



## **Promedior Presents Additional Positive Phase 2 Data for PRM-151 in Myelofibrosis at EHA Annual Meeting**

*Data demonstrate significant reduction in bone marrow fibrosis  
associated with improvements in bone marrow morphology and increased platelet counts*

Lexington, Mass., June 12, 2015 — [Promedior](#), Inc., today announced positive bone marrow fibrosis data from Stage 1 of an adaptive two-stage Phase 2 trial of PRM-151, a novel anti-fibrotic immunotherapy, in patients with myelofibrosis. These newly-presented data demonstrate a reduction of bone marrow fibrosis in 72 percent of patients receiving PRM-151 according to Computer Image Analysis (CIA), which was highly correlated with, but more sensitive than, the WHO myelofibrosis grade. Reduction in bone marrow fibrosis in patients receiving PRM-151 was associated with other improvements in bone marrow morphology, as well as increased platelet counts and increased hemoglobin. In this study, 57 percent of thrombocytopenic patients receiving PRM-151 saw an improvement in their platelet counts. These study results were described in a poster presentation at the 20<sup>th</sup> Congress of the European Hematology Association in Vienna, Austria.

“These important data provide more evidence that PRM-151 reduces fibrosis in the bone marrows of patients with advanced myelofibrosis, and that reduction in fibrosis is associated with improvements in hematologic parameters, particularly platelet counts,” said Srdan Verstovsek, MD, PhD, Professor, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and Principal Investigator for this Phase 2 trial. “Thrombocytopenia remains a significant problem for many patients with myelofibrosis, and a new treatment that is not myelosuppressive and actually increases platelet counts would be of great benefit to patients.”

“We are very excited by the results of the quantitative image analysis, which correlates with, but is potentially more precise than, morphologic grading in assessing the reduction of fibrosis in bone marrows of patients after PRM-151 treatment,” said Elizabeth G. Trehu, MD, Chief Medical Officer of Promedior. “The compelling rate of fibrosis reduction in these patients further validates the potential of PRM-151 to reduce and reverse fibrosis in numerous fibrotic diseases.”

The results of bone marrow and related analyses reported at EHA augment the [results previously reported](#) across a number of myelofibrosis parameters at the American Society of Hematology Annual Meeting in December 2014. In these updated data, 27 patients with Primary Myelofibrosis (MF), post-Polycythemia Vera MF, or post-Essential Thrombocythemia MF and  $\geq$  Grade 2 bone marrow fibrosis received PRM-151 10 mg/kg IV dosed weekly (n=8) or monthly (n=7), or ruxolitinib plus PRM-151 10 mg/kg IV dosed weekly (n=6) or monthly (n=6). Morphologic analysis was performed on serial bone marrow specimens from 25 patients by two hematopathologists blinded to patient, treatment, and time point. The fibrosis responders group had reduced collagen (p=0.0062) and a trend toward other features indicative of an improving marrow microenvironment at the last time point compared to the fibrosis non-responder group. CIA, which was performed on whole slide scans from serial bone marrow specimens from patients at the same time points as the morphologic analysis, revealed statistically significant decreased fibrosis in all treated samples (p=0.0003). Reductions in fibrosis by CIA were highly correlated with reduction in MF grade and increased platelet count

in thrombocytopenic patients treated with PRM-151. Data show that bone marrow fibrosis grade is correlated with anemia, thrombocytopenia, peripheral blasts and shortened survival<sup>1, 2</sup>.

The ongoing Phase 2 trial is a multi-center, two stage, adaptive design study to determine the efficacy and safety of PRM-151 as a single agent or added to a stable dose of ruxolitinib in patients with Primary Myelofibrosis (PMF), Post-Polycythemia Vera MF (post-PV MF), or Post-Essential Thrombocythemia MF (post-ET MF). Twenty seven patients were enrolled in Stage 1 of the study, and 84 additional patients will be enrolled in Stage 2.

Participating investigators in the PRM-151 Phase 2 study include Srdan Verstovsek, MD, PhD (University of Texas MD Anderson Cancer Center, Principal Investigator for this Phase 2 trial), Jason Gotlib, MD (Stanford University), Ruben Mesa, MD (Mayo Clinic, Scottsdale), Vikas Gupta, MD (Princess Margaret Cancer Centre), John Mascarenhas, MD (Icahn School of Medicine at Mt. Sinai Hospital), Ronald Hoffman, MD (Icahn School of Medicine at Mt. Sinai Hospital), Ellen Ritchie, MD (Weill Cornell Medical College of Cornell University), Richard Silver, MD (Weill Cornell Medical College of Cornell University), and Lynda Foltz, MD (University of British Columbia). For additional details about this clinical trial, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Myelofibrosis**

Myelofibrosis (MF), a type of myeloproliferative neoplasm, is a serious, life-limiting cancer that is characterized by fibrosis of the bone marrow. Replacement of the bone marrow by scar tissue prevents the normal production of blood cells, leading to anemia, fatigue, and increased risk of bleeding and infection. Data show that bone marrow fibrosis grade is correlated with anemia, thrombocytopenia, peripheral blasts and shortened survival<sup>1,2</sup>.

Myelofibrosis affects approximately 18,000 people per year in the U.S., with a median age of 61-66<sup>3</sup>. The only potentially curative treatment is allogeneic bone marrow transplant, which results in reversal of fibrosis and normalization of blood counts, but is a realistic option for only a small number of patients. Other currently available therapies have minimal, if any, impact on the underlying fibrosis, and often result in worsening in hemoglobin and platelets, important blood parameters which are directly linked to morbidity and mortality and remain the major unmet need in patients with myelofibrosis.

### **About PRM-151**

PRM-151 is recombinant human Pentraxin-2, an endogenous protein that regulates monocytes and macrophages at areas of tissue damage to prevent and reverse fibrosis. PRM-151 has shown broad anti-fibrotic activity in multiple preclinical models of fibrotic disease, including pulmonary fibrosis, acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration.

In addition to the clinical study in myelofibrosis, a Phase 1b study in patients with idiopathic pulmonary fibrosis (IPF) showed [encouraging results](#) in exploratory efficacy endpoints, which were presented in an oral session at the 2013 Annual Meeting of the American Thoracic Society<sup>4</sup>.

PRM-151 has Fast Track and Orphan designation in the US for treatment of myelofibrosis and Orphan Designation in the US and EU for treatment of IPF.

#### **About Promedior**

[Promedior](#) is a clinical-stage immunotherapy company pioneering the development of targeted therapeutics to treat diseases involving fibrosis. Fibrosis occurs when healthy tissue is replaced with excessive scar tissue, compromising function and ultimately leading to organ failure. Fibrosis is a common feature of several rare diseases as well as more prevalent illnesses such as age related macular degeneration, diabetic nephropathy, nonalcoholic steatohepatitis (NASH), and several types of solid tumors.

Promedior has advanced its lead program (PRM-151) into clinical trials focused on two orphan fibrotic diseases, myelofibrosis and idiopathic pulmonary fibrosis. Promedior owns world-wide rights to PRM-151 and has a significant intellectual property estate.

For additional information about Promedior, please visit [www.promedior.com](http://www.promedior.com).

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4. Van Den Blink, B. et al., "A Phase I Study Of PRM-151 In Patients With Idiopathic Pulmonary Fibrosis", American Thoracic Society 2013 Annual Meeting, May 2013. Read More: [http://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2013.187.1\\_MeetingAbstracts.A5707](http://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2013.187.1_MeetingAbstracts.A5707)

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