Kura Oncology and Kyowa Kirin Announce FDA Acceptance and Priority Review of New Drug Application for Ziftomenib in Adults with Relapsed or Refractory *NPM1*-Mutant AML

– New Drug Application based on positive results from the Phase 2 KOMET-001 trial –

– FDA assigns a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2025 –

– Potential first approval of a menin inhibitor for the treatment of adult patients with relapsed or refractory AML with an *NPM1* mutation –

SAN DIEGO and TOKYO, June 1 and 2, 2025 -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced the U.S. Food and Drug Administration (FDA) has accepted Kura's New Drug Application (NDA) seeking full approval for ziftomenib as a treatment for adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a *nucleophosmin 1* (*NPM1*) mutation. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2025.

"The FDA's acceptance of our New Drug Application marks a significant milestone for Kura and Kyowa Kirin and, more importantly, for patients living with this genetic subset of AML, who face an aggressive form of the disease with few treatment options," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "This achievement reflects the strength of the clinical data for ziftomenib as well as the incredible commitment of our teams. Along with our partners at Kyowa Kirin, we look forward to continuing to work closely with the FDA throughout the review process and to prepare for the anticipated launch of this treatment, which holds potential to meaningfully impact the lives of patients and their families."

The NDA is based on results from the Phase 2 KOMET-001 registrational trial in R/R *NPM1*-mutant (*NPM1*-m) AML (NCT #04067336). The KOMET-001 trial achieved its primary endpoint of complete remission (CR) plus CR with partial hematological recovery (CRh) and the primary endpoint was statistically significant. Ziftomenib was well-tolerated with limited myelosuppression and 3% ziftomenib-related discontinuations. The safety and tolerability of ziftomenib were consistent with previous reports, and the benefit-risk profile for ziftomenib is highly encouraging.

“Adult R/R *NPM1*-m AML patients face a significantly poor prognosis, highlighting the urgent need for innovative treatment options that can improve their outcomes,” said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. “The acceptance of this NDA is a crucial step in our ongoing efforts to explore and evaluate various therapeutic strategies for AML through our comprehensive clinical trials. Our dedicated teams at Kyowa Kirin and Kura are fully committed to working tirelessly to ensure that, once approved, ziftomenib is made available to AML patients as quickly as possible. We recognize the importance of this endeavor and are excited about the possibility of making a meaningful impact on the lives of those affected by this challenging disease.”

The KOMET-001 registration-directed trial is designed to assess evidence of clinical activity, safety and tolerability of ziftomenib, the only investigational therapy to receive Breakthrough Therapy Designation (BTD) from the FDA for treatment of R/R *NPM1*-mutant AML. In addition to BTD, ziftomenib has received Fast Track and Orphan Drug Designations. The full data analyses from the KOMET-001 trial of ziftomenib in R/R *NPM1*-m AML patients have been selected for oral presentation on Monday, June 2nd at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, and an encore presentation is planned at the 2025 European Hematology Association (EHA) Congress.

About *NPM1*-Mutant AML

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. 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 presence of such 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, 5.3 months in 3rd line, and 3.5 months following the 4th line[1]. There are currently no FDA-approved therapies targeting *NPM1*-m AML.

About Ziftomenib

Ziftomenib is a potent and selective, oral, investigational menin inhibitor currently in development for the treatment of genetically defined AML patients with high unmet need. In April 2024, ziftomenib received BTD from the FDA for the treatment of adult patients with R/R AML with an *NPM1* mutation based on data from Kura’s KOMET-001 clinical trial. Additional information about clinical trials for ziftomenib can be found at www.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 designed to target cancer signaling pathways. In November 2024, Kura Oncology entered into a global strategic collaboration agreement with Kyowa Kirin to develop and commercialize ziftomenib, a menin inhibitor, for AML and other hematologic malignancies. Enrollment in KOMET-001, a Phase 2 registration-directed trial of ziftomenib in R/R *NPM1*-m AML, has been completed, and in the second quarter of 2025, the companies announced submission of an NDA for ziftomenib for the treatment of adult patients with R/R *NPM1*-m AML. Kura and Kyowa Kirin are conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R *NPM1*-m and *KMT2A*-rearranged AML. KO-2806, a next-generation farnesyl transferase inhibitor (FTI), is being evaluated in a Phase 1 dose-escalation trial (FIT-001) as a monotherapy and in combination with targeted therapies for patients with various solid tumors. Tipifarnib, a potent and selective FTI, is currently in a Phase 1/2 trial (KURRENT-HN) in combination with alpelisib for patients with *PIK3CA*-dependent head and neck squamous cell carcinoma. For additional information, please visit Kura's website at https://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.

[1] Issa G, et al. Blood Adv 2023;7(6):933-42.