Promedior Enters Into Definitive Merger Agreement To Be Acquired By Roche

LEXINGTON, Mass., Nov. 15, 2019 /PRNewswire/ — Promedior, Inc., today announced that it has entered into a definitive merger agreement for Roche (SIX: RO, ROG;OTCQX: RHHBY) to acquire Promedior. With this acquisition, Roche will obtain full rights to Promedior's entire portfolio of molecules for serious fibrotic diseases, notably PRM-151.

Promedior, a privately held clinical-stage biotechnology company based in Lexington, Massachusetts, has successfully advanced PRM-151 in human clinical trials and received Breakthrough Therapy Designation from the FDA earlier this year for idiopathic pulmonary fibrosis (IPF). PRM-151, a recombinant form of human pentraxin-2 (PTX-2) protein, has demonstrated both prevention and reversal of fibrosis and opens up new opportunities to treat a wide range of systemic fibrotic diseases. Phase 2 trial results demonstrated that PRM-151 is the first molecule to show significant lung function improvements on top of current therapies in IPF. PRM-151 has also shown promising early clinical trial data in myelofibrosis (MF) and its anti-fibrotic mechanism has therapeutic potential in other fibrotic diseases.

Jason Lettmann, Chief Executive Officer of Promedior and General Partner of Lightstone Ventures, said: "With over a decade of research, development and investment, Promedior has demonstrated the unique ability of its pentraxin-2 platform to deliver disease-modifying potential in fibrotic disorders. Due to Roche's strong expertise in IPF, hematological cancer and other fibrotic disorders, we believe Roche is ideally positioned to bring the potential of our platform to patients and provide new treatment options within these areas of urgent unmet medical need."

"We are excited to combine Promedior's portfolio with our drug development capabilities to further advance PRM-151 in fibrotic diseases, including IPF and MF," said James Sabry, M.D., Ph.D., global head of Roche Pharma Partnering. "With our proven track record in IPF with Esbriet™ as well as in hematological cancers, we are well-positioned to leverage our clinical and commercial expertise to bring PRM-151 to patients as fast as possible."

The Pentraxin-2 Platform
Fibrosis is a common pathway that can affect nearly all tissues and organ systems, including lung, kidney, liver, bone marrow, and the eye. Despite a large unmet medical need, there are few approved, disease-modifying therapies available to treat these systemic fibrotic diseases. Promedior's drug candidates are based on Pentraxin-2 which is an endogenous human protein that is specifically active at the site of tissue damage. PTX-2 works as an agonist that acts as a macrophage polarization factor to initiate a resolution process for prevention and potential reversal of fibrosis, thereby acting as a master regulator upstream in the fibrosis cascade. Extensive studies conducted by Promedior and its collaborators have confirmed this ability of pentraxin-2 therapeutics to act as upstream agonists across many major tissue types and in several models of fibrotic disease, strongly supporting its potential as a novel anti-fibrotic agent.

Transaction Terms and Approvals
Under the terms of the merger agreement, Roche will make an upfront cash payment of USD 390

million, plus additional contingent payments of up to USD 1 billion based on the achievement of certain predetermined development, regulatory and commercial milestones.

The closing of the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary conditions.

About PRM-151
PRM-151, Promedior's lead product candidate, has shown broad anti-fibrotic activity in multiple preclinical models of fibrotic disease, including pulmonary fibrosis, myelofibrosis, acute and chronic nephropathy, liver fibrosis, and age-related macular degeneration. As published in JAMA in 2018, the randomized Phase 2 study in IPF demonstrated that PRM-151 slowed the decline of lung function and stabilized 6-minute walk distance which suggested potential benefit in overall functional decline. The open-label extension data published in Lancet Respiratory Medicine in 2019 further demonstrated evidence of a sustained benefit out to 76 weeks. Positive data from the Phase 2 study in MF highlighted PRM-151's ability to reduce bone marrow fibrosis and was recently presented at the 2019 European Hematology Association Congress.

About Idiopathic Pulmonary Fibrosis (IPF)
Idiopathic pulmonary fibrosis (IPF) is a progressive, irreversible and ultimately fatal disease characterized by progressive loss of lung function due to fibrosis (scarring) in the lungs, which hinders the ability of lungs to absorb oxygen. IPF inevitably causes shortness of breath, and a deterioration in lung function and exercise tolerance. IPF patients follow different and unpredictable clinical courses and it is not possible to predict if a patient will progress slowly or rapidly, or when the rate of decline may change. Current therapies slow the decline in FVC but are limited in their ability to improve function or halt disease progression. The median survival time from diagnosis is two to three years which makes IPF more rapidly lethal than many malignancies, including breast, ovarian and colorectal cancers.

About Myelofibrosis (MF)
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. The only potentially curative treatment is allogeneic bone marrow transplant while 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. 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 including Morgenthaler Ventures, HealthCare Ventures, Forbion, Easton Capital, Fibrotec Ventures, and Polaris Partners 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.

CONTACTS

Investors:
Sam Martin
Argot Partners
212.600.1902
sam@argotpartners.com

Media Contact:
David Pitts
Argot Partners
212.600.1902
david@argotpartners.com