



May- 27, 2026

Kissei Pharmaceutical Co., Ltd.  
(Code 4547, Tokyo Stock Exchange Prime Market)

## **Submission of New Drug Application for Acute Myeloid Leukemia Treatment "Olutasidenib" in Japan**

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announces that today we have submitted a new drug application for manufacturing and marketing approval in Japan for "olutasidenib" (generic name), indicated for relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation.

Olutasidenib works by inhibiting the metabolic enzyme isocitrate dehydrogenase-1 (IDH1), thereby suppressing the inhibition of normal differentiation of stem and progenitor cells and the promotion of neoplastic transformation caused by IDH1 gene mutations, restoring normal cell differentiation. Originally discovered by Forma Therapeutics, Inc., Rigel Pharmaceuticals, Inc. (Head Office: USA; President and CEO: Raul Rodriguez; "Rigel") announced it acquired exclusive global development and sales rights for olutasidenib in August 2022. In September 2024, Kissei acquired exclusive development and sales rights for Japan, South Korea, and Taiwan from Rigel<sup>1</sup>.

Olutasidenib was approved in the United States in December 2022 for the treatment of relapsed or refractory AML with a susceptible IDH1 mutation and is sold by Rigel. In Taiwan, our licensee, Orient EuroPharma Co., Ltd. (Head Office: Taiwan; Chairman: Peter Tsai), is developing olutasidenib<sup>2</sup>.

Kissei is focused on researching and developing new drugs for rare diseases and conditions that lack sufficient treatments. We are committed to providing new treatment options for patients suffering from these diseases.

The impact of this submission on our consolidated financial forecast for the fiscal year ending March 31, 2027, has been incorporated into the forecast disclosed on May 11, 2026.

1 News Release: September 4, 2024

Licensing Agreement for "Olutasidenib", an Acute Myeloid Leukemia Drug

2 News Release: May 1, 2026

Licensing Agreement for "Olutasidenib" with Orient EuroPharma in Taiwan

<Reference>

#### About IDH1 (Isocitrate Dehydrogenase-1)

IDH1 is a cytoplasmic metabolic enzyme that catalyzes the oxidative decarboxylation of isocitrate to  $\alpha$ -ketoglutarate ( $\alpha$ -KG) in the citric acid cycle. Mutations in the IDH1 gene are thought to promote DNA methylation, which inhibits normal cell differentiation of stem and progenitor cells and promotes neoplastic transformation.

#### About IDH1 Mutation-Positive Relapsed/Refractory Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a highly diverse blood malignancy characterized by the autonomous clonal proliferation of immature myeloid cells that have impaired differentiation and maturation ability. As a result of the abnormal proliferation of leukemia cells in the bone marrow, normal hematopoietic function is significantly inhibited, resulting in various symptoms associated with leukopenia, anemia, and thrombocytopenia. If appropriate treatment is not given, it is a serious disease that can become fatal within a short period of time due to infection or bleeding. Treatment for this disease involves induction therapy, such as the combination of anthracyclines and cytarabine, but 10-40% of patients do not achieve remission<sup>1)</sup>, and approximately half of patients relapse<sup>2)</sup>, moving on to salvage therapy for relapsed/refractory disease. The intended indication for olutasidenib is relapsed/refractory AML that is IDH1 mutation-positive, expected to be 6-9% of AML patients<sup>3)</sup>.

1) Blood (2015) 126 (3): 319-27.

2) Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3.

3) NCCN Guidelines 2026 V3

#### About Rigel Pharmaceuticals, Inc.

Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) is a biotechnology company dedicated to discovering, developing, and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. Founded in 1996, Rigel is based in South San Francisco, California. For more information on Rigel, please visit their website at <https://www.rigel.com>.