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Sumitomo Pharma America to Present New Clinical Data on Enzomenib and Nuvisertib at the 2026 American Society of Hematology Annual Meeting

– *SMPA to present first data from ongoing Phase 2 clinical trial of enzomenib in patients with relapsed or refractory acute leukemia, with KMT2A rearrangements, an aggressive subtype of leukemia –*

– *Completed dose optimization study of enzomenib in patients with relapsed or refractory acute myeloid leukemia with NPM1 mutation demonstrated enzomenib 300 mg twice a day was generally well tolerated with measurable clinical activity –*

– *Preliminary clinical data from ongoing Phase 1/2 study of nuvisertib in combination with momelotinib show encouraging clinical responses in patients with relapsed or refractory myelofibrosis –*

MARLBOROUGH, Mass., November 4, 2026 – Sumitomo Pharma America, Inc. (SMPA) today announced two oral presentations and two poster presentations at the 68th American Society of Hematology (ASH) Annual Meeting & Exposition, taking place December 12-15, 2026, in New Orleans, Louisiana. The presentations will feature new clinical data on enzomenib, an investigational oral small molecule menin inhibitor being studied in genetic subtypes of relapsed or refractory (R/R) acute leukemia (AL), and nuvisertib, an investigational oral small molecule highly selective PIM1 kinase inhibitor with added ACVR1 inhibition being evaluated in combination with momelotinib (MMB) in patients with R/R myelofibrosis (MF).

“There remains a high unmet medical need for patients with R/R acute myeloid leukemia with KMT2Ar or NPM1m for targeted therapies that yield robust response rates and durable response that are well tolerated," said Jatin Shah, M.D., Chief Medical Officer, Oncology, SMPA. “In addition, new classes of therapeutics and combination strategies to potentially improve upon the activity of JAK inhibitors are important in MF. With this in mind, we look forward to sharing encouraging new data that further support the therapeutic potential and development of our late-stage oncology pipeline at ASH."

For enzomenib, the oral presentation will report efficacy and safety data from the pivotal Phase 2 arm of the Horizen-1 study in patients with R/R KMT2A rearrangements (KMT2Ar) AL. The data will highlight the therapeutic potential of enzomenib as a targeted treatment option for patients with this high-risk subset of AL.

Additionally, a poster presentation will include clinical findings from the completed dose optimization study of enzomenib that informed the recommended Phase 2 dose (RP2D) in patients with R/R AL with NPM1 mutation (NPM1m). The data demonstrated that both 200 mg twice a day (BID) and 300 mg BID of enzomenib were generally well tolerated with measurable clinical activity. Objective response rates (ORRs) were 54% and 57% in patients receiving 200 and 300 mg BID, respectively, while the complete remission and complete remission with partial hematologic recovery (CR+CRh) rates were 35% at 200 mg BID and 43% at 300 mg BID.

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For nuvisertib, the oral presentation will report preliminary findings from the ongoing global Phase 1 dose escalation study evaluating nuvisertib and MMB in patients with MF previously treated with a JAK inhibitor show the combination appeared to be well tolerated in the dose levels evaluated. Promising clinical activity included symptom and spleen responses, anemia improvement, and cytokine modulation. These emerging clinical data support the Phase 3 clinical development of nuvisertib in combination with MMB for patients with MF and anemia.

Presentation Details

Title	Details	Presenting Author
Investigational PIM1 kinase inhibitor nuvisertib in combination with momelotinib showed promising clinical activity in patients with myelofibrosis and anemia: Preliminary data from an ongoing Phase 1/2 study *Oral Presentation*	Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Combining Forces Against Myelofibrosis Sunday, December 13, 2026 9:30—11 a.m. CST Presentation Time: 9:45—10 a.m. CST Room: R02-R05 (New Orleans Ernest N. Morial Convention Center)	Lindsay A.M. Rein, M.D.
Selective PIM1 inhibition with nuvisertib promotes megakaryocyte maturation and platelet production in myelofibrosis patients *Poster Presentation*	Session: 631. Myeloproliferative Syndromes and Chronic Myeloid Leukemia: Basic and Translational: Poster I Saturday, December 12, 2026 5:30—7:30 p.m. CST Room: Hall F (New Orleans Ernest N. Morial Convention Center)	Lilian Varricchio, Ph.D.

