# Sumitomo Pharma America Announces that Nuvisertib (TP-3654) Has Received FDA Fast Track Designation for the Treatment of Myelofibrosis

– Nuvisertib (TP-3654), an investigational highly selective oral PIM1 kinase inhibitor, is being evaluated in patients with relapsed or refractory myelofibrosis (MF) –

– Nuvisertib demonstrated symptom and spleen responses correlating with cytokine modulation in the preliminary Phase 1/2 data recently presented at the European Hematology Association (EHA) 2025 Congress –

MARLBOROUGH, Mass., June 12, 2025 /PRNewswire/ -- Sumitomo Pharma America, Inc. (SMPA) today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to nuvisertib (TP-3654) for the treatment of patients with intermediate or high-risk myelofibrosis (MF). The FDA Fast Track Designation is granted to investigational therapies being developed to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. Nuvisertib is an oral, investigational, highly selective inhibitor of PIM1 kinase, which demonstrated clinical activity including symptom and spleen responses correlating with cytokine modulation in the updated preliminary Phase 1/2 data presented at the European Hematology Association (EHA) 2025 Congress in Milan, Italy.

MF, a serious and rare type of blood cancer, is characterized by the buildup of fibrous tissues in the bone marrow which is caused by dysregulation in the Janus-associated kinase (JAK) signaling pathway. The clinical manifestations of MF include an enlarged spleen, debilitating symptoms and reduction in hemoglobin and/or platelets. MF affects 1 in 500,000 people worldwide.[1]

"This positive momentum for nuvisertib signals strong promise in our pipeline and reflects our dedication to addressing unmet medical needs on behalf of patients with myelofibrosis and their families," said Tsutomu Nakagawa, Ph.D, President and Chief Executive Officer of SMPA. "Receiving FDA Fast Track Designation for nuvisertib in the treatment of myelofibrosis reinforces our confidence in its potential as a treatment option for patients facing a poor prognosis with limited treatment options. We are committed to working closely with the FDA to progress the clinical development of nuvisertib and bring an alternative treatment option to patients with myelofibrosis."

Updated data from the ongoing Phase 1/2 study of nuvisertib in patients with relapsed/refractory MF were presented at the EHA Congress on June 12, 2025. Preliminary data showed that nuvisertib monotherapy appears to be well tolerated with no dose-limiting toxicities (DLTs). Evaluable patients showed clinical activity including a ≥25% spleen volume reduction (SVR25) in 22.2% of patients and a ≥50% reduction in total symptom score (TSS50) of 44.4% of patients, as well as improvement of bone marrow fibrosis (42.9% patients), hemoglobin (24% patients) and platelet count (26.7% patients). Data also showed that nuvisertib treatment led to significant cytokine modulation [reduction of pro-inflammatory cytokines (e.g. EN-RAGE, MIP-1β) and increase of anti-inflammatory cytokines (e.g. adiponectin)], which demonstrated significant ($p<0.001$) correlation with symptom and spleen responses. Preclinical[2] and emerging clinical data support the development of nuvisertib in combination with JAK inhibitors for the treatment of patients with MF.

"The data observed to date demonstrate promising clinical activity for nuvisertib and the strong potential for selective PIM1 inhibition to slow the progression of myelofibrosis," said Jatin Shah, MD, Chief Medical Officer, Oncology. "Patients with myelofibrosis are in need of new therapeutic approaches, including combination treatment options, that can provide increased and durable response rates with limited hematologic adverse events. The FDA Fast Track Designation reinforces the potential of nuvisertib to provide clinical benefits for patients with myelofibrosis, an unmet medical need."

**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.[2,3] Nuvisertib was observed to inhibit proliferation and increase apoptosis in murine and human hematopoietic cells expressing the clinically relevant JAK2 V617F mutation.[3] 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.[2] 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 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.

**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, 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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