Kura Oncology Reports Second Quarter 2021 Financial Results

August 5, 2021

– First patients dosed in Phase 1b expansion cohorts with menin inhibitor KO-539 –

– Clinical collaboration with Novartis to evaluate tipifarnib in combination with the PI3Kα inhibitor alpelisib in HNSCC –

– KO-2806 nominated as lead development candidate in next-generation farnesyl transferase inhibitor program –

– $567.5 million in cash, cash equivalents and investments provide runway into 2024 –

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

SAN DIEGO, Aug. 05, 2021 (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 2021 financial results and provided a corporate update.

“I am extremely proud of the progress our team has made over the past several months, underscoring our focus on operational execution,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “We continue to have strong conviction in KO-539 and its potential to be both a first-in-class and a best-in-class menin inhibitor. This confidence is supported by clinical data from KOMET-001, our Phase 1/2 trial of KO-539 in patients with relapsed or refractory acute myeloid leukemia (AML). Given the wide therapeutic window KO-539 demonstrated in the Phase 1a dose escalation portion of the trial, we have now advanced into the Phase 1b expansion cohorts in patients with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML. The Phase 1b enables us to refine the selection of a recommended Phase 2 dose while maintaining an aggressive development timeline for the program.”

“Although it is early and the results are still preliminary,” continued Dr. Wilson, “we are encouraged by observations of early signs of clinical activity in the Phase 1b expansion cohorts. We are also encouraged by the rate of patient screening and enrollment, an indication of the enthusiasm of the investigators as well as the strong execution of our clinical operations team. We intend to provide an update on both the Phase 1a and the Phase 1b at a future medical meeting, pending determination of the recommended Phase 2 dose. In the meantime, we look forward to providing qualitative updates on the progress of the Phase 1b in the months ahead.”

Recent Highlights

- **First patients dosed in Phase 1b expansion cohorts with KO-539** – In late June, Kura announced that the first patient was dosed in the Phase 1b portion of KOMET-001. Patients are now enrolled in each of the two expansion cohorts – a lower dose of 200 mg and a higher dose of 600 mg – each comprising NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients. The Company expects to complete enrollment of 12 evaluable patients in each cohort by the first quarter of 2022, then will assess those patients for safety and tolerability, pharmacokinetics and efficacy in order to determine the recommended Phase 2 dose.

- **Multiple expansion opportunities in acute leukemias** – Pending determination of a recommended Phase 2 dose, Kura is preparing to conduct a comprehensive clinical development plan for KO-539, aimed at broadening the opportunity in acute leukemias. Additional development opportunities include combination studies, other genetic subtypes, a pediatric development strategy and other indications, such as acute lymphocytic leukemia and myelodysplastic syndrome.

- **Clinical collaboration to evaluate tipifarnib and alpelisib in HNSCC** – In July, Kura announced a clinical collaboration with Novartis to evaluate the combination of tipifarnib and the PI3Kα inhibitor alpelisib in patients with head and neck squamous cell carcinoma (HNSCC). The Company is now preparing for a Phase 1/2 clinical trial (KURRENT) of tipifarnib in combination with alpelisib in patients who have HRAS- and/or PIK3CA-dependent HNSCC. The initial cohort will include patients who have PIK3CA-dependent HNSCC and the trial is expected to initiate in the fourth quarter of 2021.

- **Nomination of KO-2806 as lead development candidate** – Kura has nominated KO-2806 as its lead development candidate in the Company’s next-generation farnesyl transferase inhibitor program. KO-2806 was nominated based on its improved potency, pharmacokinetic and physicochemical properties relative to tipifarnib, and is designed to target innovative biology and address large oncology indications of high unmet need through rational combinations. The Company is now conducting investigational new drug (IND)-enabling studies and expects to submit an IND application for KO-2806 by the end of 2022.

