



Promedior Announces Initiation of a Phase 2 Clinical Study of PRM-151 in Idiopathic Pulmonary Fibrosis (IPF)

Study will evaluate the efficacy and safety PRM-151, a novel investigational anti-fibrotic immunomodulator

Lexington, Mass., September 8, 2015 — [Promedior](#), Inc., today announced the initiation of a Phase 2 trial of PRM-151, a novel investigational anti-fibrotic immunomodulator, in patients with Idiopathic Pulmonary Fibrosis (IPF). This randomized, double-blind, placebo-controlled Phase 2 study is designed to determine the efficacy and safety of PRM-151 in approximately 117 patients with IPF. Promedior is initiating this Phase 2 study of PRM-151 in patients with IPF based on data from both the Company's Phase 1b study of PRM-151 in patients with IPF and a Phase 2 study in patients with myelofibrosis.

"We are thrilled to initiate our Phase 2 study in IPF, which is based on the Phase 1b clinical data that was presented in an oral session at the American Thoracic Society 2013 Annual Meeting and a poster at the International Colloquium on Interstitial Lung Diseases in 2014," said Elizabeth G. Trehu, MD, FACP, Chief Medical Officer of Promedior. "We are investigating PRM-151's novel mechanism of action in a larger and more robust trial to determine if PRM-151 will make a meaningful difference to patients with IPF."

"Despite the recent approval of two new therapies for IPF, there is still a great need for a treatment that reverses lung fibrosis and improves pulmonary function," said Ganesh Raghu, MD, FACP, FCCP, Adjunct Professor, Laboratory Medicine Division of Pulmonary and Critical Care Medicine and Director, Interstitial Lung Disease/Sarcoid/Pulmonary Fibrosis Program at University of Washington, and co-Principal Investigator of this Phase 2 study.

"I am very enthusiastic about this Phase 2 trial," said Bernt van den Blink, MD, PhD, of Erasmus Medical Center, Principal Investigator of the Phase 1b study of PRM-151 in IPF and co-Principal Investigator of the current study. "I am delighted to have enrolled the first patient in this important study."

PRM-151 targets the underlying fibrotic pathology of IPF. A randomized, double-blind, placebo controlled Phase 1b multiple ascending dose study of PRM-151 in patients with IPF assessed changes in Forced Vital Capacity (FVC), and changes in interstitial lung disease features were explored retrospectively by quantitative imaging analysis of high resolution CT (HRCT). Data from the company's Phase 1b study in patients with IPF have been presented at an oral session at the [2013 Annual Meeting of the American Thoracic Society](#) (ATS) and at [the 18th International Colloquium on Lung and Airway Fibrosis](#) (ICLAF).

Phase 2 Study Design

The Phase 2 trial is a multi-center, randomized, double-blind, placebo-controlled study to determine the efficacy and safety of PRM-151 as compared to placebo in patients with IPF. The study will include patients currently receiving pirfenidone or nintedanib and patients on no other treatment for IPF. IPF patients

included in the study will be randomized 2:1 to PRM-151 at a dose of 10 mg/kg every 4 weeks or placebo. Efficacy will be evaluated through pulmonary function tests (PFTs) including FVC, quantitative imaging analysis of HRCT, six minute walk test (6MWT), and patient reported outcomes (PROs). The study's primary objective will be to determine the effect of PRM-151 relative to placebo in change from baseline in lung function (as measured by mean FVC% predicted). Safety will be evaluated by adverse events, physical exam, clinical labs and IPF related mortality. Patients in the study will receive PRM-151 or placebo for a minimum of 24 weeks, and all patients will be offered the opportunity to receive PRM-151 after 24 weeks in an open label extension study.

This Phase 2 study of PRM-151 in patients with IPF is planned at centers in the US, UK, Netherlands, Belgium, Spain, Germany, the Czech Republic, Hungary, and Poland. For a listing of open clinical sites and additional details about this clinical trial, please visit www.clinicaltrials.gov.

About Idiopathic Pulmonary Fibrosis

Idiopathic Pulmonary Fibrosis (IPF) is a serious, life-threatening lung disease characterized by fibrosis and scarring of the lung tissue. Replacement of normal lung tissue by scar tissue results in restriction in the ability to fill the lungs with air and decreased transfer of oxygen from inhaled air into the bloodstream. This decreased oxygen transfer results in lower oxygen delivery to the brain and other organs, and produces symptoms of shortness of breath, particularly with exertion; chronic, dry, hacking cough; fatigue and weakness, chest discomfort, loss of appetite and rapid weight loss. While estimates vary, it is believed that IPF could affect approximately 130,000 patients in the USⁱ and approximately 76,000 patients in Europe.ⁱⁱ There is no curative therapy, and the only treatment that results in significant improvement is lung transplant.

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 which is being investigated for prevention and potentially reversal of 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.

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

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.

In August, 2015, [Bristol-Myers Squibb Company](#) and [Promedior, Inc.](#) announced an agreement that grants Bristol-Myers Squibb an exclusive right to acquire Promedior and gain worldwide rights to PRM-151. Under the terms of the agreement, Bristol-Myers Squibb will make payments aggregating up to \$1.25 billion that includes an upfront cash payment of \$150 million as consideration for both the right to acquire Promedior and as payment for services in support of the MF and IPF Phase 2 clinical trials.

For additional information about Promedior, please visit www.promedior.com.

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ⁱ Raghu, G., et al. "Incidence and prevalence of idiopathic pulmonary fibrosis." *Am. J. Respir. Crit. Care Med.* 2006. **174(7)**: 810-816

ⁱⁱ European Medicines Agency. "Positive Opinion on orphan designation for recombinant human pentraxin-2 in idiopathic pulmonary fibrosis" , July 17, 2012
(http://www.emea.europa.eu/ema/index.jsp?curl=pages/medicines/human/orphans/2012/08/human_orphan_001096.jsp&mid=WC0b01ac058001d12b)