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Sumitomo Pharma America Announces Encouraging Clinical and Translational Data at EHA 2026, Highlighting Investigational Combination Therapy in Relapsed/Refractory Myelofibrosis and New Research Findings in Menin Inhibition in Leukemia

– Preliminary clinical data on nuvisertib and momelotinib combination highlight encouraging clinical responses with 60% of evaluable patients achieving responses in spleen size, symptoms, and anemia at 24 weeks –
– In addition to its primary activity as a PIM1 inhibitor, in vitro *and biochemical data demonstrated that nuvisertib also binds to and inhibits ACVR1 –*
– New translational research in leukemia and menin inhibition has identified distinct MEN1 mutational signatures associated with acquired resistance to the menin inhibitor (MI) enzomenib –

MARLBOROUGH, Mass., June 15, 2026 – Sumitomo Pharma America, Inc. (SMPA) today announced the presentation of new clinical and translational research at the European Hematology Association (EHA) 2026 Congress, held from June 11-14, 2026, in Stockholm, Sweden.

Among the data is the first-ever disclosure of preliminary clinical data for the investigational PIM1 inhibitor nuvisertib in combination with momelotinib (MMB) for patients with myelofibrosis (MF), and new translational research into the mechanistic basis for hemoglobin improvement observed in patients with MF in an ongoing Phase 1/2 study with nuvisertib. Alongside these findings, SMPA is also sharing new data gathered around acquired resistance patterns observed with enzomenib in acute leukemia.

“We are excited to present the preliminary data for our investigational combination of nuvisertib and momelotinib at EHA 2026, while also sharing learnings from our ongoing translational research of nuvisertib and enzomenib,” said Tsutomu Nakagawa, Ph.D., President and Chief Executive Officer of SMPA. “We appreciate this opportunity to share the latest data for these two programs with the oncology community, and these results reinforce our commitment to developing multi-faceted therapeutic approaches that address the most persistent challenges in treating hematologic malignancies.”

Promising clinical response with nuvisertib and momelotinib in myelofibrosis
James McCloskey, M.D., Interim Chief of the Division of Leukemia, John Theurer Cancer Center, Hackensack, USA presented preliminary clinical data from the ongoing global Phase 1/2 study (NCT04176198). As of December 6, 2025, a total of 26 patients with relapsed/refractory (R/R) MF and anemia were enrolled across four dose levels of nuvisertib (240, 360, 480, and 720 mg twice daily under fed condition) in combination with the approved dose of momelotinib in MF (200 mg once daily). This study population was particularly challenging to treat as every patient had previously received at least one approved Janus Kinase (JAK) inhibitor and 41% of patients carried high molecular risk (HMR) mutations. Despite these complexities, the combination appeared well tolerated with no dose-limiting toxicities (DLTs) observed. The most common treatment-related adverse events occurring in ≥20% patients were diarrhea, nausea, and

thrombocytopenia. The most frequent treatment-related Grade 3 adverse event was thrombocytopenia without bleeding, which occurred in three patients. Of note, mean hemoglobin and platelet count levels remained stable throughout the 24-week treatment period.

Among the efficacy evaluable patients who completed at least 12 weeks of treatment (n=15), the combination of nuvisertib and momelotinib demonstrated evidence of clinical activity. Spleen volume reduction of at least 25% (SVR25) was achieved by 73% of patients at Week 12 and reached 100% at Week 24 (n=5). Similarly, 53% of patients achieved a total symptom score reduction of at least 50% percent (TSS50) at Week 12 that further improved to 60% of patients at Week 24 (n=5). Anemia response by IWG ELN2024 criteria was observed in 50% of patients at any time. Most significantly, 60% of patients achieved a triple response at the Week 24 mark, meeting concurrent criteria for symptom reduction, spleen volume reduction, and anemia improvement.

The development of nuvisertib and momelotinib combination therapy was driven by the need to address the pathways that drive MF progression more comprehensively. While standard treatments focus on inhibiting the JAK signaling pathway, research has shown that PIM1 expression is often upregulated in MF and can be driven by JAK-independent compensatory pathways, such as Nuclear Factor kappa-light-chain-enhancer of activated B cells (NF-kB) and Ets Related Gene (ERG). These secondary pathways can allow the disease to survive and progress even during JAK inhibitor therapy. By combining nuvisertib with the JAK/Activin A Receptor Type 1 (ACVR1) inhibitor momelotinib, researchers aim to shut down these escape routes, potentially leading to deeper and more durable clinical responses for patients.

New Nuvisertib translational research presented in MF

Joseph M Scandura, M.D., Ph.D., Division of Hematology and Medical Oncology, Weill/Cornell Leukemia Program, New York, USA presented translational research further elucidating the proposed mechanism of action of nuvisertib. In addition to its primary activity as a PIM1 inhibitor, in vitro and biochemical data demonstrated that nuvisertib also binds to and inhibits ACVR1, resulting in reduced hepcidin mRNA expression, a central regulator of iron homeostasis. Consistent with these findings, preliminary clinical data from a Phase 1/2 study of nuvisertib monotherapy showed reduced hepcidin levels in patients with R/R MF, providing a potential mechanistic explanation for the hemoglobin stability and improvement observed in patients with MF treated with nuvisertib.

“Preliminary clinical data suggests that the combination of nuvisertib and momelotinib may provide a more comprehensive suppression of the disease pathways driving myelofibrosis,” said Raajit Rampal, M.D. Ph.D., Director of the Myeloproliferative Neoplasms Program at the Memorial Sloan Kettering Cancer Centre, New York, USA. “The promising symptom, spleen and anemia responses, coupled with the new nonclinical data on potential dual PIM1 and ACVR1 inhibitory activity by nuvisertib, suggest that this combination therapy may potentially offer meaningful clinical benefits for patients with myelofibrosis.”

Translational research in leukemia and menin inhibition identifies E368K mutation as key resistance signature at relapse

Also, during the conference, translational research in leukemia and menin inhibition was shared by Jevon Cutler, PhD, Assistant Professor of Cell, Developmental and Cancer Biology at the Oregon Health Sciences University School of Medicine, that identified distinct MEN1 mutational signatures associated with acquired resistance to the menin inhibitor (MI) enzomenib in patients with acute leukemia. Serial molecular profiling revealed that the E368K mutation was the predominant resistance signature identified at relapse, appearing in 53% of patients who relapsed after an initial response. Preclinical work predicted the E368K mutation to be the primary resistance mutation and that this mutation may not affect the other menin inhibitors; these findings support the further exploration of rational, sequential MI therapy to improve clinical outcomes for patients with acute leukemia.

Presentation Details

Abstract title	Lead Author
Investigational PIM1 Inhibitor Nuvisertib in Combination with Momelotinib Showed Promising Clinical Activity in Patients with Myelofibrosis and Anemia: Data from an Ongoing Global Phase 1/2 Study	James McCloskey, MD
Preclinical Evidence of Targeting ACVR1/Hepcidin by Nuvisertib, an Oral Investigational PIM1 Kinase Inhibitor, Suggests Potential Mechanistic Basis for Hemoglobin Benefit in Myelofibrosis	Joseph M Scandura, MD, PhD
Distinct MEN1 Mutational Signatures Are Associated with Acquired Resistance During MENIN-KMT2A Inhibition in a Phase 1 Enzomenib Trial	Jevon Cutler, PhD

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 addressing patient needs in oncology, urology, women's health, rare diseases, cell & gene therapies, and CNS. With products in the U.S., Canada, 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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