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**Sumitomo Pharma Oncology, Inc. Presents Updated Preliminary Data from Phase 1/2 Clinical Study Evaluating Investigational Agent TP-3654 in Patients with Myelofibrosis at European Hematology Association 2023 Hybrid Congress**

CAMBRIDGE, Mass., June 9, 2023 /PRNewswire/ -- Sumitomo Pharma Oncology, Inc., a clinical-stage company focused on novel cancer therapeutics, today presented updated preliminary data from the ongoing Phase 1/2 study evaluating TP-3654, an investigational selective oral PIM1 kinase inhibitor, in patients with myelofibrosis (MF) previously treated with or ineligible for JAK inhibitor therapy. Initial preliminary data was presented at American Society of Hematology (ASH) Annual Meeting & Exposition 2022. Updated results were presented in a poster presentation at the European Hematology Association (EHA) 2023 Hybrid Congress, being held June 8-11, 2023 in Frankfurt, Germany as well as virtually on the Congress platform from June 8-11, 2023.

Preliminary data of TP-3654 monotherapy in relapsed/refractory myelofibrosis (MF) patients showed spleen volume reduction (SVR), and total symptom score (TSS) improvement.[1] Further, TP-3654 may prompt early cytokine changes that may correlate with symptoms response.

"We are encouraged by these preliminary clinical data and are pleased that in dose ranges evaluated to date, TP-3654 has been well-tolerated with no myelosuppressive treatment-related adverse events (TRAEs). Our commitment remains to continue to advance this program with additional clinical sites and contributing to the progress of potential treatment options, which may improve outcomes for patients with myelofibrosis," said Patricia S. Andrews, Chief Executive Officer and Global Head of Oncology, Sumitomo Pharma Oncology, Inc.

As of February 9, 2023, 15 patients were enrolled across 5 dose levels from 480mg QD to 720 mg BID. The results showed SVR observed in 7 of 10 evaluable patients treated for ≥ 12 weeks. TSS improvements were observed in 9 of 10 evaluable patients. Broad reductions in cytokines were observed after TP-3654 treatment. At week 12 analysis, patients with higher cytokine reductions correlated with higher TSS improvement. BM fibrosis reduction from grade 3 to 2 was seen in one patient who also achieved spleen and symptoms responses and showed reductions in MF associated cytokines: IL6 (68%), IL12p40 (83%), MMP9 (56%), and EN-RAGE (68%), and is on active treatment for more than 18 months.[1] Overall, TP-3654 appears to be well tolerated with no dose limiting toxicity (DLT) observed to date. The most common adverse events are Grade 1 and 2 diarrhea, nausea, and vomiting.[1]

"These updated preliminary data of oral TP-3654 as a monotherapy in patients with MF presented at EHA 2023 are encouraging as we evaluate the pharmacodynamic markers changes in MF patients treated with TP-3654," said Jatin J. Shah, M.D., Chief Medical Officer and Global Head of Development, Sumitomo Pharma Oncology (SMP Oncology). "We look forward to continuing to advance this study to evaluate the potential role of TP-3654 as a monotherapy, in addition to exploring combination opportunities with JAK inhibitors, for patients with myelofibrosis." Below are the details for the SMP Oncology presentation:

| Abstract Title | Details | Presenter |
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| Preliminary Data From the Phase 1/2 Study of TP-3654, an Investigational Selective PIM1 Kinase Inhibitor, Showed Cytokine Reduction | Abstract P1031<br>June 9, 2023 at 6:00 PM CEST<br>Poster Presentation | Firas El Chaer, MD, Division of Hematology/Oncology, University of Virginia Health System, Charlottesville, VA |

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| Abstract Title | Details | Presenter |
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| and Clinical Responses in Relapsed/Refractory Myelofibrosis | | |

**About TP-3654**

TP-3654 is an oral investigational inhibitor of PIM 1 kinase, which has shown potential antitumor and anti-fibrotic activity through multiple pathways, including induction of apoptosis in preclinical models.[2,3] TP-3654 was observed to inhibit proliferation and increased apoptosis in murine and human hematopoietic cells expressing clinically relevant JAK2V617F mutation.[3] TP-3654 alone and in combination with ruxolitinib also showed normalized WBC and neutrophil counts, and reduced spleen size and bone marrow fibrosis in JAK2V617F and MPLW515L murine models of myelofibrosis.[3] TP-3654 is currently being evaluated in a Phase 1/2 study of oral TP-3654 in patients with intermediate and high-risk myelofibrosis (NCT04176198). The Food and Drug Administration (FDA) granted Orphan Drug Designation for TP-3654 for the indication of myelofibrosis in May 2022.

**About Myelofibrosis**

Myelofibrosis is rare hematological malignancy with debilitating symptoms, splenic enlargement, cytopenia, and bone marrow fibrosis. The expression of PIM 1, which is known to contribute to cancer activation, is significantly elevated in hematopoietic cells from patients with myelofibrosis. It has been suggested to be a therapeutic target for myelofibrosis.

**About Sumitomo Pharma Oncology, Inc.**

Sumitomo Pharma Oncology, Inc. is a wholly owned subsidiary of Sumitomo Pharma Co., Ltd. As a global oncology organization with teams in the U.S. and Japan, SMP Oncology is committed to the goal of advancing purposeful science by transforming new discoveries into meaningful treatments for patients with cancer. SMP Oncology's robust and diverse pipeline of preclinical and clinical-stage assets spans multiple areas, including oncogenic pathways, survival mechanisms and novel protein interactions, which aim to address unmet clinical needs in oncology. For more information, visit www.oncology.sumitomo-pharma.com.

**About Sumitomo Pharma Co., Ltd.**

Sumitomo Pharma Co., Ltd. is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries with about 6,000 employees worldwide. Sumitomo Pharma Co., Ltd. defines its corporate mission as "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." Additional information about Sumitomo Pharma Co., Ltd. is available through its corporate website at https://www.sumitomo-pharma.com.

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**References**

1. Firas El Chaer, MD, Lindsay Rein, et al. Preliminary Data From the Phase 1/2 Study Of TP-3654, an Investigational Selective Pim1 Kinase Inhibitor, Showed Cytokine Reduction and Clinical Responses in Relapsed/Refractory Myelofibrosis. European Hematology Association (EHA) 2023 Hybrid Congress. 09 June 2023.
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.
3. Nath D, Yang Y, Dutta A, Whatcott C. The PIM kinase inhibitor TP-3654 in combination with ruxolitinib exhibits marked improvement of myelofibrosis in murine models. Blood. 2018. 132(suppl 1):54. doi:10.1182/blood-2018-99-119421

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