- **Addition of industry veterans to board of directors** – Kura recently appointed Carol Schafer and Helen Collins, M.D. to its board of directors. Ms. Schafer brings more than 25 years of experience as a strategic and financial advisor to the

leadership teams of growing biopharmaceutical companies, most recently as Vice Chair of Equity Capital Markets at Wells Fargo Securities. Dr. Collins joins with more than 25 years of medical experience, most recently as Chief Medical Officer at Five Prime Therapeutics, where she was responsible for the strategy and execution of the company's clinical development plans until its acquisition by Amgen in April 2021.

Financial Results and Guidance

- Research and development expenses for the second quarter of 2021 were $21.1 million, compared to $13.7 million for the second quarter of 2020.
- General and administrative expenses for the second quarter of 2021 were $12.6 million, compared to $7.5 million for the second quarter of 2020.
- Net loss for the second quarter of 2021 was $33.7 million, compared to a net loss of $20.5 million for the second quarter of 2020. This included non-cash share-based compensation expense for the second quarter of 2021 of $6.0 million, compared to $2.6 million for the same period in 2020.
- Cash, cash equivalents and short-term investments totaled $567.5 million as of June 30, 2021, compared with $633.3 million as of December 31, 2020. The cash balance as of June 30 reflects the full repayment of the Company's debt facility.
- Operating expenses for the full year 2021 are expected to be in the range of $130 million to $140 million.
- Net cash used in operating activities for the full year 2021 is expected to be $105 million to $115 million.
- Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2024.

Upcoming Milestones

- Initiate the KURRENT Phase 1/2 study of tipifarnib in combination with alpelisib in the fourth quarter of 2021.
- Complete enrollment of 24 evaluable patients in the KOMET-001 Phase 1b expansion cohorts by the first quarter of 2022.
- Determine the recommended Phase 2 dose of KO-539 by the first quarter of 2022.
- Submit an IND application for KO-2806 by the end of 2022.

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 5, 2021, to discuss the financial results for the second quarter 2021 and provide a corporate update. The live call may be accessed by dialing (877) 516-3514 for domestic callers and (281) 973-6129 for international callers and entering the conference code: 3171857. 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. KO-539, a potent and selective menin inhibitor, is currently in a Phase 1/2 clinical trial (KOMET-001) and targeting patients with relapsed/refractory AML, including patients with NPM1 mutations or KMT2A rearrangements. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant HNSCC and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. In addition, Kura is pursuing the use of tipifarnib in combination with other oncology therapeutics to address larger genetic subsets of patients, including those who have HRAS- and/or PIK3CA-dependent HNSCC. The Company is also developing a next-generation farnesyl transferase inhibitor, which is intended to target innovative biology and larger oncology indications through rational combinations. For additional information about Kura, please visit the Company'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, tipifarnib, KO-539 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, 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,	
	2021	**2020**	**2021**	**2020**
Operating Expenses:				
Research and development	$ 21,074	$ 13,697	$ 41,398	$ 26,272
General and administrative	12,573	7,476	23,145	15,101
Total operating expenses	33,647	21,173	64,543	41,373
Other income (expense), net	(16)	686	186	1,676
Net loss	$ (33,663)	$ (20,487)	$ (64,357)	$ (39,697)
Net loss per share, basic and diluted	$ (0.51)	$ (0.40)	$ (0.97)	$ (0.82)
Weighted average number of shares used in computing net loss per share, basic and diluted	66,282	51,633	66,250	48,522

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

	June 30, 2021	**December 31, 2020**
Cash, cash equivalents and short-term investments	$ 567,494	$ 633,320
Working capital	552,342	611,268
Total assets	584,891	647,212
Long-term liabilities	5,050	10,283
Accumulated deficit	(366,859)	(302,502)
Stockholders’ equity	558,551	610,905

Contacts

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

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

Media:
Jason Spark
Managing Director
Canale Communications
(619) 849-6005

jason@canalecomm.com

Source: Kura Oncology, Inc.