Kura Oncology Reports First Quarter 2023 Financial Results

May 10, 2023

– Evolving data from Phase 1 trial of ziftomenib in NPM1-mutant AML to be presented at EHA –

– Site activation and enrollment in Phase 2 registration-directed trial of ziftomenib in NPM1-mutant AML outperforming projections –

– First combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML to dose first patients in the second quarter of 2023 –

– Preclinical data highlighting potential use of FTIs in combination with multiple targeted therapies presented at AACR –

– IND for KO-2806, a next-generation FTI, cleared by FDA –

– $406 million in cash, equivalents and investments provide runway into fourth quarter of 2025 –

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

SAN DIEGO, May 10, 2023 (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 2023 financial results and provided a corporate update.

“Our conviction in ziftomenib and its potential to be the best-in-class menin inhibitor continues to increase,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “This confidence is supported by one of the highest complete response rates reported for a targeted therapy in the setting of relapsed/refractory leukemia and is reinforced by the rapid pace of enrollment in our ongoing registration-directed trial in NPM1-mutant acute myeloid leukemia (AML). We are also encouraged by the durable remissions in our Phase 1 trial, driven primarily by the single-agent activity of ziftomenib, and we look forward to presenting an update at the European Hematology Association (EHA) Congress next month. In parallel, we aim to broaden the opportunity for ziftomenib through a series of combination studies and remain on track to initiate the first of these studies, KOMET-007, later this quarter.”

Recent Highlights

- **Evolving data from Phase 1 trial of ziftomenib in NPM1-mutant AML to be presented at EHA** – Kura expects to present updated data as of an early April data cutoff at EHA in June. Ziftomenib continues to demonstrate significant clinical activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML. As of a January 31st data cutoff, six of the 20 NPM1-mutant patients treated at the recommended Phase 2 dose achieved a complete response (CR) with full count recovery. The median duration of response (DoR) was 8.2 months with a median follow-up of approximately 8 months; four patients were still ongoing at the time of data cutoff. Ziftomenib is well tolerated, and the on-target effect of differentiation syndrome is manageable.

- **Rapid enrollment in Phase 2 registration-directed trial of ziftomenib in NPM1-mutant AML** – In February, Kura announced that the first patients had been dosed in its Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML. To date, site activation and patient enrollment in the Phase 2 study are outperforming projections. The study is expected to enroll a total of 85 patients at 62 U.S. and European sites. The primary endpoint is CR or CR with partial hematologic recovery (CRh), and key secondary endpoints include DoR, transfusion independence, safety and tolerability. 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.

- **First combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML to dose first patients this quarter** – Kura is preparing to initiate a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The Company intends to establish ziftomenib as a foundational therapy that can be combined safely with various commonly used regimens, such as venetoclax plus azacitidine, FLT3 inhibitors and standard induction cytarabine plus daunorubicin (7+3) chemotherapy, and will prioritize those combinations that represent the largest patient benefit, unmet medical need and potential commercial value. Kura has begun site activation in the first of these studies, KOMET-007, and is on track to dose the first patients this quarter.

- **Preclinical data highlighting potential use of FTIs in combination with multiple targeted therapies presented at AACR** – Kura has generated a growing body of preclinical and clinical data that support the combination of FTIs with multiple classes of targeted therapies, including EGFR inhibitors and PI3 kinase alpha inhibitors. In April, the Company

presented additional preclinical data at AACR supporting the potential use of FTIs in combination with two additional, distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic tyrosine kinase inhibitor axitinib in cell- and patient-derived xenograft models of clear cell renal cell carcinoma. The second poster reported regression of multiple models of KRAS inhibitor-resistant non-small cell lung cancer by addition of tipifarnib to adagrasib or sotorasib therapy. These preclinical data illustrate the potential for FTIs to drive enhanced anti-tumor activity and address mechanisms of innate and adaptive resistance to targeted therapies.

- **IND for KO-2806, a next-generation farnesyl transferase inhibitor (FTI)** – In January, Kura announced FDA clearance of its Investigational New Drug (IND) application for KO-2806 for the treatment of advanced solid tumors. KO-2806 is a potent inhibitor of farnesyl transferase designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. The Company is now preparing to initiate a Phase 1 dose-escalation trial (FIT-001) of KO-2806 and expects to dose the first patients in the trial in the second half of 2023. Concurrent with dose escalation as a monotherapy, Kura also plans to evaluate KO-2806 in dose escalation combination cohorts in advanced solid tumors.

Financial Results

- Research and development expenses for the first quarter of 2023 were $25.2 million, compared to $20.9 million for the first quarter of 2022.
- General and administrative expenses for the first quarter of 2023 were $11.4 million, compared to $11.9 million for the first quarter of 2022.
- Net loss for the first quarter of 2023 was $34.1 million, compared to a net loss of $32.5 million for the first quarter of 2022. This included non-cash share-based compensation expense of $6.8 million, compared to $6.7 million for the same period in 2022.
- Cash, cash equivalents and short-term investments totaled $405.9 million as of March 31, 2023, compared to $438.0 million as of December 31, 2022. Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations into the fourth quarter of 2025.

Forecasted Milestones

- Dose the first patients in the KOMET-007 combination trial of ziftomenib in the first half of 2023.
- Present updated data from the KOMET-001 trial of ziftomenib in NPM1-mutant AML at EHA in June 2023.
- Dose the first patients in the KOMET-008 combination trial of ziftomenib in the second half of 2023.
- Determine the optimal biologically active dose in the KURRENT-HN trial of tipifarnib in combination with alpelisib in mid-2023.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in the second half of 2023.

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 10, 2023, to discuss the financial results for the first quarter 2023 and to provide a corporate update. The live call may be accessed by dialing (888) 886-7786 for domestic callers and (416) 764-8658 for international callers and entering the conference ID: 52214288. 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 is a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction for the treatment of genetically defined AML patients with high unmet need. The Company is currently enrolling patients in a Phase 2 registration-directed trial (KOMET-001) of ziftomenib in NPM1-mutant relapsed or refractory AML. Kura is preparing to initiate multiple Phase 1 trials to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. 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. Kura intends to evaluate KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with other targeted therapies in adult patients with advanced solid tumors. For additional information, please visit Kura's website at www.kuraoncology.com.

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, 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 regulatory approval path for tipifarnib, 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 fourth quarter of 2025. 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 March 31,	
	2023	**2022**
Operating Expenses:		
Research and development	$ 25,192	$ 20,913
General and administrative	11,374	11,869
Total operating expenses	36,566	32,782
Other income, net	2,497	329
Net loss	$ (34,069)	$ (32,453)
Net loss per share, basic and diluted	$ (0.50)	$ (0.49)
Weighted average number of shares used in computing net loss per share, basic and diluted	68,403	66,607

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

	March 31, 2023	**December 31, 2022**
Cash, cash equivalents and short-term investments	$ 405,900	$ 437,985
Working capital	397,217	422,369
Total assets	425,975	456,306
Long-term liabilities	11,559	11,971
Accumulated deficit	(602,877)	(568,808)
Stockholders' equity	395,183	420,278

Contacts

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

Media:
Alexandra Weingarten
Senior Manager, Corporate Communications
(858) 500-8822
alexandra@kuraoncology.com

Source: Kura Oncology, Inc.