



Kyowa Kirin and Kura Oncology Initiate Japanese Phase 2 Registration-Directed Trial of Ziftomenib in R/R *NPM1*-m AML

– Regulatory Filing in Japan Planned Following Clinical Trial Completion –

TOKYO and SAN DIEGO, April 24, 2026 -- Kyowa Kirin Co., Ltd. (TSE: 4151, “Kyowa Kirin”) and Kura Oncology, Inc. (Nasdaq: KURA, “Kura”) today announced the first patient has been dosed in a Japanese Phase 2 registrational clinical trial (jRCT2031250550) studying ziftomenib, an oral menin inhibitor, for the treatment of relapsed or refractory (R/R) *NPM1*-mutated (*NPM1*-m) acute myeloid leukemia (AML). *NPM1*-m AML accounts for approximately 30% of AML patients. The initiation of this trial represents a significant step forward toward establishing a potential new treatment option for patients in Japan. Following completion of this clinical trial, Kyowa Kirin plans to file for regulatory approval in Japan.

Ziftomenib was approved by the U.S. Food and Drug Administration (FDA) in November 2025 for the treatment of adult patients with R/R *NPM1*-m AML who have no satisfactory alternative treatment options, under the brand name KOMZIFTI™.

“Patients with R/R *NPM1*-m AML often face limitations with existing treatment options and have a critical need for new therapeutic alternatives. Ziftomenib has the potential to provide a new treatment approach for these patients,” said Yoshifumi Torii, Ph.D., Chief Medical Officer of Kyowa Kirin. “The initiation of this trial is part of Kyowa Kirin's patient-centered drug development efforts in our priority area of 'hematologic malignancies and refractory hematologic disorders.' We will appropriately advance this trial and work diligently to confirm efficacy and safety, with the goal of ultimately providing a new treatment option to help address unmet needs for patients in Japan as soon as possible.”

The trial initiated by Kyowa Kirin is a multicenter, single-arm, open-label Japanese Phase 2 clinical trial evaluating the efficacy and safety of ziftomenib in adult patients with R/R *NPM1*-m AML. As the primary endpoint, the trial will assess a composite complete remission rate consisting of complete remission (CR) and complete remission with partial hematologic recovery (CRh).

“The initiation of the Phase 2 clinical trial of ziftomenib in Japan represents as a significant milestone in our global development strategy,” said Mollie Leoni, M.D., Chief Medical Officer at Kura Oncology. “In R/R *NPM1*-m AML, therapeutic options remain limited in many regions and patient populations, highlighting the urgent need for innovative therapies. In clinical trials outside of Japan, ziftomenib has consistently shown a favorable efficacy and safety profile combined with the convenience of once-daily oral administration. Advancing clinical development in Japan is a meaningful step toward establishing global access to this promising

therapy. We look forward to close collaboration with Kyowa Kirin to support the trial and deliver new hope to patients in need.”

Kyowa Kirin Co., Ltd. is committed to the research and development of innovative medicines in areas of high unmet medical need. Ziftomenib is in development in combination with standard-of-care and targeted therapies for the front-line treatment of AML harboring *NPM1* mutations, *KMT2A* translocations and *FLT3* mutations, with the potential to benefit a broad spectrum of patients earlier in their disease course.

NPM1, nucleophosmin 1, *KMT2A*, lysine methyltransferase 2A, *FLT3*, Fms-like tyrosine kinase 3

About the Strategic Collaboration Between Kyowa Kirin and Kura Oncology

Kyowa Kirin and Kura Oncology are working closely together to deliver new treatment options to patients worldwide. In November 2024, the companies entered into a global license agreement for menin inhibitors, including ziftomenib. Under this agreement, Kyowa Kirin leads development, regulatory and commercial strategy and is responsible for commercializing ziftomenib outside the United States. In the United States, Kura leads development, regulatory and commercial strategy and is responsible for manufacturing ziftomenib. The companies jointly perform commercialization activities in accordance with a co-created United States territory commercialization plan. For more details, please refer to [previous press releases](#).

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™ (ziftomenib), 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 menin inhibition and 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.