Kura Oncology Reports Third Quarter 2025 Financial Results

November 4, 2025

– New Drug Application for ziftomenib in adults with R/R *NPM1*-m AML remains under FDA Priority Review, with a PDUFA target action date of November 30, 2025 –

– KOMET 017 Phase 3 trials to evaluate ziftomenib in combination with intensive and non-intensive chemotherapy in frontline AML are accelerating; ziftomenib being investigated in settings representing more than 50% of AML patients –

– Two oral presentations at 2025 ASH Annual Meeting on ziftomenib in combination with venetoclax / azacitidine chemotherapy in frontline and R/R *NPM1*-m AML –

– Clinical data at ESMO 2025 Congress highlight promise of second strategic program – FTIs darlifarnib and tipifarnib show promising safety profile and clinical activity with targeted therapies in solid tumors –

– $609.7 million in *pro forma* cash, together with anticipated collaboration payments, expected to support ziftomenib AML program through topline results in KOMET-017 –

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

SAN DIEGO, Nov. 04, 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 third quarter 2025 financial results and provided a corporate update.

“Our momentum is accelerating across the ziftomenib program and our broader precision oncology pipeline,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer. “With the initiation of the pivotal KOMET-017 Phase 3 trials, we are executing a robust, focused development strategy to unlock ziftomenib’s best-in-class potential across the continuum of unmet need in AML. Bolstered by a strong balance sheet and our productive partnership with Kyowa Kirin, we are well positioned to advance ziftomenib toward commercialization, accelerate our frontline Phase 3 trials and create enduring value across our pipeline for patients and other key stakeholders.”

Recent Highlights

- In September 2025, we announced the first patient was dosed in the Phase 3 **KOMET-017** trial of ziftomenib in frontline AML (NCT07007312). KOMET-017 comprises two global, randomized, double-blind, placebo-controlled trials to evaluate ziftomenib in combination with both intensive and non-intensive chemotherapy regimens in patients with newly diagnosed *NPM1*-m or *KMT2A*-rearranged (*KMT2A*-r) AML.
- In October 2025, we announced the first patient was dosed in the FLT3 inhibitor cohort of the **KOMET-007** clinical trial (NCT05735184). The cohort evaluates ziftomenib combined with the FDA-approved FLT3 inhibitor, quizartinib, plus cytarabine and daunorubicin (7+3) induction chemotherapy in patients with newly diagnosed AML harboring *FLT3-ITD* / *NPM1* co-mutations.
- In September 2025, the ***Journal of Clinical Oncology*** published the full results from the pivotal KOMET-001 clinical trial (NCT04067336) evaluating ziftomenib as a monotherapy in adult patients with R/R *NPM1*-m AML. (Reprint)
- Two abstracts featuring clinical data from ziftomenib in combination with venetoclax / azacitidine (ven/aza) chemotherapy in patients with newly diagnosed and R/R *NPM1*-m or *KMT2A*-r AML were accepted for **oral presentation** at the 67th Annual Meeting of the American Society of Hematology (ASH) to be held in December 2025. (Abstract ID 764; Abstract ID 766)
- In October 2025, preliminary clinical data were presented at ESMO 2025, highlighting the potential of Kura’s farnesyl transferase inhibitors, **darlifarnib** (KO-2806) and tipifarnib, to enhance the anti-tumor activity of PI3Ka inhibitors, KRAS inhibitors and antiangiogenic tyrosine kinase inhibitors across a range of diverse tumor types by addressing a common resistance pathway.
    - Data from the FIT-001 Phase 1 trial evaluating darlifarnib and cabozantinib in patients with renal cell carcinoma (RCC) reflect a manageable safety profile across multiple dose levels of each agent, including at the full label dose of cabozantinib. Antitumor activity was observed across all dose combinations tested, including in patients with prior exposure to cabozantinib. The objective response rate (ORR) was 33-50% in ccRCC, and 17-50% in patients with prior cabozantinib exposure. (Poster)
    - Data from the KURRENT-HN trial evaluating tipifarnib and alpelisib in patients with *PIK3CA*-dependent HNSCC also reflect a manageable safety profile. An ORR of 47% was observed at a dose of tipifarnib 1200 mg/day and alpelisib 250 mg/day. Robust antitumor activity was observed in a heavily pretreated patient population where clinical benefit is not expected from either alpelisib or tipifarnib as monotherapy. (Poster)

- In October and November 2025, Kura received two $30 million **milestone payments** under its agreement with Kyowa Kirin in connection with first patient dosing in the pivotal KOMET-017 clinical trial of ziftomenib with intensive and non-intensive chemotherapy in patients with frontline AML.

