Sumitomo Pharma America to Present New Investigational Data at the 2025 American Society of Hematology Annual Meeting

- *New data from Phase 1/2 study of enzomenib (DSP-5336) in patients with relapsed/refractory acute myeloid leukemia (AML) show promising clinical activity across a wide range of potentially therapeutic doses*
- *Preliminary data from Phase 1 study of enzomenib in combination with venetoclax and azacitidine in patients with relapsed/refractory AML show encouraging early clinical activity and that the combination is well tolerated*
- *Preliminary data from Phase 1/2 study of nuvisertib (TP-3654) in combination with momelotinib in patients with relapsed/refractory myelofibrosis show encouraging early clinical activity*

MARLBOROUGH, Mass., Nov. 3, 2025 /PRNewswire/ -- Sumitomo Pharma America, Inc. (SMPA) today announced three oral presentations and one poster presentation at the 67th American Society of Hematology (ASH) Annual Meeting & Exposition taking place in Orlando, Florida, from December 6-9, 2025. The presentations will include new clinical data supporting enzomenib, an investigational, oral small molecule menin inhibitor being researched as a monotherapy and in combination with venetoclax and azacitidine (VEN/AZA) for relapsed or refractory acute leukemia, and nuvisertib, an oral investigational highly selective small molecule PIM1 kinase inhibitor being evaluated as a monotherapy and in combination with momelotinib (MMB) for the treatment of relapsed or refractory myelofibrosis (MF).

Updated clinical data from the ongoing Phase 1/2 study of enzomenib continue to show promising clinical activity across a wide range of potentially therapeutic doses in patients with relapsed or refractory acute leukemia with KMT2A-rearranged (*KMT2Ar*), NPM1-mutated (*NPM1m*), and other HOXA9/MEIS1-driven leukemia subtypes. Enzomenib is designed to target the menin and mixed-lineage leukemia (MLL) protein interaction, a key interaction for acute leukemia and cell growth in a variety of cancers. In this dose-escalation study of enzomenib monotherapy, enzomenib was escalated from 40 mg twice a day (BID) to 400 mg BID with no dose-limiting toxicities (DLTs) in 116 patients with sustained complete remission (CR) and complete remission with partial hematologic recovery (CRh) seen at doses of 200, 300 and 400 mg BID. Given the wide therapeutic window of enzomenib, these findings suggest that dosing may be tailored to the specific biology of different leukemia subtypes for potential optimal therapeutic effect.

Additionally, preliminary findings from a Phase 1 study of enzomenib in combination with VEN/AZA in patients with relapsed or refractory AML with *KMT2Ar* or *NPM1m* subtypes show enzomenib with VEN/AZA to be well-tolerated to up to 300 mg BID with no DLTs and no evidence of significant drug-drug interaction between enzomenib and VEN. Promising early clinical activity, particularly in patients without prior VEN or menin exposure, was also observed.

New clinical data from the Phase 1/2 study evaluating the safety and efficacy of nuvisertib in combination with MMB demonstrate early clinical activity and show that the treatment combination was well-tolerated supporting further development in patients with MF. Lastly, findings from the ongoing Phase 1/2 study of nuvisertib continue to support that nuvisertib monotherapy was well-tolerated with no DLTs and notable modulation of cytokine profiles demonstrating a strong correlation with clinical responses.

"Patients living with relapsed/refractory AML or MF desperately need effective therapies to overcome the poor prognoses typically associated with these cancers. The clinical data are highly compelling, especially for patients with particularly challenging forms of acute leukemia including those with *KMT2A*-rearranged and *NPM1*-mutated subtypes," said Jatin Shah, M.D., Chief Medical Officer, Oncology, SMPA. "Based on this progress, we look forward to sharing more comprehensive data further supporting the development of enzomenib and nuvisertib at the upcoming meeting in December and remain committed to advancing both of these programs."

Abstract Title	Detail	Lead Author

Nuvisertib, an oral investigational selective PIM1 kinase inhibitor, showed clinical responses strongly correlating with cytokine modulation in patients with relapsed/refractory myelofibrosis in the ongoing global phase I/II study *Poster Presentation*	Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster I Saturday, December 6. 5:30 – 7:30 p.m. EST Presentation Time and Location: 5:30 p.m. EST West Halls B3-B4 (Orange County Convention Center)	Lindsay A.M. Rein, M.D.
Preliminary data from the Phase I/II study of nuvisertib, an oral investigational selective PIM1 inhibitor, in combination with momelotinib showed clinical responses in patients with relapsed/refractory myelofibrosis *Oral Podium Presentation*	Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Between a Rock and a Ropeg - Innovative Therapies for MPNs Sunday, December 7. 9:30 – 11 a.m. EST Presentation Time and Location: 9:45 a.m. EST W414AB (Orange County Convention Center)	John Mascarenhas, M.D.
Monotherapy Update from Phase 1 Portion in Phase1/2 trial of the Menin-MLL Inhibitor Enzomenib (DSP-5336) in Patients with Relapsed or Refractory Acute Leukemia *Oral Podium Presentation*	Session: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Menin inhibitors and FLT3 inhibitors in AML Monday, December 8. 10:30 a.m. – noon EST Presentation Time and Location: 10:30 a.m. EST Chapin Theater (320) (Orange County Convention Center)	Naval G. Daver, M.D.
Preliminary data from the ongoing Phase 1 study of the menin-MLL inhibitor enzomenib (DSP-5336) in combination with venetoclax and azacitidine in patients with relapsed or refractory Acute Myeloid Leukemia *Oral Podium Presentation*	Session: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Menin inhibitors and FLT3 inhibitors in AML Monday, December 8. 10:30 a.m. – noon EST Presentation Time and Location: 11 a.m. EST Chapin Theater (320) (Orange County Convention Center)	Justin M. Watts, M.D.

