Kura Oncology Reports First Quarter 2025 Financial Results

May 1, 2025

– NDA submitted in 1Q 2025 for ziftomenib for the treatment of adult patients with relapsed or refractory AML with an NPM1 mutation –

– Data from Phase 1b/2 registration-directed trial of ziftomenib selected for oral presentation at ASCO Annual Meeting –

– $45.0 million milestone payment earned for NDA submission under collaboration agreement with Kyowa Kirin –

– First patients dosed in Phase 1 trial of ziftomenib plus imatinib in GIST –

– $703.2 million in pro forma cash, together with anticipated collaboration agreement payments, expected 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, May 01, 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 first quarter 2025 financial results and provided a corporate update.

“In the first quarter of 2025, we achieved a significant milestone with the submission of our first NDA for ziftomenib,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We are committed to working with FDA to support its review and are strategically advancing our pre-commercial activities to prepare for potential approval for the treatment of adult patients with relapsed or refractory *NPM1*-mutant AML. Beyond the monotherapy setting, we look forward to sharing data on the combination of ziftomenib with intensive and non-intensive standards of care, while gearing up for two Phase 3 studies in the frontline setting. With a strong pipeline, multiple clinical data readouts expected this year, and a solid financial foundation, we are well-positioned to drive progress across our programs.”

Recent Highlights

- **Submission of New Drug Application for ziftomenib to FDA** – Kura and Kyowa Kirin Co., Ltd. (Kyowa Kirin) announced submission of the New Drug Application (NDA) for ziftomenib for the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a nucleophosmin 1 (NPM1) mutation to the U.S. Food and Drug Administration (FDA) on March 31, 2025. From the time of submission, the FDA has a 60-day filing review period, and the Company expects to receive notification from the FDA on this preliminary evaluation in the second quarter of 2025. If Priority Review is granted, it would provide a target FDA review period of six months after NDA acceptance.

- **Abstracts accepted for presentation at ASCO and EHA** – In February 2025, Kura and Kyowa Kirin announced positive topline results from the KOMET-001, the Phase 2 registration-directed trial of ziftomenib in patients with R/R *NPM1*-mutant (*NPM1*-m) AML. These data have been accepted for oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago and accepted for an encore presentation at the European Hematology Association (EHA) Congress in Milan, Italy. In addition, preliminary clinical data from the Phase 1b expansion cohort evaluating ziftomenib in combination with intensive (7+3) in the frontline setting has been accepted for an oral presentation at EHA. Abstract titles and presentation details can be found on the ASCO and EHA meeting sites at the lift of the respective embargos.

- **Submission of the NDA for ziftomenib has triggered a $45 million milestone payment obligation from Kyowa Kirin –** As a result of the NDA submission for ziftomenib, Kura has earned a $45 million milestone payment under the global strategic collaboration agreement between Kura and Kyowa Kirin to develop and commercialize ziftomenib in acute leukemias (Kyowa Agreement). Under the terms of the Kyowa Agreement, Kura received an upfront payment of $330 million in December 2024 and accounting for this $45 million milestone payment, Kura expects to receive up to $375 million in additional, near-term milestone payments.

- **First patients dosed in KOMET-015 trial in GIST** – Earlier this week, Kura announced the first patients have been dosed in its KOMET-015 Phase 1 clinical trial of ziftomenib in patients with advanced gastrointestinal stromal tumors (GIST) after imatinib failure. In October 2024, Kura presented preclinical data 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 the treatment of GIST. 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.

- **Preclinical data for KO-2806 presented in oral minisymposium session at AACR Annual Meeting** – Last month, Kura presented preclinical data for KO-2806, the Company's next-generation farnesyl transferase inhibitor (FTI), in combination with cabozantinib for the treatment of clear cell renal cell carcinoma at the American Association for Cancer Research (AACR) Annual Meeting in Chicago. These data add to a growing body of preclinical evidence demonstrating the potential of FTIs as companion therapeutic agents to augment the antitumor activities of and to overcome resistance to various targeted therapies.

