in mid-2025.
- Initiate one or more expansion cohorts of KO-2806 and cabozantinib in patients with advanced renal cell carcinoma in the first half of 2025.
- Present data from the Phase 1 monotherapy dose escalation of KO-2806 in patients with RAS mutations in the second half of 2025.
- Present data from the Phase 1 trial evaluating KO-2806 and cabozantinib in patients with renal cell carcinoma in the second half of 2025.
- Present data from the dose escalation portion of KURRENT-HN trial evaluating tipifarnib and alpelisib in *PIK3CA*-dependent head and neck squamous cell carcinoma (HNSCC) in the second half of 2025.

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 26, 2025, to discuss the financial results for the fourth quarter and full year 2024 and to provide a corporate update. The live call may be accessed by dialing (800) 579-2543 for domestic callers and (785) 424-1789 for international callers and entering the conference ID: KURAQ4. A live webcast and archived replay of the event will be available here or 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 targeting cancer signaling pathways. Ziftomenib, a once-daily, oral menin inhibitor, is the first and only investigational therapy to receive Breakthrough Therapy Designation from the FDA for the treatment of R/R *NPM1*-m AML. In November 2024, Kura Oncology entered a global strategic collaboration agreement with Kyowa Kirin Co., Ltd. to develop and commercialize ziftomenib for AML and other hematologic malignancies. Enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R *NPM1*-m AML has been completed, and the companies anticipate submission of an NDA to the FDA in the second quarter of 2025. Kura Oncology and Kyowa Kirin are also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R *NPM1*-m and *KMT2A*-r AML. KO-2806, a next-generation farnesyl transferase inhibitor, is being evaluated in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies. Tipifarnib, a potent and selective farnesyl transferase inhibitor, is currently in a Phase 1/2 trial in combination with alpelisib for patients with *PIK3CA*-dependent HNSCC. 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; plans, trial designs and expected timing of clinical trials; the expected timing and presentation of results and data from clinical trials; the anticipated timing of submission of an NDA for ziftomenib; the potential for U.S. accelerated approval and full approval of product candidates; and the success and impact of interactions with the FDA; the potential for menin inhibitors to shift the treatment paradigm for GIST; 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, and combined with anticipated collaboration funding under the Kyowa Agreement, to support Kura's ziftomenib AML program through commercialization in the 1L combination setting. 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,	
	2024	2023	2024	2023
Collaboration revenue	$ 53,883	$ —	$ 53,883	$ —
Operating expenses				
Research and development	52,267	32,533	169,967	115,235
General and administrative	24,071	14,229	77,111	50,569
Total operating expenses	76,338	46,762	247,078	165,804
Other income, net	5,256	3,976	21,230	13,173
Income tax expense	(2,018)	—	(2,018)	—
Net loss	$ (19,217)	$ (42,786)	$ (173,983)	$ (152,631)
Net loss per share, basic and diluted	$ (0.22)	$ (0.55)	$ (2.02)	$ (2.08)
Weighted average number of shares used in computing net loss per share, basic and diluted	87,136	77,337	86,161	73,229

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 727,395	$ 423,957
Working capital	666,117	397,218
Total assets	760,159	448,935
Long-term liabilities	267,807	16,399
Accumulated deficit	(895,422)	(721,439)
Stockholders' equity	413,640	397,273

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