Kura Oncology Reports Positive Preliminary Ziftomenib Combination Data in Acute Myeloid Leukemia

January 30, 2024

– No differentiation syndrome events reported –

– 100% CR rate with 7+3 in newly diagnosed NPM1-m and KMT2A-r AML –

– 56% CR/CRh with ven/aza in menin inhibitor naïve patients with R/R AML –

– 80% of patients remain on trial as of data cutoff, including all NPM1-m patients –

– 200 mg dose of ziftomenib cleared in ven/aza cohorts, enrollment at 400 mg dose ongoing –

– Management to host virtual investor event today at 8:00 a.m. ET –

SAN DIEGO, Jan. 30, 2024 (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 preliminary clinical data from the first 20 patients in KOMET-007, a Phase 1 dose-escalation trial of the Company's potent and selective menin inhibitor, ziftomenib, in combination with standards of care, including cytarabine/daunorubicin (7+3) and venetoclax/azacitidine (ven/aza), in patients with NPM1-mutant (NPM1-m) and KMT2A-rearranged (KMT2A-r) acute myeloid leukemia (AML).

The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk[1] NPM1-m or KMT2A-r AML and 15 patients with refractory/relapsed (R/R) NPM1-m or KMT2A-r AML.

Continuous daily dosing of ziftomenib at 200 mg QD has been well tolerated and the safety profile consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed.

As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a complete remission (CR) with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-m AML and one patient with KMT2A-r AML.

The overall response rate (ORR) among R/R patients treated with ziftomenib and ven/aza was 53% (8/15). Among all patients treated with ziftomenib and ven/aza, 40% (6/15) received prior treatment with a menin inhibitor. The CR/CRh[2] rate in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-m AML and 50% (2/4) in patients with KMT2A-r AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-m AML.

As of the data cutoff, 80% (16/20) of patients remain on trial, including 100% (11/11) of all NPM1-m patients.

"Ziftomenib is one of the most exciting investigational agents being studied in AML, and I am thrilled to see the rapid pace of accrual into this first-in-human combinational study," said Amer Zeidan, MBBS, MHS, interim chief of the Division of Hematologic Malignancies, Director of Hematology Early Therapeutics Research at Yale Cancer Center and lead investigator of the KOMET-007 trial. "In this first public release of early data from the KOMET-007 trial, ziftomenib demonstrates an encouraging safety and tolerability profile in combination with 7+3 and ven/aza, enabling continuous administration while mitigating the risk of differentiation syndrome. The combinations demonstrate encouraging preliminary evidence of clinical activity in patients with refractory/relapsed disease after failure of other agents, including venetoclax, a setting with very limited effective treatment options. Further, the fact that most patients remain on study as of the data cutoff is notable in such difficult-to-treat patient populations."

The 200 mg dose of ziftomenib has been cleared in the R/R ven/aza cohorts and enrollment at the 400 mg dose is ongoing. Upon determination of a recommended Phase 2 dose, Kura plans to initiate a Phase 1b dose validation/expansion in combination with ven/aza in newly diagnosed patients with NPM1-m (without adverse risk) or KMT2A-r AML.

"We are highly encouraged by these preliminary combination data for ziftomenib and believe they support advancement into the frontline AML population," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Given that ziftomenib targets foundational mutations at the core of up to 50% of AML cases, we are encouraged by its potential to transform treatment outcomes across the continuum of care. We continue to see strong investigator enthusiasm as evidenced by rapid enrollment across studies, and we expect to complete enrollment of all 85 patients in KOMET-001, our Phase 2 registration-directed trial of ziftomenib in patients with R/R NPM1-m AML, by the middle of this year. With the recently announced financing, we remain in a strong financial position with cash runway expected into 2027, which enables us to invest aggressively in research, development and pre-commercial activities to maximize value of ziftomenib and other pipeline assets."

Virtual Investor Event

Kura will host a virtual investor event featuring company management and investigators from the KOMET-007 trial of ziftomenib today at 8:00 a.m. ET. The live call may be accessed by dialing (800) 715-9871 for domestic callers and (646) 307-1963 for international callers and entering the conference ID: 7854712. A live webcast will be available here and in the Investors section of Kura's website, with an archived replay available shortly after the event.

About Acute Myeloid Leukemia

AML is the most common acute leukemia in adults and begins when the bone marrow makes abnormal myeloblasts (white blood cells), red blood cells or platelets. Despite the many available treatments for AML, prognosis for patients remains poor and a high unmet need remains. The menin pathway is considered a driver for multiple genetic alterations of the disease, of which NPM1-mutations are among the most common, representing approximately 30% of AML cases and KMT2A-rearrangements represent approximately 5-10% of AML cases. While patients with NPM1-m AML have high response rates to frontline therapy, relapse rates are high and survival outcomes are poor, with only 30% overall survival at 12 months in the R/R setting. Additionally, NPM1 mutations frequently occur with co-mutations in other disease-associated genes, including FLT3, DNMT3A and IDH1/2, with prognosis heavily influenced by the occurrence of co-occurring mutations. Adult patients with NPM1-m AML and select co-mutations and/or R/R disease have a poor prognosis, with median overall survival of only approximately 7.8 months in 2nd line, 5 months in 3rd line and 3.5 months following the 4th line[3]. Adult patients with KMT2A-r AML have a poor prognosis with high rates of resistance and relapse following standard of care, with median overall survival for this patient population of only 6 months following 2nd line and 2.4 months following 3rd line[4]. No FDA-approved therapies targeting NPM1-m and KMT2A-r AML currently exist.

About Ziftomenib

Ziftomenib is a novel, once-daily, oral investigational drug candidate targeting the menin-KMT2A/MLL protein-protein interaction for treatment of genetically defined AML patients with high unmet need. In preclinical models, ziftomenib inhibits the KMT2A/MLL protein complex and exhibits downstream effects on HOXA9/MEIS1 expression and potent anti-leukemic activity in genetically defined preclinical models of AML. Ziftomenib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML. Additional information about clinical trials for ziftomenib can be found at kuraoncology.com/clinical-trials/#ziftomenib.

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-m R/R AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with ven/aza and 7+3 in NPM1-m and KMT2A-r newly diagnosed and R/R AML (KOMET-007). Tipifarnib, a potent and selective farnesyl transferase inhibitor (FTI), is currently in a Phase 1/2 trial in combination with alpelisib for patients with PIK3CA-dependent head and neck squamous cell carcinoma (KURRENT-HN). Kura is also evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with cabozantinib in clear cell renal cell carcinoma and adagrasib in $KRAS^{G12C}$-mutated non-small cell lung cancer (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on X 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 ziftomenib, potential benefits of combining ziftomenib with appropriate standards of care, plans regarding future clinical trials in the ziftomenib program, plans and expected timing for enrollment in the Phase 2 registration-directed trial of ziftomenib, and the Company's cash runway. 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, risks associated with Kura's cash needs, 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 (SEC), including the Company's Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 2, 2023, 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.

Amer Zeidan has consulted and received honoraria from Kura. Opinions expressed are his own and do not necessarily represent those of his employer.

Contacts

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

Media:
Alexandra Weingarten
Associate Director, Investor Relations &
Corporate Communications
(858) 500-8822
alexandra@kuraoncology.com

[1] Age > 60 years and/or treatment-related AML and/or adverse risk cytogenetics per European LeukemiaNet (ELN)
[2] CR with partial hematologic recovery
[3] Issa G, et al. Blood Adv 2023;7(6):933-42.
[4] Issa GC, et al. Blood Cancer J. 2021;11(9):162.

Source: Kura Oncology, Inc.