Promedior Announces Pivotal Path for PRM-151 in Idiopathic Pulmonary Fibrosis Following Positive End-of-Phase 2 Meeting with FDA

LEXINGTON, Mass. – January 4, 2019 – Promedior, Inc., a clinical stage biotechnology company developing novel therapeutics for the treatment of fibrosis, today announced that it has completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss the study of PRM-151, a novel investigational anti-fibrotic immunomodulator, in patients with Idiopathic Pulmonary Fibrosis (IPF). Pursuant to the FDA meeting, the Company reached an agreement with the Agency on the design of the Phase 3 study for registration. The pivotal trial will look at the primary endpoint of forced vital capacity (FVC) and the key secondary endpoint of six-minute walk distance (6MWD) on top of standard of care.

"Our interactions with the FDA have been collaborative and constructive, and their guidance clearly positions PRM-151 as a Phase 3-ready candidate," said Dr. Renu Gupta, MD, Chief Medical Officer of Promedior. "Importantly, this program offers the opportunity to include both FVC and 6MWD as labeled claims which, if supported by the Phase 3 study outcome, would provide both meaningful benefit to patients and important differentiation in the market. We look forward to initiating the Phase 3 study in 2019, and to the continued exploration of our strategic options for advancing PRM-151 in IPF, while also further advancing our development pipeline in additional serious fibrotic diseases in which it has indicated therapeutic potential."

"The need to abort the disease progression is not met with currently available treatments and the vast majority of patients regrettably do not survive beyond 3-5 years after the diagnosis of IPF is ascertained," said Ganesh Raghu, M.D., Professor of Medicine and Director of the Center for Interstitial lung diseases, University of Washington, Seattle, WA, USA. "The results of the Phase 2 study demonstrated a significant treatment effect for PRM-151 versus placebo in the change of lung function, measured as FVC and suggest the potential of PRM-151 to stabilize the distance walked over 6 minutes time in patients with IPF over a 28-week period, including those who received combination with standard of care treatment. We look forward to confirming the results of the Phase 2 study of PRM-151 in a larger Phase 3 study and to fully elucidating its disease-modifying potential."

The End-of-Phase 2 meeting followed the successful completion of a Phase 2, randomized, double-blind, trial designed to evaluate the safety and efficacy of PRM-151, a recombinant form of human pentraxin-2 protein, versus placebo in 117 patients with IPF, with 79% receiving standard of care treatment of either pirfenidone or nintedanib. Efficacy was evaluated at 28 weeks, among other measures, through pulmonary function tests including FVC, and distance walked during six-minute walk test (6MWD) as was published in JAMA in May 20, 2018.[1] The patients who were treated with PRM-151 every four weeks exhibited a change in FVC percentage of predicted value of −2.5% compared with −4.8% with placebo – a statistically significant difference (p=.001) that indicates a reduction in decline of lung function. Change in six-minute walk distance was −0.5 m among patients treated with PRM-151 compared with −31.8 m for those with placebo (p<.001) – a difference that falls within the range reported as clinically important in the IPF population. The nearly stable 6MWD result in the PRM-151 group is both unprecedented and

[1] 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

suggests a potential benefit in overall functional capacity in patients with IPF. The short monthly infusion of PRM-151 was well tolerated by the patients and study medication compliance was 97%.

Promedior plans to seek scientific advice and protocol assistance from the European Medicines Agency in early 2019 and expects to initiate the Phase 3 clinical program to support FDA registration in 2019. In parallel, the Company is evaluating strategic opportunities for advancing PRM-151 in other respiratory, oncology, hepatology, and nephrology indications.

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[2], acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration. In addition to the randomized Phase 2 study in IPF, 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

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

[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

backed by leading global healthcare venture investors and has a significant intellectual property estate relating to the discoveries and applications of pentraxin-2 therapeutics.

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