

Promedior Receives U.S. Orphan Drug Designation for PRM-151 for the Treatment of Myelofibrosis

LEXINGTON, Mass., September 2, 2014 — Promedior, Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced that the U.S. Food and Drug Administration (FDA) has granted an orphan drug designation for PRM-151, for the treatment of myelofibrosis, a serious, life-limiting cancer characterized by fibrosis of the bone marrow.

The FDA's Office of Orphan Drug Products grants orphan drug designation to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 U.S. patients. Orphan drug designation provides Promedior certain benefits, including seven years of marketing exclusivity upon regulatory approval, a waiver of Prescription Drug User Fee Act (PDUFA) filing fees, the opportunity to apply for annual grant funding, clinical trial design assistance, and tax credits for clinical research costs.

"Orphan drug designation is a significant step forward in the development of PRM-151, and we are excited to continue advancing PRM-151 to better meet the needs of patients with myelofibrosis," said Suzanne L. Bruhn, PhD, President and Chief Executive Officer of Promedior. "Based on the encouraging clinical results reported to date in myelofibrosis patients we believe that PRM-151's novel mechanism of action is compelling with its potential to target and reverse the fundamental bone marrow fibrosis that underlies patients' disease."

With a novel mechanism of action targeted to prevent and reverse fibrosis, PRM-151 has the potential to address the fundamental fibrotic pathology of myelofibrosis. Symptomatic 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. 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 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 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. Symptomatic 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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¹Mehta, J., Wang, H., Iqbal, S. U., Mesa, R., "Epidemiology of myeloproliferative neoplasms in the United States", *Leukemia & Lymphoma*, Early Online: 1-6, 2013.