



Kura Oncology and Kyowa Kirin Report Positive Combination Data for Ziftomenib at American Society of Hematology Annual Meeting

December 9, 2024

– Interim analysis from Phase 1a portion of KOMET-007 shows 100% CR rate in NPM1-m and 83% CR rate in KMT2A-r 1L adverse risk AML with 7+3

– 100% of 1L NPM1-m and 96% of 1L KMT2A-r AML patients alive as of data cutoff with median follow-up of 31 and 19 weeks, respectively –

– Promising clinical activity in R/R NPM1-m and KMT2A-r AML with ven/aza, including ven-experienced patients –

– Ziftomenib generally well tolerated in combination with standards of care at all dose levels studied –

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

SAN DIEGO and TOKYO, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") provided encouraging clinical data from KOMET-007, a Phase 1 dose-escalation trial of ziftomenib, a highly selective oral investigational menin inhibitor, 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).

These data were presented at the 2024 American Society of Hematology (ASH) Annual Meeting. An oral presentation highlighting ziftomenib combined with 7+3 in newly diagnosed (1L) NPM1-m and KMT2A-r adverse risk¹ AML, and a poster featuring ziftomenib in combination with ven/aza in relapsed/refractory (R/R) NPM1-m and KMT2A-r AML are available in the [Posters and Presentations](#) section on Kura's website.

Ziftomenib was generally well tolerated in combination at all dose levels evaluated across all cohorts in the Phase 1a dose-escalation portion of the study. No dose-limiting toxicities, evidence of ziftomenib-associated QTc prolongation, drug-drug interactions or additive myelosuppression were observed. In the 7+3 combination cohorts, on-target differentiation syndrome (DS) occurred in 2% (1/51) of patients. Grade ≥3 treatment emergent adverse events occurring in ≥20% were febrile neutropenia platelet count decreased, anemia and neutropenia count decrease and white blood cell count decreased. In the ven/aza combination cohorts, on-target DS occurred in 8% (4/53) of patients. Grade ≥3 treatment emergent adverse events occurring in ≥20% were platelet count decreased, anemia and febrile neutropenia. All instances of DS were manageable, and no patients discontinued participation due to DS. The Phase 1b expansion portion of KOMET-007 is now enrolling at 600 mg in all cohorts, including patients with 1L NPM1-m or KMT2A-r AML in combination with ven/aza.

Among the response-evaluable patients enrolled in the 7+3 combination cohort for patients with 1L NPM1-m or KMT2A-r adverse risk¹ AML, 91% (42/46) achieved a complete remission (CR) (100% for NPM1-m, 83% for KMT2A-r patients). MRD negativity was 76% in NPM1-m and 75% in KMT2A-r patients. All NPM1-m patients (24/24) and 96% (26/27) of KMT2A-r patients remained alive as of the data cutoff on October 1, 2024, with a median follow-up of 31 and 19 weeks, respectively.

A total of 54 patients were enrolled in the combination cohort with ven/aza in R/R NPM1-m or KMT2A-r AML. The NPM1-m population achieved an overall response rate (ORR) of 68% (15/22) and a composite complete remission (CRc) rate of 50% (11/22). In NPM1-m patients with previous ven exposure, ORR was 50% (7/14) and CRc was 36% (5/14). In KMT2A-r patients, 30% of patients responded, including those with prior ven exposure.

"The findings presented at ASH underscore the potential of ziftomenib in combination with standards of care as an early intervention in the frontline setting of AML and could offer a meaningful opportunity to improve patient outcomes," said Amer Zeidan, MBBS, MHS, 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. "The high rates of complete remission and MRD negativity across the 7+3 cohorts are particularly encouraging. The rapid enrollment in the Phase 1a portion of this study underscores the urgency and enthusiasm for further evaluating this combination approach."

