Mediar Advances First-in-Class Fibrosis Portfolio to the Clinic with First Cohort Dosing in Phase 1 trial of MTX-463 and Establishes Clinical Advisory Board

Phase 1 study of MTX-463 initiated after FDA Clearance of IND

IND-enabling studies completed for second antibody program with Phase 1 expected to start in Q3

Clinical Advisory Board (CAB) of global experts in fibrosis formed to advance clinical development

New preclinical data to be presented at upcoming medical meetings on WISP-1 and EphrinB2 and their roles in Idiopathic Pulmonary Fibrosis (IPF) and Systemic Sclerosis (SSc), respectively

BOSTON, Mass., May 6, 2024 – Mediar Therapeutics, Inc., a biotechnology company advancing a portfolio of first-in-class therapies that halt fibrosis progression, today announced that, following FDA clearance of its investigational new drug (IND) application, the first cohort of participants has been dosed in a Phase 1 trial evaluating the safety and tolerability of MTX-463. MTX-463 is a first-in-class human IgG1 antibody designed to neutralize WISP-1-mediated fibrotic signaling to address IPF and other fibrotic diseases. The Phase 1 study for MTX-463 is designed to assess its safety at multiple dose levels, tolerability, and pharmacokinetics, while also assessing the ability of MTX-463 to engage its target, WISP-1. The trial is enrolling healthy participants and consists of staggered single ascending dose (SAD) and multiple ascending dose (MAD) cohorts.

"Advancing our first-in-class portfolio to the clinic is an important milestone for Mediar, and an exciting moment envisioned by our founders at Mass General Brigham and advanced by our team," said Mediar's Chief Executive Officer Rahul Ballal, Ph.D. "MTX-463 is the first of two programs to begin clinical trials this year and we look forward to initiating a second Phase 1 study with our first-in-class anti-EphrinB2 molecule, MTX-474, in the third quarter."

As Mediar advances MTX-463 and MTX-474 into human studies, it will be guided by its clinical advisory board, comprising world renowned leaders in fibrosis across pulmonology, rheumatology, hepatology, and regulatory. "With the formation of our CAB, we bring together a wealth of experience and expertise to help advance the clinical development of our pipeline as we work to address the significant unmet need in fibrosis," said Mediar's Chief Medical Officer Jeff Bornstein, M.D.

The newly appointed members of the clinical advisory board are:

- Flavia Castelino, M.D., Associate Professor of Medicine, Harvard Medical School, Division of Rheumatology, Massachusetts General Hospital
- Lara Dimick-Santos, M.D., Medical Director, CTI Clinical Trial & Consulting Services, former FDA medical reviewer
- Scott Friedman, M.D., Dean for Therapeutic Discovery, Fishberg Professor of Medicine, Director, Institute for Liver Research, Icahn School of Medicine at Mount Sinai
- Robert Lafyatis, M.D., Professor of Medicine, Division of Rheumatology & Clinical Immunology, University of Pittsburgh Medical Center

- Rohit Loomba, M.D., MHSc, Professor of Medicine, Chief of the Division of Gastroenterology and Hepatology, University of California San Diego
- Toby Maher, M.D., Ph.D., Professor of Medicine, Director of Interstitial Lung Diseases, University of Southern California
- Sydney Montesi, M.D., Assistant Professor of Medicine, Harvard Medical School, Pulmonary and Critical Care Medicine, Massachusetts General Hospital
- John Varga, M.D., Professor of Medicine, Chief of the Division of Rheumatology, University of Michigan

In addition, new preclinical data supporting the application of MTX-463 in IPF will be presented at the 2024 American Thoracic Society (ATS) meeting in San Diego, May 17-22, 2024. Data supporting MTX-474 in Systemic Sclerosis (SSc) will be presented in an oral presentation at the Congress on the EPH/Ephrin System in Parma, Italy, May 16-17, 2024.

About MTX-463

MTX-463 is a first-in-class human IgG1 antibody developed against WNT1-inducible signaling pathway protein-1 (WISP-1). WISP-1 is a secreted matricellular protein shown to have a relevant role in fibrosis progression, measurable in human blood, and correlates with disease severity. Initial data indicates that MTX-463 neutralizes WISP-1-mediated fibrotic signaling that spans several fibrotic indications and significantly reduced fibrosis in vitro and in preclinical mouse models. MXT-463 is currently in Phase 1 clinical evaluation to assess its safety and tolerability in healthy participants (NCT06401213).

About MTX-474

MTX-474 is a first-in-class human IgG1 antibody designed to neutralize the EphrinB2 signaling that causes the onset and progression of fibrosis. Ephrin ligands and Eph receptors mediate biological processes involved in tissue fibrosis including cell migration, myofibroblast activation, and tissue remodeling. A growing body of evidence has implicated EphrinB2 in the fibrosis of the skin, lungs, and heart. Expression of EphrinB2 and its receptors are measurable in human blood and correlates with disease severity. Initiation of Phase 1 clinical studies for this program is anticipated in Q3-2024.

About Mediar Therapeutics

Mediar Therapeutics is pioneering a new approach to fibrosis treatment that halts the disease at a different source – the myofibroblast, the key pathogenic cell in fibrosis that drives scarring, disease progression, and ultimately organ failure. Mediar was founded based on a deep understanding of the complex science underlying fibrosis onset and progression. By combining novel targets with reliable, easily detectable blood biomarkers and familiar modalities, Mediar is derisking the path forward for fibrosis therapies in clinical development. For more information, contact info@mediartx.com or follow us on LinkedIn.

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