



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

*Data demonstrate reduction in bone marrow fibrosis along with improvements in hemoglobin and platelets*

*Overall response rate surpassed pre-specified efficacy criteria to move to next stage of study*

Lexington, Mass., December 9, 2014 — [Promedior](#), Inc., today announced positive data from Stage 1 of an adaptive two-stage Phase 2 trial of PRM-151, a novel anti-fibrotic immunotherapy, in patients with myelofibrosis. The overall response rate (ORR), defined as IWG-MRT<sup>1</sup> (International Working Group-Myeloproliferative Neoplasms Research and Treatment) responses or reduction in bone marrow fibrosis, was 43 percent at 6 months, surpassing the pre-specified efficacy criteria necessary to proceed to the next stage of Promedior's Phase 2 trial. Data presented at the American Society of Hematology (ASH) meeting demonstrate reduction of bone marrow fibrosis by at least one grade observed in 42 percent of patients which was associated in most patients with improvements in anemia and/or thrombocytopenia and, in some patients, by transfusion independence lasting at least 24 weeks. Bone marrow fibrosis grade is correlated with anemia, thrombocytopenia, peripheral blasts and shortened survival<sup>2,3</sup>. These study results were presented in an oral presentation by principal investigator Srdan Verstovsek, MD, PhD, at the ASH 2014 Annual Meeting on December 8, 2014.

"We are encouraged by the favorable safety profile and clinical activity of PRM-151 demonstrated in the first stage of this trial, and are excited to see that a reduction of bone marrow fibrosis by PRM-151 is associated with signs of improved hematopoiesis," 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. "There is tremendous enthusiasm for PRM-151 among investigators and patients, and we look forward to moving forward with Stage 2 of this important clinical trial."

"These promising clinical data in myelofibrosis patients highlight the differentiated benefits of PRM-151, showing an unprecedented rate of reversing bone marrow fibrosis. Further, by validating PRM-151's novel mechanism of action to reverse fibrosis, this study demonstrates the broad potential in a range of other fibrotic diseases," said Suzanne L. Bruhn, PhD, President and Chief Executive Officer of Promedior. "We will continue to move PRM-151 forward as a new treatment option for patients with myelofibrosis and other fibrotic diseases. We expect to initiate the next stage of PRM-151's Phase 2 clinical program in myelofibrosis in the first half of 2015."

In the first stage of this two-stage Phase 2 trial, 11 out of 25 evaluable patients had reduction in bone marrow fibrosis by at least one grade, and 10 of 21 patients with baseline Hgb < 100 g/L or platelet count < 100x10<sup>9</sup>/L had substantial increases in hemoglobin and/or platelets accompanied by transfusion independence lasting at least 24 weeks in some patients. Improvements in symptoms, including 4 IWG-MRT Clinical Improvement Symptom responses, were also observed, along with modest reductions in splenomegaly. Improvements were observed in all four independent treatment groups of myelofibrosis patients who received PRM-151 weekly or monthly and as either a single agent or in patients showing no further improvements on a stable

dose of ruxolitinib. PRM-151 was safe and well tolerated on weekly and monthly dosing schedules, both alone and in combination with ruxolitinib, with no evidence of myelosuppression. Most adverse events were Grade 1 or 2 and most were considered unrelated to PRM-151. Fourteen patients are continuing treatment in a study extension, and clinical benefits appear to be increasing with longer treatment duration.

This 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, 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>2,3</sup>.

Myelofibrosis affects approximately 18,000 people per year in the U.S., with a median age of 61-66<sup>4</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 MF.

### **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>5</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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