Forecasted Milestones

- Continued regulatory interactions with the FDA ahead of the November 30, 2025 PDUFA target action date for ziftomenib as a monotherapy for adult patients with relapsed or refractory *NPM1*-m AML.
- Present preliminary clinical data in newly diagnosed *NPM1*-m AML and updated clinical data in R/R *NPM1*-m and *KMT2A*-r AML from KOMET-007 cohorts evaluating ziftomenib in combination with ven/aza at ASH Annual Meeting to be held in December 2025.
- Present preliminary data from the KOMET-008 cohort evaluating ziftomenib in combination with the FLT3 inhibitor **gilteritinib** in patients with R/R *NPM1*-m AML in 2026.
- Initiate FIT-001 Phase 1b expansion cohorts of darlifarnib and cabozantinib in patients with advanced RCC in the first half of 2026.
- Present updated dose-escalation data from the combination of darlifarnib and **cabozantinib** in patients with advanced **RCC** in 2026.
- Present preliminary clinical data from the combination of darlifarnib and **adagrasib** in patients with ***KRAS^{G12C}*-**mutated solid tumor indications in 2026.

Financial Results

- Collaboration revenue from our Kyowa Kirin partnership for the third quarter of 2025 was $20.8 million, compared to no revenue for the third quarter of 2024.
- Research and development expenses for the third quarter of 2025 were $67.9 million, compared to $41.7 million for the third quarter of 2024.
- General and administrative expenses for the third quarter of 2025 were $32.8 million, compared to $18.2 million for the third quarter of 2024.
- Net loss for the third quarter of 2025 was $74.1 million, compared to a net loss of $54.4 million for the third quarter of 2024. Net loss for the third quarter included non-cash share-based compensation expense of $11.0 million, compared to $8.3 million for the same period in 2024.
- As adjusted for the two $30 million clinical trial milestone payments earned under our collaboration agreement with Kyowa Kirin, Kura had, on a *pro forma* basis, cash, cash equivalents and short-term investments of $609.7 million as of September 30, 2025.
- Based on our current plans, we believe that our cash, cash equivalents and short-term investments as of September 30, 2025 will be sufficient to enable us to fund our current operating expenses into 2027, and, combined with anticipated funding under our collaboration agreement with Kyowa Kirin, should support our ziftomenib AML program through topline results from KOMET-017.

Conference Call and Webcast - Third Quarter 2025 Financial Results

Kura's management will host a webcast and conference call at 8:00 a.m. ET / 5:00 a.m. PT today, November 4, 2025, to discuss the financial results for the third quarter of 2025 and to provide a corporate update. 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.

Conference Call and Webcast – ASH 2025 Annual Meeting

Kura plans to host a virtual analyst and investor event at 12:30 p.m. ET / 9:30 a.m. PT on Monday, December 8, 2025, to discuss the Company's presentations from ziftomenib in combination with ven/aza chemotherapy in patients with newly diagnosed and R/R *NPM1*-m or *KMT2A*-r AML at the 67th Annual Meeting of the American Society of Hematology. A live webcast and archived replay of the event will be available 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 of small molecule drug candidates is designed to target cancer signaling pathways and address high-need hematologic malignancies and solid tumors. Kura is developing ziftomenib, a menin inhibitor targeting certain genetic drivers of acute myeloid leukemias, and it continues to pioneer advancements in menin inhibition for acute leukemias and solid tumors and in farnesyl transferase inhibition to address mechanisms of adaptive and innate resistance in the treatment of solid tumors. For additional information, please visit the Kura website at https://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, ziftomenib's best-in-class potential across the continuum of unmet need in AML; Kura's ability to advance ziftomenib toward commercialization, accelerate our frontline Phase 3 trials and create enduring value for patients and other stakeholders; 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; continued regulatory interactions with the FDA; the efficacy, safety and therapeutic potential of Kura's product candidates, ziftomenib, darlifarnib and tipifarnib; the expected timing of clinical trials; the expected timing and presentation of results and data from clinical trials; the strength of Kura's balance sheet and the sufficiency of cash, cash equivalents and short-term investments to fund Kura's current operating expenses into 2027 and, combined with anticipated funding under our collaboration agreement with Kyowa Kirin, to support Kura's ziftomenib AML program through topline results from KOMET-017. Factors that may cause actual results to differ materially include risks associated with the commercialization of ziftomenib, 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, 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.

FLT3, Fms-like tyrosine kinase 3; HNSCC, head and neck squamous cell carcinoma; *KMT2A*, lysine methyltransferase 2A; *NPM1,* nucleophosmin 1; R/R, relapsed / refractory; ven/aza, venetoclax / azacitidine.

KURA ONCOLOGY, INC.
Statements of Operations Data
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 20,750	$ —	$ 50,146	$ —
Operating expenses				
Research and development	67,908	41,705	186,666	117,700
General and administrative	32,839	18,179	80,843	53,040
Total operating expenses	100,747	59,884	267,509	170,740
Other income, net	5,881	5,480	19,922	15,974
Income tax expense	—	—	(226)	—
Net loss	$ (74,116)	$ (54,404)	$ (197,667)	$ (154,766)
Net loss per share, basic and diluted	$ (0.85)	$ (0.63)	$ (2.26)	$ (1.80)
Weighted average number of shares used in computing net loss per share, basic and diluted	87,645	86,950	87,550	85,834

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

	September 30, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	$ 549,665	$ 727,395
Working capital	499,359	666,117
Total assets	649,381	760,159
Long-term liabilities	285,535	267,807
Accumulated deficit	(1,093,089)	(895,422)
Stockholders' equity	242,542	413,640

Contacts

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Source: Kura Oncology, Inc.