



Kura Oncology Reports Second Quarter 2023 Financial Results

August 3, 2023

- Enrollment in registration-directed trial of ziftomenib in NPM1-mutant AML continues to outperform projections –
 - First patients dosed in combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML –
 - Late-breaking clinical data for ziftomenib in NPM1-mutant AML presented at EHA –
- Continued evidence of clinical activity observed in trial of tipifarnib plus alpelisib in PIK3CA-dependent HNSCC –
 - First-in-human study of next-generation FTI KO-2806 to begin in second half of 2023 –
 - \$477 million in cash, equivalents and investments provide runway to mid-2026 –
 - Management to host webcast and conference call today at 4:30 p.m. ET –

SAN DIEGO, Aug. 03, 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 second quarter 2023 financial results and provided a corporate update.

"With its safety, tolerability and clinical activity profile, we believe ziftomenib has the ideal properties to become part of the backbone of acute myeloid leukemia (AML) therapy across the continuum of patient care," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Our confidence in the program is strengthened by the late-breaking clinical data presented at the European Hematology Association (EHA) Annual Congress in June, which showed one of the highest response rates reported for a targeted therapy in the setting of relapsed/refractory AML. Building on momentum generated by these data, enrollment in our Phase 2 registration-directed trial of ziftomenib in patients with relapsed/refractory NPM1-mutant AML continues to outperform our projections, an indication of both the size of this population and its significant unmet need. In addition, we are now treating NPM1-mutant and KMT2A-rearranged AML patients with ziftomenib in combination with chemotherapy- and venetoclax-based regimens, and we look forward to sharing preliminary data from this first combination study later this year or early next."

Recent Highlights

- **Late-breaking clinical data for ziftomenib in NPM1-mutant AML** – In June, Kura reported updated data from the KOMET-001 trial of ziftomenib, including durable activity in patients with heavily pretreated and co-mutated relapsed/refractory NPM1-mutant AML. The data were featured during a late-breaking oral session at the EHA Annual Congress in Frankfurt. As of an April 12th data cutoff, seven of the 20 patients with NPM1-mutant AML treated at the recommended Phase 2 dose (RP2D) of 600 mg achieved complete remission (CR) with full count recovery, for a CR rate of 35% and an overall response rate of 45%. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after stem cell transplant and remained on study as of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the cutoff date. The median duration of response for all NPM1-mutant patients was 8.2 months, with a median follow-up of 8.8 months. Continuous once-daily dosing of ziftomenib was well tolerated in the Phase 1 trial and the reported adverse event profile remained consistent with features of underlying disease.
- **Enrollment in registration-directed trial of ziftomenib continues to outperform projections** – Enrollment in Kura's Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML continues to outperform the Company's projections. The trial is expected to enroll a total of 85 patients in the U.S. and Europe, with a primary endpoint of CR or CR with partial hematologic recovery (CRh). 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.
- **Multiple patients dosed in combination study of ziftomenib in NPM1-mutant and KMT2A-rearranged AML** – Kura is conducting a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations. The Company is now dosing patients in the first of its combination studies, KOMET-007, in patients with NPM1-mutant and KMT2A-rearranged AML in the newly diagnosed and relapsed/refractory settings. KOMET-007 is a Phase 1 study designed to assess safety, tolerability and preliminary activity of ziftomenib in combination with venetoclax/azacitidine (ven/aza) or standard induction cytarabine/daunorubicin chemotherapy (7+3). Kura anticipates having preliminary data from the KOMET-007 study in the fourth quarter of 2023 or first quarter of 2024.