About Enzomenib

Enzomenib is an investigational, oral, small molecule inhibitor of the menin and mixed-lineage leukemia (MLL) protein interaction, a key interaction in acute leukemia and other tumor cell proliferation and growth. Menin is a scaffold nuclear protein which plays key roles in gene expression and protein interactions involved in many biological pathways, including cell growth, cell cycle, genomic stability, and hematopoiesis.[1,2] In preclinical studies, enzomenib has shown selective growth inhibition in human acute leukemia cell lines with KMT2A (MLL) rearrangements or NPM1 mutations.[1,3] 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 MLL rearrangements and NPM1 mutation.[4,5] The safety and efficacy of enzomenib is currently being clinically evaluated in a Phase 1/2 dose escalation/dose expansion study in patients with relapsed or refractory acute leukemia (NCT04988555). The FDA granted Orphan Drug Designation for enzomenib for the indication of acute myeloid leukemia in June 2022. The FDA granted Fast Track Designation for enzomenib for the indication of relapsed or refractory

acute myeloid leukemia with MLLr or NPM1m in June 2024. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) granted Orphan Drug Designation for enzomenib for the indication of relapsed or refractory acute myeloid leukemia with MLLr or NPM1m in September 2024.

About Nuvisertib (TP-3654)
Nuvisertib (TP-3654) is an oral investigational selective inhibitor of PIM1 kinase, which has shown potential antitumor and antifibrotic activity through multiple pathways, including induction of apoptosis in preclinical models.[6,7] Nuvisertib was observed to inhibit proliferation and increase apoptosis in murine and human hematopoietic cells expressing the clinically relevant JAK2 V617F mutation.[7] Nuvisertib alone and in combination with ruxolitinib showed white blood cell and neutrophil count normalization, and also reduced spleen size and bone marrow fibrosis in JAK2 V617F and MPLW515L murine models of myelofibrosis.[6] The safety and efficacy of nuvisertib is 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 FDA granted Fast Track Designation to nuvisertib for the indication of myelofibrosis in June 2025, and the European Medicines Agency granted Orphan Drug Designation to nuvisertib for the treatment of myelofibrosis in July 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.), Canada (Sumitomo Pharma Canada, Inc.), and Europe (Sumitomo Pharma Switzerland GmbH) focused on addressing patient needs in oncology, urology, women's health, rare diseases, psychiatry & neurology, and cell & gene therapies. With several marketed products in the U.S., Canada, and Europe, and a diverse pipeline of early- to late-stage investigational 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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References

- Cierpicki T, Grembecka J. Challenges and opportunities in targeting the menin-MLL Interaction.*Future Med Chem*. 2014; 6(4):447-462. doi:10.4155/fmc.13.214.
- Matkar S, Thiel A, Hua X. Menin: a scaffold protein that controls gene expression and cell signaling.*Trends Biochem Sci*. 2013; 38(8):394-402. doi:10.1016/j.tibs.2013.05.005.
- Kuhn MWM, Song E, Feng Z, et al. Targeting chromatin regulators inhibits leukemogenic gene expression in NPM1 mutant leukemia. *Cancer Discov*. 2016;6(10):1166-1181. doi:10.1158/2159-8290.CD-16-0237.
- Eguchi K, Shimizu T, Kato D, et al. Preclinical Evaluation of a Novel Orally Bioavailable Menin-MLL Interaction Inhibitor, DSP-5336, for the Treatment of Acute Leukemia Patients with MLL-Rearrangement or NPM1 Mutation. *Blood* 2021; 138 (Supplement 1): 3339. Available at: https://doi.org/10.1182/blood-2021-152050.
- Daver N, Zeidner JF, Yuda J, et al. Phase 1/2 First-in-Human Study of the Menin-MLL Inhibitor DSP-5336 in Patients with Relapsed or Refractory Acute Leukemia. *Blood* 2023; 142 (Supplement 1): 2911. Available at: https://doi.org/10.1182/blood-2023-179252.
- Dutta A., Nath D, Yang Y, et al. Genetic ablation of Pim1 or pharmacologic inhibition with TP-3654 ameliorates myelofibrosis in murine models. *Leukemia*. 2022; 36 (3): 746-759. doi: 10.1038/s41375-021-01464-2.
- Foulks JM, Carpenter KJ, Luo B, et al. A small-molecule inhibitor of PIM kinases as a potential treatment for urothelial carcinomas. *Neoplasia*. 2014;16(5):403-412.

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