Kura Oncology Reports First Quarter 2022 Financial Results

May 4, 2022

– Enrollment completed in Phase 1b expansion cohorts for ziftomenib; topline data expected in third quarter, full data presentation in fourth quarter –

– Enrollment in PIK3CA-dependent cohort in KURRENT-HN trial of tipifarnib plus alpelisib continues; first patient in HRAS overexpression cohort expected by third quarter –

– First patient in Phase 1 KURRENT-LUNG trial of tipifarnib plus osimertinib expected in third quarter –

– $480 million in cash, cash equivalents and investments provide runway through 2024 –

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

SAN DIEGO, May 04, 2022 (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 2022 financial results and provided a corporate update.

"We continue to operate from a position of strength, armed with three independent drug development programs, near-term clinical milestones and cash runway through 2024," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Our team continues to execute, having completed enrollment of the Phase 1b expansion cohorts for our menin inhibitor, ziftomenib, and we remain very encouraged by the safety profile, tolerability and clinical activity we are observing in the study. We continue to assess patients in the Phase 1b for safety and tolerability, pharmacokinetics and exposure, as well as efficacy, and we look forward to identifying a recommended Phase 2 dose for ziftomenib and reporting topline data from the study next quarter."

Recent Highlights

- **Enrollment completed in Phase 1b expansion cohorts for ziftomenib** – Kura has completed enrollment of the patients in the Phase 1b portion of KOMET-001 required to identify a recommended Phase 2 dose for ziftomenib. The Phase 1b portion was designed to enroll two expansion cohorts – 200 mg and 600 mg – with each cohort comprised of patients with NPM1-mutant or KMT2A-rearranged relapsed and/or refractory acute myeloid leukemia (AML). The goal of the Phase 1b portion is dose optimization, and the two doses were selected based on the encouraging clinical activity, safety profile and tolerability demonstrated in the Phase 1a portion of KOMET-001. Kura remains on track to identify the recommended Phase 2 dose for ziftomenib and report topline data from the Phase 1b portion of KOMET-001 in the third quarter of 2022, with a more complete dataset reserved for presentation at a medical meeting in the fourth quarter of 2022.

- **Expanded opportunity for tipifarnib in head and neck squamous cell carcinoma** – Enrollment continues in the Phase 1/2 clinical trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib in patients with head and neck squamous cell carcinoma (HNSCC). The initial cohort includes patients who have PIK3CA-dependent HNSCC, and Kura expects to dose the first patient in an HRAS overexpression cohort in the third quarter of 2022. The Company believes the combination with alpelisib has the potential to drive deeper and more durable responses than either agent as monotherapy and to increase the total addressable population for tipifarnib to as much as 50% of patients with HNSCC.

- **Preclinical data support use of tipifarnib to prevent relapse to osimertinib** – In April 2022, preclinical data supporting the potential of tipifarnib to prevent emergence of resistance to osimertinib in EGFR mutant non-small cell lung cancer (NSCLC) were reported at the American Association for Cancer Research Annual Meeting. Kura is now preparing to initiate a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in treatment-naïve locally advanced/metastatic EGFR mutated NSCLC and expect to dose the first patient in the third quarter of 2022. The Company intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, Kura's next-generation farnesyl transferase inhibitor (FTI), through investigational new drug (IND)-enabling studies.

Financial Results

- Research and development expenses for the first quarter of 2022 were $20.9 million, compared to $20.3 million for the first quarter of 2021. The increase in R&D expenses was primarily due to increases in ziftomenib clinical trial and personnel costs.

- General and administrative expenses for the first quarter of 2022 were $11.9 million, compared to $10.6 million for the first

quarter of 2021. The increase in G&A expenses was primarily due to increases in professional fees and non-cash share-based compensation.

- Net loss for the first quarter of 2022 was $32.5 million, compared to a net loss of $30.7 million for the first quarter of 2021. This included non-cash share-based compensation expense of $6.7 million, compared to $5.1 million for the same period in 2021.

- Cash, cash equivalents and short-term investments totaled $480.1 million as of March 31, 2022, compared with $518.0 million as of December 31, 2021. Based on its current plans, management expects that current cash, cash equivalents and short-term investments will fund current operations through 2024.

2022 Milestones

- Identify the recommended Phase 2 dose of ziftomenib and report topline data from the Phase 1b study in the third quarter.

- Present updated data from KOMET-001 at a medical meeting in the fourth quarter.

- Dose the first patient in the HRAS overexpression cohort of the KURRENT-HN trial by the third quarter.

- Dose the first patient in the KURRENT-LUNG trial in the third quarter.

- Submit an IND application for KO-2806 in the fourth quarter.

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 4, 2022, to discuss the financial results for the first quarter 2022 and to provide a corporate update. The live call may be accessed by dialing (844) 826-3035 for domestic callers and (412) 317-5195 for international callers and entering the conference code: 10166202. 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 (KO-539), a potent and selective menin inhibitor, is currently in a Phase 1b clinical trial (KOMET-001) for patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable FTI, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC and is currently in a registration-directed trial (AIM-HN) in patients with this devastating disease. In addition, Kura is conducting a Phase 1/2 trial (KURRENT-HN) of tipifarnib in combination with the PI3Kα inhibitor alpelisib to address larger genetic subsets of HNSCC patients, including those whose tumors are dependent on HRAS and/or PI3Kα pathways. The Company is also preparing to initiate a Phase 1 trial (KURRENT-LUNG) of tipifarnib in combination with osimertinib in treatment-naïve locally advanced/metastatic EGFR mutated NSCLC. Kura intends to perform initial clinical evaluation with tipifarnib while in parallel advancing KO-2806, the Company's next-generation FTI, through IND-enabling studies. 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 adequacy of cash on hand. 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, including the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2022, 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,	
	2022	2021
Operating Expenses:		
Research and development	$ 20,913	$ 20,324
General and administrative	11,869	10,572
Total operating expenses	32,782	30,896
Other income, net	329	202
Net loss	$ (32,453)	$ (30,694)
Net loss per share, basic and diluted	$ (0.49)	$ (0.46)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,607	66,218

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 480,075	$ 517,960
Working capital	469,309	499,834
Total assets	498,585	534,051
Long-term liabilities	4,610	4,987
Accumulated deficit	(465,421)	(432,968)
Stockholders' equity	476,250	506,609

Contacts

Company:
Pete De Spain
Senior Vice President, Investor Relations &
Corporate Communications
(858) 500-8803
pete@kuraoncology.com

Investors:
Robert H. Uhl
Managing Director
ICR Westwicke
(858) 356-5932
robert.uhl@westwicke.com

Media:
Jason Spark
Managing Director
Canale Communications
(619) 849-6005
jason@canalecomm.com

Source: Kura Oncology, Inc.