Kura Oncology and Kyowa Kirin Announce FDA Approval of KOMZIFTI™ (ziftomenib), the First and Only Once-Daily Targeted Therapy for Adults with Relapsed or Refractory *NPM1*-Mutated Acute Myeloid Leukemia

– *NPM1* mutations, one of the most common genetic drivers of AML, are now actionable for patients –

– Acute unmet need in R/R *NPM1*-mutated AML defined by historically poor outcomes and low survival rates at relapse –

– FDA grants full approval of KOMZIFTI ahead of PDUFA target action date –

– Approval is based on the KOMET-001 trial, in which KOMZIFTI demonstrated deep responses, a potentially best-in-class safety profile, once-daily administration, and ease of co-administration with common supportive medications in adult patients with R/R *NPM1*-mutated AML –

– KOMZIFTI approval granted with no Boxed Warning related to QTc prolongation or Torsades de Pointes –

SAN DIEGO and TOKYO, November 13 and 14, 2025 – Kura Oncology, Inc. (Nasdaq: KURA) and Kyowa Kirin Co., Ltd. (TSE: 4151) today announced the U.S. Food and Drug Administration (FDA) has granted full approval of KOMZIFTI™ (ziftomenib) for adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options. KOMZIFTI is the first and only once-daily, oral menin inhibitor approved for R/R *NPM1*-mutated (*NPM1*-m) AML, a devastating blood cancer with limited treatment options.

“KOMZIFTI combines compelling efficacy, a favorable safety profile, compatibility with concomitant medications, and convenient once-daily oral administration in a population with few effective treatment options. These features highlight KOMZIFTI’s potential to serve as the menin inhibitor of choice in its approved indication,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “Together with our partner, Kyowa Kirin, we remain committed to advancing development of KOMZIFTI across the treatment continuum for AML, where its best-in-class profile offers potential for even greater impact in combination regimens and earlier lines of therapy. We are

fully prepared to launch KOMZIFTI today and deliver this new medicine to patients in need."

NPM1 mutations are among the most common founder mutations in AML, occurring in approximately 30% of cases. Historically, approximately 20% of patients with *NPM1*-m AML do not respond to front-line therapy. Of those who do respond, 70% will relapse within 3 years, most within 12 months. Early relapse and declining survival with each recurrence underscore the urgent need for treatment approaches that deliver lasting remission.

Approval is supported by the pivotal KOMET-001 trial (NCT04067336), which evaluated KOMZIFTI's safety and efficacy in 112 R/R *NPM1*-m AML patients. The rate of complete remission (CR) plus CR with partial hematologic recovery (CRh) was 21.4% (95% CI: 14.2, 30.2). The median duration of CR+CRh was 5.0 months (95% CI: 1.9, 8.1) and the median time to first response in patients who achieved a CR or CRh was 2.7 months (range: 0.9 to 15 months). 88% of patients who achieved CR or CRh did so within 6 months of initiating KOMZIFTI. These data from the Prescribing Information are generally consistent with findings recently published in the *Journal of Clinical Oncology.*[1]

"KOMZIFTI addresses a critical need for adult patients with R/R *NPM1*-m AML, many of whom are older and unable to tolerate intensive chemotherapy or transplant," said Eunice Wang, M.D., Chief of the Leukemia Service and Professor of Oncology at Roswell Park Comprehensive Cancer Center. "The clinical data demonstrate deep and durable responses with a manageable safety profile, including no drug-drug interactions and no Boxed Warnings for QTc prolongation or Torsades de Pointes – key advantages for patients on multiple concurrent medications. This approval equips physicians with a new oral therapy to integrate into care and improve outcomes for this vulnerable patient population."

The most common adverse reactions (≥20%), including laboratory abnormalities, were aspartate aminotransferase increased, infection without an identified pathogen, potassium decreased, albumin decreased, alanine aminotransferase increased, sodium decreased, creatinine increased, alkaline phosphatase increased, hemorrhage, diarrhea, nausea, fatigue, edema, bacterial infection, musculoskeletal pain, bilirubin increased, potassium increased, differentiation syndrome, pruritus, febrile neutropenia, and transaminases increased. KOMZIFTI includes a Boxed Warning for differentiation syndrome, a well-studied mechanism-based risk in drugs that restore differentiation. Absence of clinically meaningful drug-drug interactions can ease the use of KOMZIFTI with concomitant therapies, including those that cause QTc interval prolongation. QTc interval prolongation was ≤ Grade 3 in 12% of patients and no Grade 4 or Grade 5 QTc

interval prolongation was reported. QTc interval prolongation of any cause occurred in 10% of the 70 patients 65 years of age or older.

“The approval of KOMZIFTI underscores our commitment to advancing precision medicines to address the genetic drivers of disease in hematology and oncology,” said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. “In AML, where many patients face severe disease progression and limited treatment options, the evolution toward targeted therapies such as KOMZIFTI represents a major step forward and offers potential to transform existing standards of care. We are proud to partner with Kura Oncology in bringing this important therapy to patients and their families.”

In November 2024, Kura Oncology and Kyowa Kirin entered into a global strategic collaboration to develop and commercialize KOMZIFTI. The collaboration builds on Kyowa Kirin’s leadership and expertise in hematologic malignancies. Under the terms of the collaboration, Kura leads development, regulatory and commercial strategy in the U.S. and is responsible for manufacturing KOMZIFTI. The companies will jointly perform certain commercialization activities in accordance with a co-created U.S. territory commercialization plan. Outside the U.S., Kyowa Kirin leads development, regulatory and commercial strategy and is responsible for commercializing KOMZIFTI.

1. Wang *et al.* 2025 *J Clin Oncol*: JCO2501694, online ahead of print. Reprint available here.

About KOMZIFTI™
KOMZIFTI (ziftomenib) is an oral menin inhibitor approved for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options.KOMZIFTI is in development for the front-line treatment of AML harboring *NPM1* mutations, *KMT2A* translocations and *FLT3* mutations, with the potential to be combined with approved therapies and benefit a broad spectrum of patients earlier in their disease course.

About Kura Oncology
Kura Oncology is a biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Kura’s pipeline of small molecule drug candidates is designed to target cancer signaling pathways and address high-need hematologic malignancies and solid tumors. Kura developed and is commercializing KOMZIFTI, the FDA-approved once-daily, oral menin inhibitor for the treatment of adults with relapsed or refractory *NPM1*-mutated acute myeloid leukemia, and continues to pioneer advancements in farnesyl transferase inhibition. For additional information, please visit the Kura 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.