Financial Results

- Collaboration revenue from our Kyowa Kirin partnership for the first quarter of 2025 was $14.1 million, compared to no revenue for the first quarter of 2024.
- Research and development expenses for the first quarter of 2025 were $56.0 million, compared to $36.3 million for the first quarter of 2024.
- General and administrative expenses for the first quarter of 2025 were $22.8 million, compared to $18.2 million for the first quarter of 2024.
- Net loss for the first quarter of 2025 was $57.4 million, compared to a net loss of $49.5 million for the first quarter of 2024.
- Net loss for the first quarter of 2025 included non-cash, share-based compensation expense of $7.8 million. This compares to $8.5 million for the same period in 2024.
- As of March 31, 2025, Kura had cash, cash equivalents and short-term investments of $658.2 million, compared to $727.4 million as of December 31, 2024.
- As adjusted for the $45 million NDA submission milestone payment earned under our collaboration agreement with Kyowa Kirin, Kura had, on a pro forma basis, $703.2 million in cash, cash equivalents and short-term investments as of March 31, 2025.
- Based on our current plans, we believe our cash, cash equivalents and short-term investments as of March 31, 2025 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 frontline combination setting.

Forecasted Milestones

- Present data from the KOMET-001 Phase 1b/2 registration-directed trial in R/R *NPM1*-m AML at ASCO and EHA 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) in the frontline setting at EHA in the second quarter of 2025.
- Present preliminary clinical data from the KOMET-007 Phase 1b expansion cohort evaluating ziftomenib with venetoclax and azacitidine in the frontline setting at a medical meeting in the second 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.
- Nominate a development candidate for next-generation menin inhibitor program in diabetes in mid-2025.
- Initiate one or more FIT-001 expansion cohorts of KO-2806 and cabozantinib in patients with advanced renal cell carcinoma in the second half of 2025.
- Present data from the FIT-001 Phase 1 trial evaluating KO-2806 and cabozantinib in patients with renal cell carcinoma in the second half of 2025.
- Present data from the FIT-001 Phase 1 monotherapy dose escalation of KO-2806 in patients with RAS mutations in the second half of 2025.
- Present data from the 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, May 1, 2025, to discuss the financial results for the first quarter of 2025 and to provide a corporate update. The live call may be accessed by dialing (800) 245-3047 for domestic callers and (203) 518-9765 for international callers and entering the conference ID: KURAQ1. A live webcast and archived replay of the event will be available here or online from the investor relations section of the Company's 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 designed to target 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 into a global strategic collaboration agreement with Kyowa Kirin 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 in the second quarter of 2025, the companies announced submission of an NDA for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML. Kura and Kyowa Kirin are 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-rearranged AML. KO-2806, a next-generation FTI, is being evaluated in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with targeted therapies for patients with various solid tumors. 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. 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, KO-2806 and tipifarnib; the expected timing of clinical trials; the expected timing and presentation of results and data from clinical trials; the anticipated timing of FDA's notification on its preliminary evaluation of the NDA for ziftomenib; the potential duration of FDA's review of the NDA; the potential FDA approval of product candidates; the success and impact of interactions with the FDA; 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, 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, the risk that the collaboration with Kyowa Kirin is unsuccessful, 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 March 31,	
	2025	**2024**
Collaboration revenue	$ 14,108	$ —
Operating expenses		
Research and development	55,973	36,268
General and administrative	22,835	18,184
Total operating expenses	78,808	54,452
Other income, net	7,497	4,927
Income tax expense	(226)	—
Net loss	$ (57,429)	$ (49,525)
Net loss per share, basic and diluted	$ (0.66)	$ (0.59)
Weighted average number of shares used in computing net loss per share, basic and diluted	87,415	83,905

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	$ 658,191	$ 727,395
Working capital	634,432	666,117
Total assets	743,764	760,159
Long-term liabilities	289,592	267,807
Accumulated deficit	(952,851)	(895,422)
Stockholders' equity	364,406	413,640

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Source: Kura Oncology, Inc.