Promedior Receives Fast Track Designation for PRM-151 for the Treatment of Myelofibrosis

Lexington, Mass., November 3, 2014 — Promedior, Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to PRM-151 for the treatment of myelofibrosis (MF), a serious, life-limiting cancer characterized by fibrosis of the bone marrow. This Fast Track designation covers Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, and Post-Essential Thrombocythemia Myelofibrosis.

The FDA grants Fast Track designation to a product that is intended to treat a serious condition and that has demonstrated the potential to address an unmet medical need. The advantages of Fast Track designation include actions to expedite development and FDA review including opportunities for frequent interactions with the FDA review team and eligibility for priority review depending on clinical data at the time of Biologics License Application submission. PRM-151 was awarded orphan drug designation for myelofibrosis in September 2014.

"We are extremely pleased to have received Fast Track designation for PRM-151 as we believe that PRM-151 offers the potential to better meet the needs of patients with myelofibrosis," said Beth Tréhu, MD, FACP, Chief Medical Officer of Promedior. "This designation validates our perspective that there is a clear and compelling need for a novel mechanism for the treatment of myelofibrosis that specifically targets the underlying fibrotic processes of the disease. We will continue to work expeditiously to advance this program through the clinic and look forward to presenting the full data set from the first stage of our Phase 2 study later this year."

Myelofibrosis affects approximately 18,000 people per year in the U.S., with a median age of 61-66.[1] The only potentially curative treatment is allogeneic bone marrow transplant, which results in reversal of fibrosis and normalization of blood counts, but is a realistic option for only a small number of patients. Other currently available therapies have minimal, if any, impact on the underlying fibrosis, and often result in worsening in hemoglobin and platelets, important blood parameters which are directly linked to morbidity and mortality and remain the major unmet need in patients with myelofibrosis. Preliminary data from a Phase 2 study of PRM-151 demonstrated benefits across all clinically relevant measures of myelofibrosis, including decreases in bone marrow fibrosis, symptom responses, improvements in hemoglobin and platelets, and reductions in spleen size, with a well-tolerated safety profile and no treatment related myelosuppression. These interim data were presented on June 2, 2014, at the American Society for Clinical Oncology (ASCO) 2014 Annual Meeting, as detailed here.

About Fast Track

The U.S. Food and Drug Administration (FDA) established the Fast Track designation process to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. The purpose of Fast Track is to

get important new drugs to patients earlier. For more information about Fast Track, please visit http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf.

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 monocyte/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. PRM-151 has Orphan Designation in the US for myelofibrosis and in both the US and EU for treatment of Idiopathic Pulmonary Fibrosis.

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. Myelofibrosis affects approximately 18,000 people per year in the US, with a median age of 61-66.[1] 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 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, with an anti-fibrotic immunotherapy approach, works to prevent and reverse fibrosis.

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