Kura and Kyowa Kirin recently announced plans for KOMET-017, a global, pivotal Phase 3 study evaluating ziftomenib in combination with standards of care for adults with newly diagnosed KMT2A-r or NPM1-m AML. The trial includes two independently powered, randomized, double-blind, placebo-controlled studies: a non-intensive therapy arm testing ziftomenib with ven/aza, and an intensive therapy arm testing ziftomenib with 7+3. The positive results from KOMET-007 reported at ASH reinforce Kura's and Kyowa Kirin's commitment to evaluating ziftomenib for patients across the continuum of frontline treatment options. The KOMET-017 study is expected to initiate in mid-2025.

"Starting patients on therapy early is essential to improving outcomes in AML," said Mollie Leoni, M.D., Executive Vice President, Clinical Development at Kura Oncology. "The updated KOMET-007 data underscore the combination potential of ziftomenib in the frontline setting, strengthening our confidence in its ability to provide a valuable treatment option for a significant portion of the AML population. Together, the KOMET-007 Phase 1b trial and the KOMET-017 pivotal Phase 3 study will allow us to further explore this approach and the potential to transform care if approved for AML patients worldwide."

"More than half of AML patients with an NPM1 mutation will relapse with poor survival outcomesⁱⁱ, making it a significant area of unmet medical need in the frontline setting," said Takeyoshi Yamashita, Ph.D., Senior Managing Executive Officer and Chief Medical Officer of Kyowa Kirin. "The data observed to date represent the potential of ziftomenib to help address the treatment gap and improve upon current standards of care. Leveraging our hemato-oncology expertise and commitment to patients, we are committed to rapidly advancing the clinical development of ziftomenib."

Virtual Investor Event

Kura will host a webcast and conference call featuring Kura Oncology management and Key Opinion Leaders Amir T. Fathi, MD, Associate Professor of Medicine at Harvard Medical School and Director of the Leukemia Program at Massachusetts General Cancer Center, and Amer Zeidan, MBBS, MHS, interim chief of the Division of Hematologic Malignancies, Director of Hematology Early Therapeutics Research at Yale Cancer Center. 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: 4326549. 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 Ziftomenib

Ziftomenib is a selective and oral menin inhibitor currently in development for the treatment of genetically defined AML patients with high unmet need. In April 2024, ziftomenib received Breakthrough Therapy Designation (BTD) by the FDA for the treatment of R/R NPM1-mutant AML based on data from Kura's ongoing KOMET-001 clinical trial. 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 being investigated as a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction, has received BTD for the treatment of R/R NPM1-mutant AML. Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-mutant AML (KOMET-001). The Company is also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R NPM1-mutant and KMT2A-rearranged AML. Kura is evaluating KO-2806, a next-generation farnesyl transferase inhibitor (FTI), in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies (FIT-001). Tipifarnib, a potent and selective 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). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on [X](#) and [LinkedIn](#).

About Kyowa Kirin

Kyowa Kirin aims to discover and deliver novel medicines and treatments with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, Kyowa Kirin has invested in drug discovery and biotechnology innovation for more than 70 years and is currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients with high unmet medical needs, such as bone & mineral, intractable hematological diseases/hemato-oncology and rare diseases. A shared commitment to Kyowa Kirin's values, to sustainable growth, and to making people smile unites Kyowa Kirin across the globe. You can learn more about the business of Kyowa Kirin at www.kyowakirin.com.

Kura 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 pursuit of a broad ziftomenib development program including frontline indications and combinations with targeted therapies; the efficacy, safety and therapeutic potential of ziftomenib; potential benefits of combining ziftomenib with appropriate standards of care, including chemotherapies; and progress and expected timing of the ziftomenib program and clinical trials, including the timing of initiation of the pivotal Phase 3 frontline study. 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, the risk that the collaboration with Kyowa Kirin is unsuccessful, 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, 2024 filed with the SEC on November 7, 2024, 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.

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ⁱ Age ≥ 60 years and/or treatment-related AML and/or adverse risk cytogenetics per European LeukemiaNet (ELN)

ⁱⁱ Prata PH, Bally C, Prebet T, et al. NPM1 mutation is not associated with prolonged complete remission in acute myeloid leukemia patients treated with hypomethylating agents. *Haematologica*. 2018;103(10):e455-e457.



Source: Kura Oncology, Inc.