

Promedior Receives U.S. Orphan Drug Designation for PRM-151 for the Treatment of Idiopathic Pulmonary Fibrosis (IPF)

PRM-151 in Phase 1b Clinical Study in IPF Patients

MALVERN, PA, March 7, 2012 – [Promedior](#), Inc., a clinical stage biotechnology company developing novel biologic therapeutics for the treatment of fibroproliferative diseases, today announced that the United States Food and Drug Administration (FDA) Office of Orphan Products Development has granted an Orphan Drug designation to Promedior's lead drug candidate, PRM-151, for the treatment of idiopathic pulmonary fibrosis (IPF). There are currently no FDA approved treatments for IPF, a progressive, debilitating and fatal disease that affects approximately 200,000 people in Europe and the United States combined.

Promedior is developing PRM-151 for the treatment of rare systemic fibrotic diseases such as idiopathic pulmonary fibrosis (IPF) and myelofibrosis. PRM-151 is a recombinant form of human Pentraxin-2 (rhPTX-2), a naturally circulating human protein that treats fibrosis by regulating the monocyte-derived cells (macrophages and fibrocytes) that control the fibrotic process. In a Phase 1 clinical study, PRM-151 was shown to be generally safe and well tolerated. In a subset of Phase 1 study participants with IPF, PRM-151 showed activity against efficacy biomarkers through reductions in IPF-related blood fibrocytes levels and serum IL-6 levels. PRM-151 currently is being tested in a Phase 1b clinical study in IPF patients to evaluate its safety, tolerability and biological activity on exploratory pharmacodynamic and prognostic biomarkers of IPF progression.

Under the Orphan Drug Act, FDA's Office of Orphan Products Development can grant orphan designation to drug candidates that meet certain criteria, including treatment of diseases with small patient populations and unmet medical needs, such as IPF. Orphan designation of PRM-151 for IPF qualifies Promedior for certain commercial and marketing incentives.

"Obtaining the Orphan Drug designation for PRM-151 is a noteworthy achievement for Promedior, as it validates the significant therapeutic potential of PRM-151 for the treatment of IPF and other serious fibrotic diseases," said Dominick Colangelo, President and Chief Executive Officer of Promedior. "This designation positions Promedior to continue the rapid development of PRM-151 for the treatment of rare systemic fibrotic diseases, which represent many of the greatest unmet needs in medicine today."

About PRM-151

PRM-151 (rhPTX-2) is a recombinant form of human Pentraxin-2, an endogenous human protein that regulates monocyte-derived cells (macrophages and fibrocytes) that control the fibrotic process and drive pathologic neovascularization. Pentraxin-2 therapeutics have broad therapeutic potential across a variety of important unmet medical conditions, including rare systemic diseases, such as IPF and myelofibrosis, as well as fibrotic complications of diabetes and obesity, such as diabetic retinopathy, diabetic nephropathy and non-alcoholic steatohepatitis (NASH). Promedior and its collaborators have demonstrated the therapeutic activity of Pentraxin-2 in numerous validated models of fibrotic and neovascular disease, confirming the potential of Pentraxin-2 therapeutics to treat fibrovascular diseases across all

major tissue types, including lung, eye, kidney, heart, liver and several others. With a novel mechanism of action that is highly differentiated from other approaches to treat fibrosis, Promedior's Pentraxin-2 therapeutics offer the potential to effectively reverse fibrotic disease processes and promote normal healing.

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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 per year 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 percent. There are no medicines approved in the United States for the treatment of IPF.

About Promedior

[Promedior](http://www.promedior.com) is a clinical-stage biotechnology company developing a pipeline of novel Pentraxin-2 therapeutics for the treatment of fibrovascular diseases. Pentraxin-2 therapeutics treat fibrovascular diseases by naturally regulating monocyte-derived cells (macrophages and fibrocytes) that control the fibrotic process and drive pathologic neovascularization. Based on a unique [mechanism of action](#), Pentraxin-2 localizes to sites of tissue damage and stimulates monocytes to differentiate into regulatory macrophages rather than pro-fibrotic macrophages and fibrocytes, thereby reversing inflammatory, fibrotic and neovascular processes and promoting normal healing. By acting upstream of these pathologic processes using a natural regulatory pathway, Pentraxin-2 therapeutics provide a superior therapeutic approach and an inherently safer profile. For additional information about Promedior, please visit <http://www.promedior.com>.

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