Kura Oncology Reports Third Quarter 2024 Financial Results

November 7, 2024

– Topline results from registration-directed trial of ziftomenib in R/R NPM1-mutant AML expected in early 2025; Phase 1 results published in *The Lancet Oncology* –

– Data from 100 patients in Phase 1a dose-escalation study of ziftomenib combined with ven/aza in R/R AML and 7+3 in 1L adverse risk AML to be presented at ASH –

– Phase 1b expansion study of ziftomenib in combination with standards of care now enrolling at 600 mg in all cohorts –

– Preclinical data support opportunity for ziftomenib in GIST; proof-of-concept study expected to begin in 1H 2025 –

– First patient dosed in study of KO-2806 and adagrasib in $KRAS^{G12C}$-mutated NSCLC –

– $455.3 million in cash, cash equivalents and investments provide runway into 2027 –

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

SAN DIEGO, Nov. 07, 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 third quarter 2024 financial results and provided a corporate update.

“We approach the end of 2024 in a strong position, with a series of important catalysts ahead,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “First, we look forward to sharing a robust dataset from more than 100 patients in our Phase 1a dose-escalation study of ziftomenib in combination with standards of care in acute myeloid leukemia (AML) at the upcoming American Society of Hematology (ASH) Annual Meeting, followed by topline results from our registration-directed trial of ziftomenib in relapsed/refractory (R/R) NPM1-mutant (NPM1-m) AML early next year. In the meantime, we continue to enroll rapidly across all our ziftomenib studies, further supporting the broad development of our menin inhibitor programs.”

Recent Highlights

- **Topline results from registration-directed trial of ziftomenib in early 2025** – In May 2024, Kura completed enrollment of 85 patients in the Phase 2 portion of KOMET-001, a registration-directed clinical trial of its menin inhibitor, ziftomenib, in patients with R/R NPM1-m AML. Ziftomenib is the first and only investigational therapy to be granted Breakthrough Therapy Designation (BTD) for the treatment of R/R NPM1-m AML, which accounts for approximately 30% of new AML cases annually and represents a disease of significant unmet need for which no approved targeted therapy exists. Results from the Phase 1 portion of KOMET-001 were recently published in the leading clinical oncology journal, *The Lancet Oncology*.
- **Data from Phase 1a dose-escalation study of ziftomenib at ASH** – Two abstracts reporting preliminary data from the Phase 1a dose-escalation study of ziftomenib in combination with standards of care in patients with NPM1-m and KMT2A-rearranged (KMT2A-r) AML have been accepted for presentation at the ASH Annual Meeting in December. As of the June 21, 2024 data cutoff, the abstracts continue to support a potential best-in-class safety and tolerability profile for ziftomenib, as well as robust and durable activity in combination with standards of care, including venetoclax plus azacitidine (ven/aza) as well as cytarabine plus daunorubicin (7+3). Kura expects to present a more mature dataset from more than 100 patients in the Phase 1a dose-escalation study in the presentations at ASH.
- **Phase 1b expansion study of ziftomenib now enrolling in all cohorts –** All four cohorts in the Phase 1a dose-escalation study have cleared the highest dose and advanced into the Phase 1b expansion study at 600 mg. The Phase 1b expansion study includes multiple combination cohorts, including ziftomenib plus ven/aza in newly diagnosed NPM1-m or KMT2A-r AML and ziftomenib plus 7+3 in newly diagnosed NPM1-m or KMT2A-r AML without qualification for high-risk disease. Each of the seven combination cohorts is expected to enroll at least 20 patients. A total of 45 patients have already enrolled in the study since the first dose-expansion cohort opened in August 2024. The Company anticipates sharing preliminary data from the Phase 1b expansion study at a medical meeting in 2025.
- **Preclinical data support opportunity for ziftomenib in GIST** – Last month, at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, Kura reported preclinical data supporting the combination of ziftomenib and imatinib for the treatment of advanced gastrointestinal stromal tumors (GIST). The combination showed unexpectedly robust and durable antitumor activity in both imatinib-sensitive and imatinib-resistant GIST patient-derived xenograft models, and in all cases was significantly superior to imatinib monotherapy. The Company received FDA

clearance of its Investigational New Drug application for ziftomenib for the treatment of advanced GIST in August and expects to initiate a proof-of-concept study in the first half of 2025 evaluating ziftomenib and imatinib in patients with advanced GIST who have failed imatinib.

