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Promedior Announces Publication of Preclinical Studies in Science Translational Medicine Demonstrating that hSAP Inhibits Kidney Fibrosis

MALVERN, Pa.--([BUSINESS WIRE](#))-- Promedior, Inc., a leader in the development of novel therapeutics for the treatment of fibrotic diseases and tissue remodeling, announced today the publication of results from preclinical studies demonstrating that human Serum Amyloid P (hSAP) potently inhibited fibrosis in two independent model systems of kidney fibrosis. The study results indicate a potential role for hSAP in treating kidney diseases such as diabetic nephropathy and transplant nephropathy where interstitial fibrosis plays a significant pathological role. The results are published in the November 4, 2009 issue of Science Translational Medicine, and confirm previously published data demonstrating the broad anti-fibrotic activity of SAP in models of pulmonary fibrosis and cardiac fibrosis.

Acute and chronic tissue injuries stimulate a primary innate injury response that is broadly similar across all tissues, including the kidney. These injuries are first recognized by the innate immune system through novel exposure and release by injured tissues of damage-associated molecular patterns, also known as danger molecules. Recognition of these danger molecules by the innate immune system activates monocyte-derived cell populations to orchestrate the injury response. Whether the outcome of this innate injury response is resolution of injury and restoration of normal tissue homeostasis or progressive fibrotic disease is controlled by the type of cell populations that are recruited to, and activated at, the site of injury.

In this collaborative research study led by Dr. Jeremy Duffield of the Brigham and Women's Hospital and Harvard Medical School, hSAP mediated its suppressive function by recognition of danger molecules on damaged cells and tissues at sites of injury. This recognition by hSAP was specific, Ca⁺⁺-dependent and caused hSAP and the attached danger molecules to bind to, and be cleared by, the Fcγ family of receptors (FcγRs) on macrophages. The result of this activity was that hSAP suppressed inflammatory and fibrotic gene and protein expression in monocyte-derived cells recruited to the injured tissue and potently blocked fibrosis, an effect that depended upon expression of the anti-inflammatory cytokine IL-10.

“These study results are encouraging and demonstrate that hSAP has the potential to block very aggressive fibrotic pathology caused by a variety of injuries,” said Mark Luper Jr., Ph.D., Senior Vice President, Discovery Research at Promedior. “This represents a novel approach to treating renal fibrosis as well as other monocyte-driven diseases. hSAP is unique in its ability to suppress multiple

monocyte-derived cell populations playing a pathogenic role in fibrosis, and to do so specifically at the site of injury.”

In the studies, hSAP was administered systemically to mice that received either unilateral ureteric obstruction or unilateral ischemia reperfusion mediated kidney injury. In both settings, hSAP potently suppressed fibrotic collagen protein and collagen gene expression and these effects were sustained throughout the duration of each study.

“We were very impressed with the robustness of the hSAP data, particularly at later time points in the study,” said Jeremy Duffield, M.D., Ph.D., Assistant Professor of Medicine, Brigham and Women’s Hospital and Harvard Medical School. “We typically don’t see such sustained responses with other anti-fibrotic approaches.”

Promedior’s lead product candidate, PRM-151 (rhSAP), is a recombinant form of human Serum Amyloid P, a highly conserved natural human serum protein that mediates its anti-fibrotic activity by targeting the specific monocyte and macrophage cell populations that orchestrate fibrosis and tissue remodeling. PRM-151 has demonstrated an outstanding safety profile and robust preclinical efficacy by reducing fibrosis in multiple tissues, organs, and disease models. Promedior initiated a Phase 1 clinical trial of PRM-151 in July 2009 to evaluate the safety, tolerability, pharmacokinetics and exploratory pharmacodynamics of ascending single intravenous doses of PRM-151.

About Promedior, Inc.

Promedior is a product-focused biopharmaceutical company developing novel therapeutics for the treatment of fibrotic diseases and tissue remodeling. Fibrosis is a key component of multiple diseases affecting all tissues and organ systems and is a leading cause of morbidity and mortality for millions of people worldwide. Promedior has developed a novel platform to treat fibrotic diseases which focuses on targeting the specific monocyte and macrophage cell populations that orchestrate fibrosis and tissue remodeling. This new paradigm for treating fibrotic diseases is upstream and dominant to traditional approaches and takes advantage of universal biology common to all tissues to promote healing without scarring.

Current investors include Morgenthaler Ventures, Polaris Venture Partners, HealthCare Ventures and Easton Capital. For more information about Promedior, please visit www.promedior.com.

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