



Kura Oncology and Kyowa Kirin Announce Global Strategic Collaboration to Develop and Commercialize Ziftomenib in Acute Leukemias

November 20, 2024

- Kura to receive a \$330 million upfront payment and up to \$1.2 billion in total milestone payments, including \$420 million in near-term milestone payments and opt-in right for solid tumors –
- Companies to jointly develop and commercialize ziftomenib; 50/50 profit share in the U.S.; Kura to lead U.S. development and commercial activities and book sales; Kyowa Kirin has exclusive commercialization rights outside the U.S. –
- Companies to jointly pursue broad development program targeting acute leukemias, including frontline indications, combinations with targeted therapies and post-transplant maintenance setting –
- Kura anticipates collaboration funding along with current cash balance to support AML program advances through commercialization in frontline combination therapy –

SAN DIEGO and TOKYO, Nov. 20, 2024 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd. (TSE: 4151) today announced they have entered into a global strategic collaboration to develop and commercialize ziftomenib, Kura's selective oral menin inhibitor, being investigated for the treatment of patients with acute myeloid leukemia (AML) and other hematologic malignancies.

Under the terms of the agreement, Kura will receive an upfront payment of \$330 million and expects to receive up to \$420 million in near-term milestone payments, including a payment upon the launch of ziftomenib in the monotherapy relapsed/refractory (R/R) setting. In addition, Kura is eligible to receive additional development, regulatory and commercial milestone payments of \$741 million, totaling up to \$1.161 billion in payments for milestones and the opt-in for solid tumor indications.

In the U.S., Kura will lead development, regulatory and commercial strategy and be responsible for manufacturing ziftomenib. The companies will jointly perform commercialization activities in accordance with a co-created U.S. territory commercialization plan and will share equally in any potential profits and losses.

Outside the U.S., Kyowa Kirin will lead development, regulatory and commercial strategy and is responsible for commercializing ziftomenib. Kura will be eligible to receive tiered double-digit royalties on net product sales.

As a Japan based global specialty pharmaceutical company, Kyowa Kirin aims to create treatments with life-changing value that bring smiles to people living with disease. The company will leverage its hemato-oncology experience and capabilities, and its deep commitment to partnerships, to successfully bring ziftomenib to market globally.

"We believe that ziftomenib is a very promising investigational treatment for genetically defined AML patients," said Yasuo Fujii, MBA, Chief Strategy Officer, Managing Executive Officer of Kyowa Kirin. "The addition of ziftomenib will complement Kyowa Kirin's existing hemato-oncology portfolio and pipeline and expand our clinical development efforts into combination therapies designed to generate improved outcomes for cancer patients. We look forward to collaborating closely with the team at Kura and adding ziftomenib to our portfolio of oncology candidates as part of our commitment to bringing new, advanced treatment options to patients and the clinical community around the world."

Ziftomenib is the first and only investigational therapy to receive breakthrough designation from the U.S. Food and Drug Administration (FDA) for the treatment of R/R NPM1-mutant AML, a mutation that is associated with poor outcomes^{i,ii,iii}. Enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-mutant AML has been completed and the companies anticipate submission of a New Drug Application (NDA) in 2025. Kura 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 expects to initiate registrational Phase 3 frontline studies in both the fit and unfit frontline AML patient populations in 2025.

"This collaboration is an important step toward fulfilling Kura's commitment to realizing the promise of precision medicines for the treatment of cancer, and it substantially advances our goal of building a sustainable, fully integrated biopharmaceutical company," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Kyowa Kirin is a wonderful partner for Kura, bringing the expertise and scale of a global pharmaceutical company. On behalf of our leadership team and board of directors, we are thrilled to be working with Kyowa Kirin to realize the potential of ziftomenib as a transformational therapy for AML patients."

"Importantly," Dr. Wilson continued, "we believe the upfront and anticipated milestone payments from this collaboration combined with our current cash position should provide sufficient funding to support the ziftomenib program to commercialization in the frontline setting, which we believe is a market opportunity of up to \$3 billion annually in the U.S. alone."

Additional Details About the Collaboration

Following regulatory approval, Kura will book sales and take the lead role in U.S. commercial strategy development and both parties will share in commercialization activities. Profits and losses from the commercialization activities will be shared equally in the U.S. Outside the U.S., Kyowa Kirin will lead and perform commercialization activities, book sales and be responsible for the conduct and funding of commercialization of ziftomenib, and Kura is eligible to receive tiered double-digit royalties on net product sales.

As part of the strategic collaboration, the companies will share responsibility for the conduct of clinical trials delineated within an agreed-upon global development plan. For the global development plan, Kura will fund the development costs until the end of 2028, and from 2029 onwards, both companies will share the costs at a 50:50 ratio. The companies will share equally the funding of future trials in the U.S. The agreement includes plans to launch multiple Phase 2 and Phase 3 studies of ziftomenib in AML and other hematologic malignancies over the next several years. Development and commercialization activities under the collaboration will be managed through a shared governance structure.

Under the Agreement, Kyowa Kirin has an option to participate in the development and commercialization of ziftomenib in gastrointestinal stromal tumors (GIST) and other solid tumor indications upon opt-in after receipt of clinical data from the ongoing proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST not successfully treated with imatinib. If Kyowa Kirin exercises its option, Kura is eligible for upfront and milestone payments totaling \$228 million and the parties' roles and responsibilities follow the same structure as the collaboration in AML and other heme malignancies. Excluded from the collaboration are Kura's ongoing efforts to advance multiple, next-generation menin inhibitor drug candidates targeting certain oncology indications, as well as diabetes and other metabolic diseases.

Kura was advised in the transaction by BofA Securities and represented by Cooley LLP.

Conference Call

Kura will host a webcast and conference call featuring management from both companies at 5:30 pm ET today, November 20, 2024. 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: 6978447. 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, 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/hematology 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, Kura's potential receipt of milestone payments and tiered double-digit royalties under the collaboration; the pursuit of a broad ziftomenib development program including frontline indications, combinations with targeted therapies and post-transplant maintenance setting; Kura's ability to fund its AML program to commercialization in frontline combinations through the collaboration plus its current cash balance; the efficacy, safety and therapeutic potential of ziftomenib, potential benefits of combining ziftomenib with appropriate standards of care, and progress and expected timing of the ziftomenib program and clinical trials, including the timing of submission of an NDA and initiation of registrational Phase 3 frontline studies; the market opportunity of ziftomenib in the frontline setting; plans to launch multiple Phase 2 and Phase 3 studies of ziftomenib in AML and other hematologic malignancies over the next several years; and Kura's potential receipt of additional upfront and milestone payments if KKC exercises its option. 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 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.

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ⁱ Burrows F et al. Poster presented at: AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics: Discovery, Biology, and Clinical Applications; October 26-30, 2017; Philadelphia, PA

ⁱⁱ Issa GC et al. Blood Adv. 2023;7(6):933-942. doi:10.1182/bloodadvances.2022008316

ⁱⁱⁱ Ostronoff F et al. J Clin Oncol. 2015;33(10):1157-1164. doi:10.1200/JCO.2014.58.0571



Source: Kura Oncology, Inc.