



## **KOMZIFTI™ (ziftomenib) Added to National Comprehensive Cancer Network® (NCCN) Guidelines for Acute Myeloid Leukemia (AML)**

*KOMZIFTI, the first and only once-daily FDA-approved menin inhibitor for R/R NPM1-mutated AML, is now commercially available in the United States*

**SAN DIEGO and TOKYO, November 25 and 26, 2025** -- Kura Oncology, Inc. (Nasdaq: KURA, "Kura") and Kyowa Kirin Co., Ltd. (TSE: 4151, "Kyowa Kirin") today announced KOMZIFTI™ (ziftomenib), the first and only once-daily oral menin inhibitor to be approved for adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible *NPM1* mutation, has been included in the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a Category 2A recommended treatment option for adults with relapsed/refractory AML with *NPM1* mutation.

KOMZIFTI received full approval by the U.S. Food and Drug Administration on November 13, 2025, for the treatment of adults with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options. The approval was supported by data from the KOMET-001 clinical trial, including a 21.4% CR/CRh rate and median duration of CR/CRh response of 5 months.<sup>1,2</sup> KOMZIFTI is now commercially available to prescribers in the U.S. and is available for purchase from a limited network of specialty pharmacies and distributors.

"The addition of KOMZIFTI to the NCCN Guidelines® in Oncology underscores the potential impact of KOMZIFTI for patients with R/R *NPM1*-mutated AML and supports our commitment to ensuring that patients have access to this important treatment option," said Mollie Leoni, M.D., Chief Medical Officer of Kura. "*NPM1*-mutated disease carries a substantial risk of relapse and historically poor outcomes in the relapsed or refractory setting. We are pleased to have received inclusion in the NCCN guidelines so rapidly after FDA approval and are committed to making KOMZIFTI available to patients in the United States."

### References:

1. KOMZIFTI (ziftomenib). Prescribing Information. San Diego, CA: Kura Oncology, Inc.; 2025.
2. [Wang et al. \*J Clin Oncol\* 43, 3381-3390 \(2025\).](#)

**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 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](http://www.kyowakirin.com).