Promedior Attains Patient Enrollment Milestone in Phase 2 Clinical Study of PRM-151 in Myelofibrosis

Rapid Enrollment Advances Promedior's Novel Clinical Candidate with Disease-Modifying Potential

Lexington, Mass., January 8, 2014 — Promedior, Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced that it completed enrollment in the first stage of its adaptive Phase 2 trial to evaluate PRM-151, its lead product candidate, in patients with myelofibrosis. The Phase 2 trial rapidly completed enrollment, enrolling 25 patients in just over 12-weeks. Formally initiated in October 2013 at several sites in the United States and Canada, this first stage is expected to be completed in 2014.

"We believe our attainment of this milestone speaks to both the need for new disease-modifying therapies for myelofibrosis and the promise others see in Promedior's lead product candidate, PRM-151," said Elizabeth G. Trehu, MD, FACP, Promedior's Chief Medical Officer. "We look forward to continuing to expedite this trial to bring PRM-151 forward as a potential new treatment option for patients with myelofibrosis. Additionally, we expect the findings from this study to inform the advancement of PRM-151 in other diseases, such as idiopathic pulmonary fibrosis."

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]. Twenty-four patients were enrolled in just over 12 weeks in the first stage of the study as planned, with over enrollment by one additional patient; up to 80 additional patients will be enrolled 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 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, preventing and potentially 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.

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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