- Continued evidence of clinical activity observed with tipifarnib plus alpelisib in PIK3CA-dependent HNSCC –**
 Previously, Kura reported the first demonstration of a durable clinical response with the combination of its farnesyl transferase inhibitor (FTI) tipifarnib and the PI3K alpha inhibitor alpelisib in PIK3CA-mutant head and neck squamous cell carcinoma (HNSCC). In the meantime, dose escalation in the Company's KURRENT-HN trial of tipifarnib and alpelisib has continued, with ongoing evidence of clinical activity at multiple doses and no dose-limiting toxicities to date. Kura is now evaluating patients in the trial's highest planned dose cohort to inform selection of the optimal biologically active dose for the combination, after which the Company intends to initiate a small dose expansion of patients with PIK3CA-mutant HNSCC to validate the safety profile and activity of the combination at the RP2D. Head and neck cancer is the seventh most common cancer worldwide and remains a significant unmet need, with no approved small molecule targeted therapies.
- First-in-human study of KO-2806 to begin in second half of 2023 –** KO-2806 is a next-generation inhibitor of farnesyl transferase designed to improve upon potency, pharmacokinetic and physicochemical properties of earlier FTI drug candidates. Earlier this year, Kura received FDA clearance of its Investigational New Drug application for KO-2806. Site activation has now begun in a Phase 1 dose-escalation trial of KO-2806 (FIT-001) and the Company expects to dose the first patients 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, beginning with clear cell renal cell carcinoma (ccRCC).

Financial Results

- Research and development expenses for the second quarter of 2023 were \$28.2 million, compared to \$24.3 million for the second quarter of 2022.
- General and administrative expenses for the second quarter of 2023 were \$11.8 million, compared to \$11.1 million for the second quarter of 2022.
- Net loss for the second quarter of 2023 was \$37.2 million, compared to a net loss of \$34.8 million for the second quarter of 2022. This includes non-cash share-based compensation expense of \$7.0 million, compared to \$6.5 million for the same period in 2022.
- As of June 30, 2023, Kura had cash, cash equivalents and short-term investments of \$477.0 million, compared to \$438.0 million as of December 31, 2022. This includes net proceeds of approximately \$93.6 million from the Company's public offering completed in June 2023.
- Based on its operating plan, management expects that cash, cash equivalents and short-term investments will fund current operations to mid-2026.

Forecasted Milestones

- Dose the first patients in the KOMET-008 trial of ziftomenib in combination with additional standards of care, including the FLT3 inhibitor gilteritinib, in the second half of 2023.
- Preliminary data from the KOMET-007 trial of ziftomenib in combination with ven/aza or 7+3 in the fourth quarter of 2023 or first quarter of 2024.
- Dose the first patients in the ziftomenib post-transplant maintenance program in the first quarter of 2024.
- Initiate dose expansion in the KURRENT-HN trial of tipifarnib and alpelisib in mid-2024.
- Dose the first patients in the FIT-001 monotherapy dose-escalation trial of KO-2806 as a monotherapy in the second half of 2023.
- Dose the first patients in the FIT-001 dose-escalation trial of KO-2806 in combination with a targeted therapy in ccRCC in the second half of 2024.

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 3, 2023, to discuss the financial results for the second 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: 26884460. 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. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with venetoclax/azacitidine and standard induction cytarabine/daunorubicin chemotherapy in NPM1-mutant and KMT2A-rearranged newly diagnosed and relapsed/refractory AML (KOMET-007). Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial in combination with apelisib for patients with PIK3CA-dependent HNSCC (KURRENT-HN). Kura is also preparing to evaluate KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with other targeted therapies, beginning with ccRCC (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on [Twitter](#) 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, 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 mid-2026. 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development	\$ 28,182	\$ 24,258	\$ 53,374	\$ 45,171
General and administrative	11,821	11,075	23,195	22,944
Total operating expenses	40,003	35,333	76,569	68,115
Other income, net	2,829	564	5,326	893
Net loss	\$ (37,174)	\$ (34,769)	\$ (71,243)	\$ (67,222)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.52)	\$ (1.03)	\$ (1.01)
Weighted average number of shares used in computing net loss per share, basic and diluted	69,795	66,672	69,103	66,639

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	\$ 476,979	\$ 437,985
Working capital	461,747	422,369
Total assets	494,737	456,306
Long-term liabilities	11,160	11,971
Accumulated deficit	(640,051)	(568,808)
Stockholders' equity	459,678	420,278

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Source: Kura Oncology, Inc.