# Kura Oncology Reports First Quarter 2021 Financial Results

May 6, 2021

– Menin inhibitor KO-539 continues to demonstrate compelling clinical activity, favorable safety/tolerability and a wide therapeutic window –

– KOMET-001 trial amended to include Phase 1b expansion cohorts enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients –

– Data from Phase 2 trial of tipifarnib in HRAS mutant head and neck squamous cell carcinoma highlighted in *Journal of Clinical Oncology* –

– $603.9 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, May 06, 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 first quarter 2021 financial results and provided a corporate update.

“We believe KO-539 is well-positioned as a potentially best-in-class and first-in-class menin inhibitor,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “This confidence is supported by a growing body of clinical data, including compelling activity, a favorable safety and tolerability profile and a wide therapeutic window. As such, we intend to conduct a comprehensive clinical development strategy for KO-539, both as a monotherapy and in combination, aimed at providing the greatest benefit to patients with acute leukemia, and we are well funded to execute on this strategy.”

“A critical component of our KO-539 development plan is the determination of an optimal Phase 2 dose,” continued Dr Wilson. “Given the wide therapeutic window of KO-539, we have amended our KOMET-001 trial to include two genetically enriched Phase 1b expansion cohorts. This should enable us to maximize the benefit-risk for KO-539 in our target patient populations and better inform an optimal dose for Phase 2 and beyond. Enrollment in these Phase 1b expansion cohorts is expected to begin mid-year, and we look forward to sharing our progress as we work to bring this important therapeutic option to patients.”

**Recent Highlights**

- **Enrollment in KOMET-001 Phase 1b expansion cohorts to begin shortly** – KO-539 continues to demonstrate a wide therapeutic window and compelling single-agent activity in an all-comer population of patients with relapsed or refractory acute myeloid leukemia (AML), including patients with NPM1 mutations and KMT2A rearrangements. In order to better inform an optimal Phase 2 dose, Kura has amended its KOMET-001 trial of KO-539 to include two Phase 1b expansion cohorts. Both cohorts will be enriched with NPM1-mutant and KMT2A-rearranged relapsed/refractory AML patients. The Company expects to enroll at least 12 patients in each of the Phase 1b expansion cohorts and assess those patients for safety and tolerability, pharmacokinetics/pharmacodynamics and efficacy in order to determine the recommended Phase 2 dose. In addition, the amended Phase 1b protocol gives the Company flexibility to enroll up to 18 additional patients per cohort, as appropriate. Kura believes the patients enrolled in the cohort selected as the recommended Phase 2 dose have the potential to be included in the subsequent, registration-directed portion of the KOMET-001 trial. Patient enrollment in the genetically enriched Phase 1b expansion cohorts is expected to begin at existing and new clinical sites in mid-2021.

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

- **Publication of tipifarnib Phase 2 data in *Journal of Clinical Oncology*** – Data from Kura’s Phase 2 clinical trial (RUN-HN) of tipifarnib were recently published in the *Journal of Clinical Oncology*. These data formed the basis of the Breakthrough Therapy Designation granted by the U.S. Food and Drug Administration (FDA) earlier this year for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC). Tipifarnib is currently being evaluated in an ongoing registration-directed clinical trial (AIM-HN) in this indication of high unmet need.

- **Breakthrough Device Designation for HRAS companion diagnostic** – The FDA has granted Breakthrough Device

Designation (BDD) to Illumina for a companion diagnostic to detect HRAS mutations in HNSCC in support of Kura's tipifarnib program, as the device provides for more effective treatment of a life-threatening disease. The next-generation sequencing-based companion diagnostic is being developed in collaboration with Illumina leveraging the content of TruSight Oncology 500. The BDD enables frequent interactions with the FDA and prioritized review on regulatory submissions.

**Financial Results**

- Research and development expenses for the first quarter of 2021 were $20.3 million, compared to $12.6 million for the first quarter of 2020.
- General and administrative expenses for the first quarter of 2021 were $10.6 million, compared to $7.6 million for the first quarter of 2020.
- Net loss for the first quarter of 2021 was $30.7 million, compared to a net loss of $19.2 million for the first quarter of 2020. This included non-cash share-based compensation expense of $5.1 million, compared to $3.2 million for the same period in 2020.
- Cash, cash equivalents and short-term investments totaled $603.9 million as of March 31, 2021, compared with $633.3 million as of December 31, 2020. Management expects that current cash, cash equivalents and short-term investments will be sufficient to fund current operations into 2024.

**Upcoming Milestones**

- Initiation of genetically enriched Phase 1b expansion cohorts in KOMET-001 in mid-2021
- Additional Phase 1 data from KOMET-001 in the second half of 2021
- Initiation of a Phase 1/2 proof-of-concept study of tipifarnib in combination with a PI3Kα inhibitor in the second half of 2021
- Nomination of a next-generation farnesyl transferase inhibitor Development Candidate in mid-2021

**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 6, 2021, to discuss the financial results for the first quarter 2021 and provide a corporate update. The live call may be accessed by dialing (888) 771-4371 for domestic callers and (847) 585-4405 for international callers and entering the conference code: 50156205. 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 acute myeloid leukemia, including patients with NPM1 mutations. Tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor, has received Breakthrough Therapy Designation for the treatment of patients with HRAS mutant head and neck squamous cell carcinoma and is currently in a registration-directed study (AIM-HN) in patients with this devastating disease. Kura 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 and KO-539, 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 March 31, | |
|---|---|---|
| | **2021** | **2020** |
| Operating Expenses: | | |
| Research and development | $ 20,324 | $ 12,575 |
| General and administrative | 10,572 | 7,625 |
| Total operating expenses | 30,896 | 20,200 |
| Other income, net | 202 | 990 |
| Net loss | $ (30,694) | $ (19,210) |
| Net loss per share, basic and diluted | $ (0.46) | $ (0.42) |
| Weighted average number of shares used in computing net loss per share, basic and diluted | 66,218 | 45,411 |

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

| | **March 31, 2021** | **December 31, 2020** |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 603,873 | $ 633,320 |
| Working capital | 585,566 | 611,268 |
| Total assets | 620,263 | 647,212 |
| Long-term liabilities | 9,137 | 10,283 |
| Accumulated deficit | (333,196) | (302,502) |
| Stockholders' equity | 585,987 | 610,905 |

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Source: Kura Oncology, Inc.