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Sumitomo Pharma America to Present New Investigational Data at the 2024 American Society of Hematology Annual Meeting

- *Nuvisertib (TP-3654), an oral investigational highly selective PIM1 kinase inhibitor, is being evaluated in a Phase 1/2 study in patients with relapsed/refractory myelofibrosis*

- *Enzomenib (DSP-5336), an investigational, oral small molecule designed to inhibit the menin and KMT2A protein interaction, is being evaluated in a Phase 1/2 study in patients with relapsed/refractory acute leukemia*

MARLBOROUGH, Mass., November 6, 2024 -- Sumitomo Pharma America, Inc. (SMPA) today announced three presentations at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition taking place in San Diego, California from December 7-10, 2024. The presentations will include new clinical data supporting nuvisertib, an investigational small molecule being researched for the treatment of relapsed/refractory myelofibrosis (MF), and enzomenib, an investigational, oral small molecule being researched for relapsed/refractory acute leukemia.

Findings from the ongoing Phase 1/2 study of nuvisertib continue to support that nuvisertib monotherapy was well-tolerated with no dose-limiting toxicities (DLTs) and promising early clinical activity. The global study is now being expanded to evaluate nuvisertib in combination with JAK inhibitors ruxolitinib, the first approved JAK inhibitor, and momelotinib, a recently approved JAK inhibitor for MF patients with anemia, to assess safety and clinical activity.

In addition, new clinical data from the enzomenib Phase 1/2 study demonstrated promising clinical activity in patients across a wide therapeutic range of doses, with encouraging safety data as enzomenib was well-tolerated with no DLTs or discontinuations due to adverse events related to enzomenib observed.

“For patients with relapsed AML or myelofibrosis, there is a critical need for new, effective treatment options to meaningfully improve the poor prognoses associated with these cancers. We’re encouraged by these data and continue to rapidly progress our development programs in relapsed/refractory MF and acute leukemia,” said Jatin Shah, M.D., Chief Medical Officer, Oncology, SMPA. “We look forward to sharing updated results, which further support the development of nuvisertib and enzomenib, at the upcoming meeting in December and remain committed to advancing new developments within our pipeline.”

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Abstract Title	Detail	Lead Author
Phase 1/2 First-in-Human Study 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 in AML Saturday, December 7. 2:00 p.m. – 3:30 p.m. PST Presentation Time and Location: 2:30 p.m. PST Ballroom 20CD (San Diego Convention Center)	Joshua F. Zeidner, M.D.
Nuvisertib (TP-3654), an Investigational Selective PIM1 Kinase Inhibitor, Showed Durable Clinical Response and Sustained Hematological Improvement in Relapsed/Refractory Myelofibrosis Patients *Oral Podium Presentation*	Session 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Advancing Treatment Paradigms in Myeloproliferative Neoplasms and Mastocytosis Sunday, December 8. 4:30 – 6:30 p.m. PST Presentation Time and Location: 4:30 p.m. PST Grand Hall D (Manchester Grand Hyatt San Diego)	Firas El Chaer, M.D.
Cytokine Modulation Correlates Strongly with Symptom Improvement in Patients with Myelofibrosis Treated with Nuvisertib (TP-3654), an Investigational Selective PIM1 Kinase Inhibitor *Poster Presentation*	Session: 634. Myeloproliferative Syndromes: Clinical and Epidemiological: Poster II Sunday, December 8 6:00 p.m. – 8:00 p.m. PST Halls G-H (San Diego Convention Center)	Lindsay A.M. Rein, M.D.

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About enzomenib (DSP-5336)
Enzomenib (DSP-5336) is an investigational small molecule inhibitor of the menin and mixed-lineage leukemia (MLL) protein interaction. 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.

About nuvisertib (TP-3654)
Nuvisertib (TP-3654) is an oral investigational 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 induce apoptosis in murine and human hematopoietic cell lines expressing the clinically relevant JAK2V617F mutation.[6] 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 JAK2V617F and MPLW515L murine models of myelofibrosis.[7] 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 U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for nuvisertib for the treatment of myelofibrosis in May 2022.

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 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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