



**Promedior to Present Positive Preliminary Phase 2 Data for PRM-151 in Myelofibrosis
at ASCO Annual Meeting**

Data showed improvements in patients across all treatment groups with excellent safety profile

Anti-fibrotic immunotherapy approach with PRM-151 showed clinical activity as single agent and in combination with ruxolitinib

Lexington, Mass., May 30, 2014 — [Promedior](#), Inc., today announced positive preliminary data from its Phase 2 trial of PRM-151, an anti-fibrotic immunotherapy, in patients with myelofibrosis which demonstrated biologic activity with improvements across clinically relevant measures, including bone marrow fibrosis, hemoglobin, platelets, spleen, and symptoms. Clinical data showed improvements in four independent treatment groups of myelofibrosis patients who received PRM-151 weekly or monthly, either as a single agent or in patients with no further improvements on a stable dose of ruxolitinib¹. Importantly, PRM-151 demonstrated safety and tolerability both alone and in combination with ruxolitinib, with no evidence of the myelosuppression commonly observed with other treatments. Study results will be presented at the American Society for Clinical Oncology (ASCO) 2014 Annual Meeting on June 2, 2014, at 1:15-5:00 pm CT, in S Hall A2.

“These early clinical data with PRM-151 in patients with myelofibrosis are encouraging, and demonstrate the potential of the compound’s novel mechanism of action,” 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. “The improvements seen in patients who have either progressed on JAK inhibitors or were deriving no further benefit from ruxolitinib speaks to the need for new therapies that target fundamental mechanisms of the disease.”

“These findings are very promising and we are particularly excited to see improvements in bone marrow pathology in myelofibrosis patients receiving PRM-151. We believe PRM-151’s ability to precisely target the fundamental fibrotic pathology validates its broad potential to treat and reverse fibrosis in a wide range of fibrotic diseases,” said Suzanne L. Bruhn, PhD, President and Chief Executive Officer of Promedior. “We will continue to work to move as quickly as possible to bring PRM-151 forward as a potential new treatment option for patients with fibrotic diseases which have few, if any, treatment options today.”

The preliminary Phase 2 data for PRM-151 were presented for 27 patients with myelofibrosis, 18 of whom completed 24 weeks of therapy. PRM-151 demonstrated a 50% reduction in symptoms according to the MPN-SAF² Total Symptom Score in 7 patients, 5 of which have persisted for ≥ 12 weeks and are therefore confirmed IWG-MRT³ Clinical Improvement symptom responses; 5 reductions in bone marrow fibrosis by ≥ 1 grade, with 2 of 3 patients confirmed 12 weeks later and 2 patients pending confirmatory biopsy; a $\geq 20\%$ reduction in spleen volume reduction in 5 patients with one 50% reduction lasting 8 weeks; and improvements in hemoglobin and platelets. Each treatment group demonstrated improvements that met the pre-specified efficacy criteria for further exploration of PRM-151 in the second stage of this adaptive

Phase 2 trial. Fifteen out of 18 patients who have completed the 24 week study are continuing treatment in a study extension.

In this study, 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 observed in the study were Grade 1 or 2 and considered unrelated to PRM-151. Overall, there were 14 severe adverse events (SAEs) in 5 study patients, including 3 deaths, 2 from pneumonia and 1 from progressive multi-organ failure. Other SAEs were abdominal pain, bone marrow biopsy site hematoma, sialadenitis, gastroenteritis and respiratory syncytial virus. The Company expects to report the complete first stage results of this ongoing Phase 2 study by the end of 2014.

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). 27 patients were enrolled in the first stage of the study; up to 80 additional patients will be enrolled in the second stage.

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.

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. Production of blood cells shifts to the spleen and liver (extramedullary hematopoiesis), which become enlarged, causing severe discomfort, inability to eat, and weakness. Symptomatic myelofibrosis affects approximately 18,000 people per year in the US, with a median age of 61-66.⁴ The only potentially curative treatment is allogeneic bone marrow transplant, which results in reversal of fibrosis and all symptoms, but is a realistic option for only a small number of patients. Other currently available therapies address the symptoms, but have minimal if any impact on the underlying fibrosis.

About PRM-151

PRM-151, Promedior's lead product candidate, is a recombinant form of an endogenous human protein, Pentraxin-2 (PTX-2), that is specifically active at the site of tissue damage. PRM-151 is an agonist that acts as a monocyte/macrophage differentiation factor to prevent and potentially 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.

Phase 1a and 1b clinical studies in healthy subjects and IPF patients have demonstrated that PRM-151 was well tolerated. Additionally, a Phase 1b study in patients with IPF showed [encouraging results](#) in exploratory efficacy endpoints, which were presented in an oral session at the 2013 Annual Meeting of the American Thoracic Society⁵. Recent clinical data in myelofibrosis demonstrated the potential of this immuno-oncology approach in fibrotic cancers.

About Promedior

[Promedior](#) is a clinical stage biotechnology company pioneering the development of targeted therapeutics to treat diseases involving fibrosis. Fibrosis is a harmful process that occurs in many diseases, when normal healthy tissue is replaced with excessive scar tissue, compromising function and ultimately leading to organ failure. Promedior's proprietary platform is based upon Pentraxin-2, an endogenous human protein that is specifically active at the site of tissue damage and, with an anti-fibrotic immunotherapy approach, works to prevent and reverse fibrosis.

Promedior has successfully advanced its lead therapeutic candidate in human clinical trials, and is initially focused on rare fibrotic diseases, including myelofibrosis and idiopathic pulmonary fibrosis (IPF). Promedior is backed by leading global healthcare venture investors, has a significant intellectual property estate relating to the discoveries and applications of Pentraxin-2 therapeutics and is led by an experienced management team. For additional information about Promedior, please visit www.promedior.com.

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1. Ruxolitinib is available under the trade names JAKAFI® and JAKAVI®, which are the registered trademarks of Incyte and Novartis, respectively.
2. Emanuel, R.M. et al., "Myeloproliferative Neoplasm (MPN) Symptom Assessment Form Total Symptom Score: Prospective International Assessment of an Abbreviated Symptom Burden Scoring System Among Patients with MPNs," J Clin Oncol 30:4098-4103; 2012.
3. Tefferi, A., et al., "Revised Response Criteria for Myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report," Blood 122(8): 1395-8; 2013.

4. Mehta, J., Wang, H., Iqbal, S. U., Mesa, R., "Epidemiology of myeloproliferative neoplasms in the United States", *Leukemia & Lymphoma*, Early Online: 1-6, 2013.
5. 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/airccm-conference.2013.187.1_MeetingAbstracts.A5707