Promedior Initiates Phase 2 Clinical Study of PRM-151 in Myelofibrosis

Development Progress Builds on Encouraging Clinical Data in Idiopathic Pulmonary Fibrosis (IPF)

LEXINGTON, Mass.--(BUSINESS WIRE)-- Promedior, Inc., a clinical stage biotechnology company developing novel biologic therapeutics for the treatment of fibrosis, announced today that it has initiated a Phase 2 clinical trial to evaluate PRM-151, its lead product candidate, in patients with myelofibrosis. Promedior is advancing PRM-151, a recombinant form of an endogenous human protein that offers the potential to prevent and potentially reverse fibrosis. The Phase 2 clinical study of PRM-151 in patients with myelofibrosis, which is expected to complete in 2014, expands Promedior's clinical focus beyond IPF to myelofibrosis, another serious, life-limiting orphan disease with significant unmet medical need.

"Advancing the clinical development of PRM-151, our lead product candidate, into clinical studies in myelofibrosis patients is a significant milestone for Promedior," said Elizabeth G. Trehu, MD, FACP, Promedior's Chief Medical Officer. "We are optimistic that data from this study, combined with the encouraging data in IPF, will demonstrate that PRM-151's novel mechanism of action is applicable to a wide range of fibrotic diseases."

Promedior's clinical development program in myelofibrosis with PRM-151 builds upon a randomized, placebo-controlled clinical study in patients with IPF, in which PRM-151 was generally safe and well-tolerated and resulted in a mean improvement in Forced Vital Capacity (FVC) at 8 weeks after dosing for only two weeks, whereas patients receiving placebo had a decline in FVC. In addition, PRM-151 has demonstrated broad anti-fibrotic activity in multiple industry standard preclinical models of fibrotic disease, including pulmonary fibrosis, acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration.

"Despite the success of JAK inhibitors, there is still a critical need for new therapeutic approaches for patients with myelofibrosis. With its unique mechanism of action that offers the potential to prevent and reverse fibrosis, Promedior's PRM-151 has the potential to become a first-in-class disease-modifying treatment for this debilitating disease," said Srdan Verstovsek, MD, PhD, Professor and Section Chief for Myeloproliferative Neoplasms, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, and principal investigator for the study.

This clinical trial is a multi-center, two stage, adaptive design Phase 2 study to determine the efficacy and safety of PRM-151 as a single agent or added to a stable dose of ruxolitinib in patients with Primary Myelofibrosis (PMF), Post-Polycythemia Vera MF (post-PV MF), or Post-Essential Thrombocythemia MF (post-ET MF). The

primary endpoint is response rate according to the International Working Group-Myeloproliferative Neoplasms Research and Treatment criteria, a comprehensive assessment tool designed by an international group of experts to objectively measure the effectiveness of treatments for MF[1]. Approximately 24 patients are expected to enroll in the first stage of the study, with up to 80 additional patients in the second stage. For additional details about this clinical trial, please visit www.clinicaltrials.gov.

About Myelofibrosis

Myelofibrosis (MF), a type of myeloproliferative neoplasm, is a serious, life-limiting cancer that is characterized by fibrosis of the bone marrow. Replacement of the bone marrow by scar tissue prevents the normal production of blood cells, leading to anemia, fatigue, and increased risk of bleeding and infection. Production of blood cells shifts to the spleen and liver (extramedullary hematopoiesis), which become enlarged, causing severe discomfort, inability to eat, and weakness. Symptomatic myelofibrosis affects approximately 18,000 people per year in the US, with a median age of 61-66.[2]. The only potentially curative treatment is allogeneic bone marrow transplant, which results in reversal of fibrosis and all symptoms, but is a realistic option for only a small number of patients. Other currently available therapies address the symptoms, but have minimal if any impact on the underlying fibrosis.

About PRM-151

PRM-151, Promedior's lead product candidate, is a recombinant form of an endogenous human protein, Pentraxin-2 (PTX-2), that is specifically active at the site of tissue damage. PRM-151 is an agonist that acts as a macrophage differentiation factor to prevent and potentially reverse fibrosis. PRM-151 has shown broad anti-fibrotic activity in multiple preclinical models of fibrotic disease, including pulmonary fibrosis, acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration.

Phase 1a and 1b clinical studies in healthy subjects and IPF patients have demonstrated that PRM-151 was safe and well tolerated. Additionally, a Phase 1b study in patients with IPF showed encouraging results in exploratory efficacy endpoints, which were presented in an oral session at the 2013 Annual Meeting of the American Thoracic Society[3].

About Promedior

Promedior is a clinical stage biotechnology company pioneering the development of targeted therapeutics to treat diseases involving fibrosis. Fibrosis is a harmful process that occurs in many diseases, when normal healthy tissue is replaced with excessive scar tissue, compromising function and ultimately leading to organ failure. Promedior's proprietary platform is based upon Pentraxin-2, an endogenous human protein that is specifically active at the site of tissue damage and works as an agonist, potentially preventing and reversing fibrosis.

Promedior has successfully advanced its lead therapeutic candidate in human clinical trials, and is initially focused on rare fibrotic diseases, including idiopathic pulmonary

fibrosis (IPF) and myelofibrosis. Promedior is backed by leading global healthcare venture investors, has a significant intellectual property estate relating to the discoveries and applications of Pentraxin-2 therapeutics and is led by an experienced management team. For additional information about Promedior, please visit www.promedior.com.

1. Tefferi, A., et al, “Revised Response Criteria for Myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report,” Blood 122(8): 1395-8; 2013.

2. Mehta, J., Wang, H., Iqbal, S. U., Mesa, R., “Epidemiology of myeloproliferative neoplasms in the United States”, Leukemia & Lymphoma, Early Online: 1-6, 2013.

3. Van Den Blink, B. et al., “A Phase I Study Of PRM-151 In Patients With Idiopathic Pulmonary Fibrosis”, American Thoracic Society 2013 Annual Meeting, May 2013. Read More: http://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2013.187.1_MeetingAbstracts.A5707

Source: Promedior, Inc.

Powered by BusinessWire

View this news release online at:
http://www.businesswire.com/news/home/20131009005448/en