
Press Release

June 10, 2026

Sumitomo Pharma Co., Ltd.

Update on Patient Enrollment in Phase 2 Study of Enzomenib for Acute Leukemia

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, an investigational anticancer agent, in patients with relapsed or refractory acute leukemia with KMT2A rearrangement.

The results of the interim analysis are expected to be available in 2026 and will be promptly disclosed, with detailed data to be presented at an upcoming medical congress. If the primary endpoint is met, the Company plans to promptly proceed with preparations for regulatory submissions, with the aim of obtaining approval in the U.S. and Japan during FY2027.

In addition, enrollment in a pivotal Phase 2 monotherapy study of enzomenib in patients with relapse or refractory acute myeloid leukemia with NPM1 mutation is ongoing.

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

(Reference)

Enzomenib

Enzomenib is a small molecule inhibitor of the menin and lysine methyltransferase 2A (KMT2A) protein interaction. Acute myeloid leukemia with KMT2A rearrangement or nucleophosmin 1 (NPM1) mutation relies on the menin-KMT2A interaction for upregulation of genes instrumental to leukemogenesis. 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 granted Fast Track Designation for the treatment of relapsed or refractory acute myeloid leukemia with KMT2A rearrangement or NPM1 mutation in June 2024. 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.

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