Initial report of the Phase 2 pivotal data in patients with relapsed or refractory KMT2Ar acute leukemia from the phase 1/2 trial of the investigational menin inhibitor enzomenib (DSP-5336) *Oral Presentation*	Session: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies - Novel Combinations with Menin, FLT3 and BCL2 Inhibitors Sunday, December 13, 2026 4:30—6 p.m. CST Presentation Time: 5—5:15 p.m. CST Room: Hall B (New Orleans Ernest N. Morial Convention Center)	Harry P. Erba, M.D., Ph.D.
Enzomenib dose optimization and determination of the recommended Phase 2 dose in patients (pts) with relapsed or refractory NPM1m acute leukemia *Poster Presentation*	Session: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Poster III Monday, December 14, 2026 6—8 p.m. CST Presentation Time: 6—8 p.m. CST Room: Hall F (New Orleans Ernest N. Morial Convention Center)	Cristina Papayannidis, M.D., Ph.D.

About Enzomenib (DSP-5336)

Enzomenib is an investigational, oral, small molecule inhibitor of the menin and lysine (K)-specific methyltransferase 2A (KMT2A) protein interaction, a key interaction in acute leukemia and other tumor cell proliferation and growth.[1] Menin is a scaffold nuclear protein that plays key roles in gene expression and protein interactions involved in many biological pathways, including cell growth, cell cycle, genomic stability, and hematopoiesis.[2,3] In preclinical studies, enzomenib has shown selective growth inhibition in human acute leukemia cell lines with KMT2A rearrangements or NPM1 mutations.[4] Enzomenib reduced the expression of the leukemia-associated genes HOXA9 and MEIS1 and increased the expression of the

differentiation gene CD11b in human acute leukemia cell lines with KMT2A rearrangements or NPM1 mutations.[1,4] The safety and efficacy of enzomenib are currently being clinically evaluated in a Phase 1/2 dose-escalation/dose-expansion study in patients with relapsed or refractory acute leukemia (NCT04988555) and the registrational Phase 2 Horizen-1 R/R mono AML/ALL (KMT2Ar + NPM1m) study. The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022 and the indication of acute lymphoblastic leukemia in July 2026. The FDA granted Fast Track Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with KMT2Ar or NPM1m in June 2024 and Breakthrough Therapy Designation for the treatment of patients with relapsed/refractory acute leukemia with KMT2Ar in October 2026. Japan's Ministry of Health, Labour and Welfare (MHLW) granted Orphan Drug Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with KMT2Ar or NPM1m in September 2024.

About Nuvisertib (TP-3654)

Nuvisertib is an oral investigational selective inhibitor of PIM1 kinase with added ACVR1 inhibition, which has shown potential antitumor and antifibrotic activity through multiple pathways, including induction of apoptosis in preclinical models.[5-7] Nuvisertib was observed to inhibit proliferation and increase apoptosis in murine and human hematopoietic cells expressing the clinically relevant *JAK2* V617F mutation.[6] Nuvisertib alone and in combination with ruxolitinib showed reduction of spleen size and bone marrow fibrosis in *JAK2* V617F and *MPLW515L* murine models of myelofibrosis.[6] In addition to its primary activity against PIM1, nuvisertib has been shown to bind and inhibit ACVR1 in preclinical studies, which may contribute to hemoglobin responses in patients with myelofibrosis.[7] The safety and efficacy of nuvisertib monotherapy or in combination with a JAK inhibitor are currently being clinically evaluated in a Phase 1/2 study in patients with intermediate- and high-risk myelofibrosis (NCT04176198). The FDA granted Orphan Drug Designation to nuvisertib for the indication of myelofibrosis in May 2022. The Japan Ministry of Health, Labour and Welfare (MHLW) granted Orphan Drug Designation to nuvisertib for the treatment of myelofibrosis in November 2024. The European Medicines Agency (EMA) granted Orphan Drug Designation to nuvisertib for the treatment of myelofibrosis in July 2025. The FDA granted Fast Track Designation to nuvisertib for the indication of myelofibrosis in June 2025.

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.) focused on developing and delivering innovative pharmaceutical and regenerative medicines to meet patient needs across oncology, urology, women's health, rare diseases, and CNS. With several marketed products in the U.S. and Europe, and a diverse pipeline of early- to late-stage assets, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information on SMPA, visit our website https://www.us.sumitomo-pharma.com or follow us on LinkedIn.

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For further information: SMPA CONTACT: Dave Murdoch, Sumitomo Pharma America, Inc., david.murdoch@us.sumitomo-pharma.com, +1 (774) 405-5570