Press Release

Promedior Announces Positive Long-term Safety and Efficacy Data from Open Label Extension Study of PRM-151 in Idiopathic Pulmonary Fibrosis

Lexington, Mass., May 20, 2019 /PRNewswire/ — Promedior, Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced that positive safety and efficacy data from the Company's open-label extension study of PRM-151 in patients with Idiopathic Pulmonary Fibrosis (IPF) were simultaneously published in The Lancet Respiratory Medicine and presented at the American Thoracic Society 2019 International Conference. The Lancet Respiratory Medicine article, titled "Long-term treatment with recombinant human pentraxin 2 protein in patients with idiopathic pulmonary fibrosis: an open-label extension study," is available online here.

The 76-week open-label extension study of PRM-151 demonstrated evidence of sustained benefit with continued treatment with PRM-151 on the reduction in decline of forced vital capacity (FVC), and 6 minute walking distance (6MWD). These results were consistent with those observed during the 28-week double-blind period. In addition, a positive treatment effect was observed in patients who crossed over to PRM-151 from placebo.

"We are excited to present these positive long-term data for PRM-151 in IPF, a serious, life-limiting lung disease for which despite existing therapies, patient prognosis remains poor with a median survival of 3-5 years," said Jason Lettmann, Chief Executive Officer of Promedior. "These data continue to support the disease-modifying potential of PRM-151 in combating IPF and, ultimately, in the treatment of additional fibrotic diseases. We look forward to advancing into our pivotal program for PRM-151 in early 2020."

IPF Phase 2 Results

IPF patients in the placebo group when switched to treatment with PRM-151 demonstrated both a significant reduction in the rate of decline of FVC and in 6MWD. In addition, a persistent treatment effect of PRM-151 was observed in patients who continued treatment in the open-label extension period out to 76 weeks. In patients who switched to PRM-151 during the open-label extension study, the rate of decline in FVC percent predicted reduced from −8.7% per year while on placebo to −0.9% per year on PRM-151 ($p < 0.0001$). Importantly, this benefit was also observed in 6MWD which improved from −54.9 m per year on placebo to −3.5 m per year on PRM-151 ($p=0.0224$). The safety profile was consistent with prior studies of PRM-151 and with disease-related morbidities.

IPF Phase 2 Study Design
Patients who completed the Phase 2, 28-week double-blind period of the PRM-151-202 trial were eligible to participate in the open-label extension study. Patients previously enrolled in the PRM-151 group continued this treatment and those previously in the placebo group crossed over to PRM-151. All patients received PRM-151 in a dose of 10 mg/kg every 4 weeks.

The primary objective of the open-label extension study was to assess the long-term safety and tolerability of PRM-151, which were assessed by analyzing adverse events (AEs) up to week 76 in all patients who received at least one dose of PRM-151 during the open-label extension study. Exploratory efficacy analyses were done by assessing changes from baseline in percentage of predicted FVC and 6MWD, with descriptive statistics to week 76 and with random-intercept mixed models to week 52.

The open-label extension study analyzed 111 patients (74 from the PRM-151 group and 37 from the placebo group) of the 116 patients who completed the double-blind treatment period. 84 (76%) of 111 patients received concomitant IPF therapy (pirfenidone n=55 or nintedanib n=29).

ATS Presentation
These data were presented at the ATS 2019 International Conference taking place May 17 - 22, 2019 in Dallas, TX. Details for the presentation are as follows:

Title: Long-Term Safety and Efficacy of Recombinant Human Pentraxin-2 in Patients with Idiopathic Pulmonary Fibrosis
Date and time: Monday, May 20, 2019; 9:15-9:30 a.m. CT
Location: Room C155-C156 (Level 1), KBHCCD

About Idiopathic Pulmonary Fibrosis
IPF is a serious, life-limiting lung disease characterized by fibrosis and scarring of lung tissue with a median survival of 3-5 years after diagnosis. Replacement of normal lung tissue by fibrosis results in restriction in the ability to fill the lungs with air and decreased transfer of oxygen from inhaled air into the bloodstream resulting in lower oxygen delivery to the brain and other organs. Patients with IPF most often suffer from progressive shortness of breath, particularly with exertion; chronic cough; fatigue and weakness, and chest discomfort. Currently available approved drugs slow down but do not halt disease progression and the only curative therapy is lung transplant, an option merely available for a small group of patients. While estimates vary, it is believed that IPF could affect approximately 130,000 patients in the US and approximately 76,000 patients in Europe.

About PRM-151
PRM-151, Promedior's lead product candidate, is a recombinant form of the endogenous human innate immunity protein pentraxin-2 (PTX-2), which is specifically active at the site of tissue damage. PRM-151 is an agonist that acts as a macrophage polarization 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, myelofibrosis[1], acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration. In addition to the randomized Phase 2 study in IPF published in

JAMA in 2018[2], Phase 1a and 1b clinical studies in healthy subjects and IPF patients have demonstrated that PRM-151 was well-tolerated. Additionally, the Phase 1b study in patients with IPF showed encouraging results in exploratory efficacy endpoints[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, 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 and myelofibrosis. Promedior is backed by leading global healthcare venture investors and has a significant intellectual property estate relating to the discoveries and applications of pentraxin-2 therapeutics.

Additional information is available at www.promedior.com.

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[1]Verstovsek, S. et al. 2016. Role of neoplastic monocyte derived fibrocytes in primary myelofibrosis. J. Exp. Med. 213:1723-1740.

[2] Raghu G, van den Blink B, Hamblin MJ, et al. Effect of recombinant human pentraxin 2 vs placebo on change in forced vital capacity in patients with idiopathic pulmonary fibrosis: a randomized clinical trial [published online May 20, 2018]. JAMA. doi:10.1001/jama.2018.6129

[3] Van Den Blink, B. et al. 2016. Recombinant human pentraxin-2 therapy in patients with idiopathic pulmonary fibrosis: safety, pharmacokinetics and exploratory efficacy. Respir. J.47:889-97. http://erj.ersjournals.com/content/47/3/889.long