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## **Promedior Initiates Clinical Study of Anti-Fibrotic Therapeutic, PRM-151, in Patients with Idiopathic Pulmonary Fibrosis (IPF)**

*First-In-Class Pentraxin Therapeutic Has Novel Mechanism for Treating Fibrotic Diseases*

MALVERN, Pa.--([BUSINESS WIRE](#))-- Promedior, Inc., a clinical stage biotechnology company developing novel therapies to treat fibrotic and inflammatory diseases, announced today that it has initiated a Phase 1b clinical study of PRM-151 to explore the safety, tolerability, pharmacokinetics, and pharmacodynamics of PRM-151 in the treatment of patients with idiopathic pulmonary fibrosis (IPF). The study will be conducted at sites in the United States and Europe. There currently are no approved anti-fibrotic drug therapies in the United States or Europe for any fibrotic disease, including IPF.

Promedior's lead product, PRM-151, is a recombinant form of a naturally circulating human protein, Pentraxin-2 (PTX-2), that regulates a fundamental mechanism of the innate immune system and activates the body's natural ability to resolve tissue damage in disease processes that cause fibrosis and inflammation. PRM-151 has shown broad anti-fibrotic and anti-inflammatory activity in multiple preclinical models of fibrotic disease and inflammation, including pulmonary fibrosis, kidney fibrosis, and glaucoma. Promedior successfully completed a Phase 1a clinical study of PRM-151 in healthy volunteers and pulmonary fibrosis patients in 2010.

"We are excited to advance PRM-151 into this clinical study in patients with IPF, as we believe that PRM-151 represents a novel and powerful first-in-class agent to prevent and treat a wide variety of serious fibrotic diseases, including IPF," said Dominick Colangelo, President and Chief Executive Officer of Promedior. "This is the third clinical trial for our anti-fibrotic platform, and builds upon our recently completed Phase 1a study in which we observed positive effects of PRM-151 on IPF patient biomarkers associated with disease pathology and progression. Looking forward, we are making rapid progress in the clinic in multiple disease indications, and we expect to initiate a third clinical program of PRM-151 in an additional ophthalmology indication in 2011."

The multicenter, multinational, randomized, double-blind, placebo controlled, ascending multiple-dose Phase 1b study will primarily assess the safety, tolerability, pharmacokinetics and pharmacodynamics of PRM-151 administered intravenously to patients with IPF. Pharmacodynamic indications of PRM-151's potential therapeutic

efficacy will be explored throughout the study by assessment of specific plasma protein biomarkers and whole blood fibrocyte content, which have been associated with IPF pathology and disease progression. Pulmonary function data and six-minute walk distance will also be collected.

PRM-151 currently is being tested in a Phase 2a clinical study to evaluate the efficacy, safety, and tolerability of PRM-151 in preventing post-surgical scarring in glaucoma patients following glaucoma filtration surgery. PRM-151 was granted Orphan Medicinal Product Designation by the European Commission in September 2009 for use in the prevention of scarring post glaucoma filtration surgery.

## **About IPF**

Idiopathic pulmonary fibrosis (IPF) is a progressive, debilitating and fatal disease that affects approximately 200,000 people in Europe and the United States combined, with approximately 30,000 new cases reported annually in each region.

IPF is characterized by inflammation and fibrosis in the lungs, hindering the ability to process oxygen and causing shortness of breath. IPF is a progressive disease, meaning that over time, lung scarring and related respiratory symptoms increase in severity. The median survival time from diagnosis is two to five years, with a five-year survival rate of approximately 20%. There are no medicines approved in the United States or Europe for the treatment of IPF.

## **About Pentraxin Therapeutics**

Promedior's proprietary platform of pentraxin therapeutics is based upon breakthrough discoveries in how the body's innate response to injury results in pathologic fibrosis and the loss of tissue and organ function. Promedior's novel therapeutics are designed to treat and prevent fibrotic pathology by regulating the common cellular mechanisms that control the initiation and progression of fibrosis across a variety of tissues and organ systems. Promedior's initial drug products are based upon the unique structure of Pentraxin-2, a naturally-occurring protein which has demonstrated a unique role in targeting monocytes at sites of tissue damage. Promedior's approach leverages the natural role of Pentraxin-2 in regulating the response of important immune and inflammatory processes in the body. Promedior has built a comprehensive patent estate for Pentraxin therapeutics, including recombinant human Pentraxin-2 (rhPTX2 or rhSAP), for a broad range of therapeutic applications in fibrosis and other inflammatory diseases.

## **About Promedior**

Promedior has developed a novel drug discovery platform to regulate the monocyte-derived cell populations that play key roles in fibrotic, inflammatory and autoimmune diseases. By specifically targeting these cells at the site of injury, Promedior is able to

treat the source of aberrant immune system responses, promote tissue healing and resolution, and greatly reduce the risk of systemic side effects inherent in current therapeutic approaches. Utilizing this novel approach, Promedior is initially developing drugs to address the most severe and difficult-to-treat fibrotic and inflammatory conditions of the eye, lung and kidney such as glaucoma, age-related macular degeneration, and diabetic retinopathy (eye); pulmonary fibrosis, scleroderma and COPD (lung); and acute and chronic nephropathy (kidney). For additional information about Promedior, please visit <http://www.promedior.com>.