- **First patient dosed in study of KO-2806 and adagrasib in KRAS^{G12C}-mutated NSCLC** – In August 2024, Kura began dosing patients in its study of KO-2806, a next-generation farnesyl transferase inhibitor (FTI), in combination with adagrasib in KRAS^{G12C}-mutated non-small cell lung cancer (NSCLC). The Company's findings suggest that combining KO-2806 with adagrasib may drive tumor regressions and enhance both duration and depth of antitumor response in preclinical models of KRAS^{G12C}-mutated NSCLC. The study of KO-2806 and adagrasib is supported by a clinical collaboration and supply agreement with Mirati, now a Bristol Myers Squibb company.
- **Preclinical data support potential for menin inhibitor in diabetes** – In June 2024, Kura reported data showing that ziftomenib induces insulin production, improves insulin sensitivity and reduces insulin resistance in a preclinical *in vivo* model of type 2 diabetes. Ziftomenib demonstrated meaningful levels of glycemic control, including reduced fasting blood glucose levels and %HbA1C within 27 days, as well as consistent improvement in both insulin sensitivity and insulin production. The data were presented at the American Diabetes Association Scientific Sessions in Orlando. The Company expects to nominate a next generation menin inhibitor candidate targeting diabetes in the first half of 2025.

Financial Results

- Research and development expenses for the third quarter of 2024 were $41.7 million, compared to $29.3 million for the third quarter of 2023.
- General and administrative expenses for the third quarter of 2024 were $18.2 million, compared to $13.1 million for the third quarter of 2023.
- Net loss for the third quarter of 2024 was $54.4 million, compared to a net loss of $38.6 million for the third quarter of 2023. This included non-cash share-based compensation expense of $8.3 million, compared to $7.1 million for the same period in 2023.
- As of September 30, 2024, Kura had cash, cash equivalents and short-term investments of $455.3 million, compared to $424.0 million as of 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

- Present updated data from the KOMET-007 trial of ziftomenib in combination with ven/aza and 7+3 at ASH in December 2024.
- Report topline results from the KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant R/R AML in early 2025.
- Present preliminary data from the Phase 1b expansion portion of KOMET-007 at a medical meeting in 2025.
- Initiate proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST in the first half of 2025.
- Nominate a next generation menin inhibitor development candidate targeting diabetes in the first half of 2025.
- Identify the maximum tolerated dose for KO-2806 as a monotherapy in the second half of 2024.
- Initiate one or more expansion cohorts for the combination of KO-2806 and cabozantinib in renal cell carcinoma in the first half of 2025.
- Present data from the KURRENT-HN trial of tipifarnib in combination with alpelisib in PIK3CA-dependent head and neck squamous cell carcinoma (HNSCC) in the first 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, November 7, 2024, to discuss the financial results for the third quarter 2024 and to provide a corporate update. The live call may be accessed by dialing (800) 225-9448 for domestic callers and (203) 518-9708 for international callers and entering the conference ID: KURAQ3. 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, a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction, has received BTD for the treatment of R/R NPM1-m AML. Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-m AML (KOMET-001). The Company is 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. Kura is evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies (FIT-001). 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). 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, 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 strength of Kura's balance sheet and the sufficiency of cash, cash equivalents and short-term investments to fund its current operating plan into 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating Expenses:				
Research and development	$ 41,705	$ 29,328	$ 117,700	$ 82,702
General and administrative	18,179	13,145	53,040	36,340
Total operating expenses	59,884	42,473	170,740	119,042
Other income, net	5,480	3,871	15,974	9,197
Net loss	$ (54,404)	$ (38,602)	$ (154,766)	$ (109,845)
Net loss per share, basic and diluted	$ (0.63)	$ (0.50)	$ (1.80)	$ (1.53)
Weighted average number of shares used in computing net loss per share, basic and diluted	86,950	77,241	85,834	71,845

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 455,297	$ 423,957
Working capital	422,817	397,218
Total assets	478,837	448,935
Long-term liabilities	14,694	16,399
Accumulated deficit	(876,205)	(721,439)
Stockholders' equity	423,771	397,273

Contacts

Investors:
Pete De Spain
Executive Vice President, Investor Relations &
Corporate Communications
(858) 500-8833
pete@kuraoncology.com

Media:
Cassidy McClain
Vice President
Inizio Evoke Comms

(619) 849-6009
cassidy.mcclain@inizioevoke.com

Source: Kura Oncology, Inc.