Sumitomo Pharma

Press Release

November 25, 2026

Sumitomo Pharma Co., Ltd.

Update on Patient Enrollment in Phase 2 Study of Enzomenib for Acute Myeloid Leukemia with NPM1 Mutation

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura) announced that enrollment of the pre-specified number of patients required for the interim analysis has been completed in the ongoing pivotal Phase 2 monotherapy study of enzomenib (generic name, development code: DSP-5336), an investigational anticancer agent, in patients with relapsed or refractory acute myeloid leukemia with NPM1 mutation.

In addition, as announced on June 10, 2026, enrollment of the pre-specified number of patients required for the interim analysis has also been completed in the pivotal Phase 2 monotherapy study of enzomenib in patients with relapsed or refractory acute leukemia with KMT2A rearrangement, with initial results from the interim analysis to be presented at the American Society of Hematology Annual Meeting in December 2026.

Sumitomo Pharma will continue to advance the development of enzomenib, aiming to achieve early regulatory approval and to deliver a new treatment option to patients.

*Sumitomo Pharma issued the following press releases related to this matter.
“Sumitomo Pharma America to Present New Clinical Data on Enzomenib and Nuvisertib at the 2026 American Society of Hematology Annual Meeting”:
https://www.sumitomo-pharma.com/news/assets/pdf/ene20261105_1.pdf
“Sumitomo Pharma America Announces Enzomenib (DSP-5336) Receives FDA Breakthrough Therapy Designation for Treatment of R/R KMT2A-Rearranged Acute Leukemia”:
https://www.sumitomo-pharma.com/news/assets/pdf/ene20261027_1.pdf
“Update on Patient Enrollment in Phase 2 Study of Enzomenib for Acute Leukemia”:
https://www.sumitomo-pharma.com/news/20260610.html

(Reference)
Enzomenib
Enzomenib is an oral small molecule inhibitor of the menin and lysine methyltransferase 2A (KMT2A) protein interaction, which is a key molecular mechanism involved in tumor cell proliferation in acute leukemia and various other cancers. Acute myeloid leukemia with KMT2A rearrangement or nucleophosmin 1 (NPM1) mutation relies on the menin-KMT2A interaction for aberrant upregulation of genes required for hematopoietic stem cell maintenance, including HOXA9 and MEIS1, which is thought to be associated with the development and maintenance of acute

myeloid leukemia. Enzomenib has been shown to have anti-cancer activity through downregulation of these genes by inhibition of menin-KMT2A interaction in preclinical studies. The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and acute lymphoblastic leukemia in July 2026, Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in June 2024, and Breakthrough Therapy Designation for the treatment of relapsed or refractory acute leukemia with KMT2A rearrangement in October 2026. Furthermore, the MHLW granted Orphan Drug Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in September 2024. In August 2026, the MHLW expanded the scope of the Orphan Drug Designation for acute myeloid leukemia to include newly diagnosed patients with KMT2A rearrangement or NPM1 mutation and also granted Orphan Drug Designation for relapsed or refractory acute lymphoblastic leukemia with KMT2A rearrangement.

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