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Promedior Presents Clinical Data for PRM-151 (rhPTX-2) in Idiopathic Pulmonary Fibrosis at American Thoracic Society 2011

Data Highlights Safety and Biomarker Activity in Patients with IPF

MALVERN, Pa.--(BUSINESS WIRE)-- Promedior, Inc., a clinical stage biotechnology company developing novel therapies to treat fibrotic and inflammatory diseases, presented data from a clinical study of PRM-151 (recombinant human Pentraxin-2 (PTX-2)) at the 2011 American Thoracic Society International Conference (ATS 2011). The poster presentation entitled ”The Effects Of Recombinant Human Pentraxin-2, (PRM-151), On Circulating Fibrocytes In Idiopathic Pulmonary Fibrosis (IPF)” included clinical data from a completed Phase 1 study of PRM-151 that evaluated comprehensive safety endpoints and exploratory biomarker activity in healthy subjects and IPF patients. Across all study participants, PRM-151 was shown to be generally safe and well tolerated; and in a subset of study participants with IPF, PRM-151 showed activity against efficacy biomarkers through reductions in IPF-related blood fibrocytes levels and serum IL-6 levels.

"We are excited to present data from this clinical study, which underscore the potential of PRM-151 as a novel and powerful first-in-class agent to treat IPF, one of the most serious and difficult-to-treat fibrotic diseases,” said Mark L. Lupher, Jr., Ph.D., Chief Scientific Officer. "Looking forward, we are making rapid clinical progress in a Phase 1b multiple dose trial of PRM-151 in IPF which we initiated earlier this year. We also are continuing our progress with additional clinical trials for our novel pentraxin therapeutics for other fibrotic diseases.”

The presentation at ATS 2011 summarized data from a randomized, double masked, placebo controlled study that was initially performed in 26 healthy human volunteers. In the study, single doses of PRM-151 from 0.1mg/kg to 20mg/kg were administered by intravenous injection. After completion of dosing of the healthy volunteers, three patients with idiopathic pulmonary fibrosis were administered a single dose of 10mg/kg intravenously to confirm the safety, pharmacokinetics, and to assess the pharmacodynamic effects of PRM-151, on serum cytokine and fibrocyte biomarkers.

Noteworthy results from the current study included:

- Single doses of PRM-151 up to 20mg/kg were safe and well tolerated in both healthy volunteers and IPF patients.
- There were no dose limiting adverse events and all adverse events were self limiting, and no severe or serious adverse events occurred.

- At the highest dose tested, PRM-151 levels increased dose dependently in healthy volunteers and raised baseline Pentraxin-2 levels at least tenfold. The safety and pharmacokinetics of the 10mg/kg dose were comparable in IPF patients with a 7 to 10 fold increase in baseline circulating levels of Pentraxin-2 after administration of a single 10mg/kg dose.
- Analysis of efficacy biomarkers comparing healthy volunteers and IPF patients showed a 50% reduction of CD45+/collagen-1+ fibrocytes within peripheral blood of all IPF patients at 24 hours, and fibrocytes remained suppressed for up to 21 days in the majority of patients. Analysis also indicated that elevated serum IL-6 levels observed at baseline in IPF patients decreased up to 50% ($P<0.05$) when measured 48 hours after PRM-151 dosing, the last serum sampling timepoint.

Fibrocytes and IL-6 are known to be at increased blood levels in IPF patients compared to healthy subjects. Importantly, increases in fibrocyte levels within IPF patients have been associated with acute exacerbation of disease, and high fibrocyte levels in IPF patients have been associated with increased mortality. Conversely, levels of Pentraxin-2, a potent suppressor of fibrocytes, have been shown to be decreased in IPF patients, and higher Pentraxin-2 levels in IPF patients have been associated with greater lung function. Therefore, these new data indicating that PRM-151 therapy can modulate fibrocyte levels in IPF patients is highly suggestive of a potential for therapeutic benefit with chronic dosing.

About PRM-151

PRM-151, Promedior's lead product, is a recombinant form of a naturally circulating human protein, Pentraxin-2 (PTX-2), that regulates a fundamental mechanism of the innate immune system response to injury and activates the body's natural ability to resolve tissue damage in disease processes that cause fibrosis, inflammation, and neovascularization. PRM-151 has shown broad anti-fibrotic and anti-inflammatory activity in multiple preclinical models of fibrotic disease and inflammation, including pulmonary fibrosis, acute and chronic nephropathy, glaucoma, age-related macular degeneration, diabetic macular edema and diabetic retinopathy.

PRM-151 is currently being tested in a Phase 1b clinical study in Idiopathic Pulmonary Fibrosis (IPF) to evaluate the safety, tolerability and dose-responsive changes in validated cellular and soluble biomarkers of disease activity. For further information about this trial, please go to http://www.clinicaltrials.gov/ct2/show/NCT01254409?term=PRM-151&rank=2, or e-mail clinicaltrials@promedior.com. PRM-151 is also 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.

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. Monocyte-derived cells have been shown to regulate inflammation and fibrosis as well as pathologic neovascularization. Promedior's approach leverages the natural role of Pentraxin-2 in regulating the response of these 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 and neovascular 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, autoimmune and neovascular 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.

Source: Promedior, Inc.