



NEWS & EVENTS: Press Releases

Promedior Announces Initiation of Phase 2a Clinical Study of Anti-Fibrotic Therapeutic, PRM-151, in the Prevention of Post-Surgical Scarring in Glaucoma Patients

First Pentraxin Therapeutic to Enter Clinical Efficacy Study has Novel Mechanism for Treating Fibrotic Diseases

MALVERN, PA – September 7, 2010 – Promedior, Inc., a clinical stage biotechnology company developing novel therapies to treat fibrotic and inflammatory diseases, announced today that it has initiated a Phase 2a clinical study of PRM-151 to evaluate the efficacy, safety, and tolerability of PRM-151 in preventing post-surgical scarring in glaucoma patients following glaucoma filtration surgery. There currently are no approved drugs for preventing post-surgical scarring in glaucoma, and there are no approved anti-fibrotic drug therapies in the U.S. or Europe for any fibrotic disease.

Promedior's lead product, PRM-151, is a recombinant form of a naturally circulating human protein, Pentraxin-2 (PTX-2, also called human SAP), 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 glaucoma, pulmonary fibrosis, and acute and chronic nephropathy. Promedior successfully completed a Phase 1 clinical study of PRM-151 earlier in 2010.

"The initiation of this clinical trial represents important progress for Promedior as we believe that PRM-151 represents a novel and powerful first-in-class agent to prevent and treat fibrotic diseases," said Dominick Colangelo, President and Chief Executive Officer of Promedior. "This study is designed to clearly demonstrate the anti-fibrotic activity of PRM-151 which we believe, based upon a common cellular immune mechanism across tissues and organs, may translate into potential therapeutic utility of PRM-151 in other ophthalmic surgical procedures and chronic eye diseases involving fibrosis, as well as other chronic systemic diseases such as pulmonary fibrosis and kidney fibrosis."

This multicenter, multinational, randomized, double-masked, placebo-controlled Phase 2 study is expected to enroll approximately 130 patients. The primary efficacy endpoints of the study will be improvement and maintenance of intraocular pressure and reduction in post-surgical scarring as assessed by optical coherence tomography (OCT) and a clinical assessment scale. PRM-151 will be administered as a subconjunctival injection at the end of surgery and at additional designated timepoints following 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. Beyond the current Phase 2a glaucoma surgery study, Promedior anticipates initiating a Phase 1b multiple-dose study in patients with idiopathic pulmonary fibrosis (IPF) and a Phase 1b study in a second ophthalmic indication within the next year.

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 Glaucoma Filtration Surgery

Glaucoma, one of the leading causes of blindness in the world, is a disease that affects the optic nerve and leads to progressive loss of vision. Glaucoma filtration surgery generally is used to treat patients with advanced glaucoma and persistently elevated intraocular pressure (IOP) that are at high risk for visual loss. Post-surgical scarring due to fibrotic disease processes is a serious complication that diminishes the effectiveness of glaucoma filtration surgery, resulting in the loss of IOP control and risk of progression to visual loss or blindness.

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, diabetic retinopathy and dry eye disease (eye); pulmonary fibrosis, scleroderma and COPD (lung); and acute and chronic nephropathy (kidney). For additional information about Promedior, please visit <http://www.promedior.com>.

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