



## **Promedior Announces Presentation of Retrospective Quantitative Imaging Analysis of Phase 1b Data in Idiopathic Pulmonary Fibrosis**

*Correlation between two complimentary imaging techniques with improvements in pulmonary function provides opportunity for accelerated clinical development*

Lexington, Mass., September 22, 2014 — [Promedior](#), Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced that retrospective quantitative imaging data from the Company's Phase 1b clinical trial of PRM-151, for the treatment of idiopathic pulmonary fibrosis (IPF), was presented in a poster at the 18<sup>th</sup> International Colloquium on Lung and Airway Fibrosis (ICLAF), which is being held in Mont Tremblant, Quebec, Canada, from September 20-24, 2014. The data show that changes seen with structural and functional imaging of IPF patient's lungs generally correlate with and appear complementary to pulmonary function tests. Both methods showed correlation with increases in Forced Vital Capacity (FVC) % predicted, normal lung, and lobar volumes in some subjects treated with PRM-151. In all placebo patients, decreases in both FVC % predicted and normal lung were observed, with decreased lobar volumes in some patients.

With a novel mechanism of action that is targeted to prevent and reverse fibrosis, PRM-151 has the potential to address the fundamental fibrotic pathology of IPF. Retrospective analyses of High Resolution CTs (HRCT) from the Phase 1b study assessed both volumetric quantification of interstitial lung abnormalities (ILA) and lobar volumes. The data support prospective use of these imaging techniques as biomarker endpoints to provide a more robust signal determination to support rapid development and require fewer patients in future clinical trials of PRM-151 in IPF.

Details of the poster presentation at ICLAF are as follows:

**Title:** Structural and Functional Quantitative Imaging Techniques are Complimentary in Retrospective Analysis of PRM-151 Data in Idiopathic Pulmonary Fibrosis (IPF)  
**Time:** September 21-22, 2014  
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The Phase 1b clinical trial was a randomized, double-blind, placebo-controlled study in 21 patients with IPF. In the study, PRM-151 doses of 1, 5 and 10 mg/kg or placebo were administered intravenously on days 1, 3, 5, 8 and 15. Patients were followed for 57 days after receiving their first dose. The study's primary endpoint was safety and tolerability, and PRM-151 was shown to be generally safe and well tolerated across all study participants, with no serious adverse events. Additionally, the clinical study measured exploratory clinical

endpoints, including Forced Vital Capacity (FVC), Diffusion Capacity of the Lung for Carbon Monoxide (DLCO), six minute walk test, quality of life, and several biomarkers of 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 is generally 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 Society<sup>i</sup>. Recent [clinical data in myelofibrosis](#) demonstrated the potential of this immuno-oncology approach in fibrotic cancers. PRM-151 has Orphan Designation in the US and EU for treatment of IPF and in the US for the treatment of myelofibrosis.

### **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 US<sup>ii</sup> and approximately 76,000 patients in Europe.<sup>iii</sup> There is no curative therapy, and the only treatment that results in significant improvement is lung transplant.

### **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](http://www.promedior.com).

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<sup>i</sup> 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)

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

<sup>iii</sup> 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](http://www.emea.europa.eu/ema/index.jsp?curl=pages/medicines/human/orphans/2012/08/human_orphan_001096.jsp&mid=WC0b01ac058001d12b))