Kura Oncology Reports Second Quarter 2024 Financial Results

August 8, 2024

– Topline data from registration-directed trial of ziftomenib in R/R NPM1-mutant AML expected in early 2025 –

– Breakthrough Therapy Designation granted for ziftomenib in R/R NPM1-mutant AML –

– Data from 100 patients in KOMET-007 trial of ziftomenib in combination with ven/aza and 7+3 expected in Q4; Phase 1b expansion study in 1L AML now enrolling –

– Investigational New Drug (IND) application cleared for ziftomenib in GIST –

– Preclinical data at ADA support potential for menin inhibitor in diabetes –

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

– $491.5 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, Aug. 08, 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 second quarter 2024 financial results and provided a corporate update.

“This past quarter was highlighted by strong execution across the organization,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We completed enrollment in our KOMET-001 registration-directed trial of ziftomenib in patients with relapsed/refractory (R/R) NPM1-mutant acute myeloid leukemia (AML), and we were delighted to have ziftomenib receive Breakthrough Therapy Designation from the FDA in that indication. In the KOMET-007 study, the safety, tolerability and clinical activity of ziftomenib continue to support advancement of ziftomenib into the frontline (1L) population, and the Phase 1b expansion study in combination with venetoclax and azacitidine (ven/aza) and cytarabine plus daunorubicin (7+3) is now open for enrollment. We are generating a robust clinical data package to support the broad development of ziftomenib, including enrollment of more than 100 patients in the KOMET-007 study, and we look forward to providing an update on this study at a medical meeting later this year, followed by topline data from our registration-directed trial in early 2025.”

Recent Highlights

- **Completion of enrollment in pivotal trial of ziftomenib in R/R NPM1-mutant AML** – 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-mutant AML. 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. The Company expects to report topline data from the trial in early 2025.
- **Breakthrough Therapy Designation for ziftomenib in NPM1-mutant AML** – In April 2024, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to ziftomenib for the treatment of R/R NPM1-mutant AML. FDA granted BTD based on data from the KOMET-001 trial of ziftomenib in patients with R/R NPM1-mutant AML. BTD is awarded for a drug that treats a serious or life-threatening condition and may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.
- **Phase 1b expansion portion of KOMET-007 open for enrollment –** Kura recently began dosing patients in the Phase 1b expansion portion of its KOMET-007 combination study of ziftomenib. The Phase 1b expansion study includes multiple combination cohorts, including ven/aza in newly diagnosed NPM1-mutant or KMT2A-rearranged AML and 7+3 in newly diagnosed NPM1-mutant or KMT2A-rearranged AML without qualification for high-risk disease. Each combination cohort is expected to enroll approximately 20 patients at 600 mg. The Company expects to present updated data from the KOMET-007 study at a medical meeting in the fourth quarter of 2024.
- **IND for ziftomenib in GIST; proof-of-concept study to begin in early 2025** – Earlier today, Kura announced FDA clearance of its IND application for ziftomenib for the treatment of advanced gastrointestinal stromal tumors (GIST) in combination with imatinib. Preclinical data suggest ziftomenib has potential to resensitize patients to imatinib and induce deep, durable responses. The Company expects to present the preclinical data for the combination at an upcoming scientific meeting, followed by a proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST in the first half of 2025.
- **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 (ADA) Scientific Sessions in Orlando. The Company expects to nominate the first in a series of next-generation development candidates targeting diabetes in early 2025.

- **First patient dosed in study of KO-2806 and adagrasib in KRAS^{G12C}-mutated NSCLC** – Kura recently 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.

Financial Results

- Research and development expenses for the second quarter of 2024 were $39.7 million, compared to $28.2 million for the second quarter of 2023.
- General and administrative expenses for the second quarter of 2024 were $16.7 million, compared to $11.8 million for the second quarter of 2023.
- Net loss for the second quarter of 2024 was $50.8 million, compared to a net loss of $37.2 million for the second quarter of 2023. This included non-cash share-based compensation expense of $8.4 million, compared to $7.0 million for the same period in 2023.
- As of June 30, 2024, Kura had cash, cash equivalents and short-term investments of $491.5 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 a medical meeting in the fourth quarter of 2024.
- Report topline data from the KOMET-001 registration-directed trial of ziftomenib in NPM1-mutant R/R AML in early 2025.
- Present preclinical data supporting opportunity for ziftomenib in GIST at a scientific meeting in the second half of 2024.
- 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 in early 2025.
- Identify the maximum tolerated dose for KO-2806 as a monotherapy in the second half of 2024.
- Complete enrollment of two expansion cohorts in KURRENT-HN and identify the optimal biologically active dose of tipifarnib and alpelisib by the end of 2024.
- 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, August 8, 2024, to discuss the financial results for the second quarter 2024 and to provide a corporate update. The live call may be accessed by dialing (877) 300-8521 for domestic callers and (412) 317-6026 for international callers and entering the conference ID: 10190278. 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 Breakthrough Therapy Designation for the treatment of R/R NPM1-mutant AML. Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-mutant 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-mutant and KMT2A-rearranged 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating Expenses:				
Research and development	$ 39,727	$ 28,182	$ 75,995	$ 53,374
General and administrative	16,677	11,821	34,861	23,195
Total operating expenses	56,404	40,003	110,856	76,569
Other income, net	5,567	2,829	10,494	5,326
Net loss	$ (50,837)	$ (37,174)	$ (100,362)	$ (71,243)
Net loss per share, basic and diluted	$ (0.59)	$ (0.53)	$ (1.18)	$ (1.03)
Weighted average number of shares used in computing net loss per share, basic and diluted	86,635	69,795	85,270	69,103

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

	June 30, 2024	**December 31, 2023**
Cash, cash equivalents and short-term investments	$ 491,519	$ 423,957
Working capital	466,317	397,218
Total assets	515,116	448,935
Long-term liabilities	15,595	16,399
Accumulated deficit	(821,801)	(721,439)
Stockholders' equity	466,070	397,273

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