Mediar Therapeutics Initiates Second Clinical Program in Portfolio of Novel First-In-Class Antibodies Designed to Halt Fibrosis

First cohort of participants dosed in Phase 1 trial evaluating safety and tolerability of MTX-474, a human IgG1 antibody designed to neutralize EphrinB2 signaling

Phase 1 study for MTX-463, an antibody neutralizing WISP1-mediated fibrotic signaling, enrolling ahead of schedule with most cohorts dosed

MTX-463 granted FDA orphan drug and fast track designations

BOSTON, Mass., August 7, 2024 – Mediar Therapeutics, Inc., a clinical stage biotechnology company advancing a portfolio of first-in-class therapies designed to halt fibrosis progression, today announced the first cohort of participants has been dosed in a Phase 1 trial evaluating the safety and tolerability of MTX-474, a human IgG1 antibody designed to neutralize EphrinB2 signaling. The study, taking place in Australia, is designed to assess the safety, tolerability, pharmacokinetics, and target engagement of MTX-474 in healthy participants through staggered single ascending dose (SAD) and multiple ascending dose (MAD) cohorts.

The company also reports continued progress in its US Phase 1 study of its WISP1 targeting antibody, MTX-463, with approximately three quarters of the cohorts dosed, and completion of the trial expected by the end of 2024. Additionally, MTX-463 was granted orphan drug and fast track designations by the FDA, underscoring the potential of WISP1 to address significant unmet needs in treating rare fibrotic diseases, including Idiopathic Pulmonary Fibrosis (IPF).

“I am excited about the emerging clinical portfolio at Mediar and its unique approach to directly target the myofibroblast, the key pathogenic cell in fibrosis,” said Toby Maher, M.D., Ph.D., Professor of Medicine and Director of Interstitial Lung Diseases at University of Southern California, and member of Mediar’s Clinical Advisory Board. “Both the EphrinB2 and WISP1 antibody programs offer potential novel approaches to halt and maybe even reverse fibrosis. I look forward to completion of the Phase 1 studies and future planned Phase 2 trials in systemic sclerosis and IPF, respectively.”

"We are gratified to see our first-in-class programs advance from exciting science to clinical studies,” said Rahul Ballal, Ph.D., Chief Executive Officer of Mediar Therapeutics. "Dosing participants in our MTX-474 trial marks another important milestone for Mediar and, alongside our ongoing Ph-1 MTX-463 study, opens new potential pathways to target fibrosing diseases. Furthermore, FDA granting both orphan drug and fast track designations for MTX-463 emphasizes the potential of this novel therapy to address the high unmet need in IPF.”

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. Phase 1 clinical studies were initiated for this program in July 2024 (NCT06535841).

About MTX-463

MTX-463 is a first-in-class human IgG1 antibody developed against WNT1-inducible signaling pathway protein-1 (WISP1). WISP1 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 WISP1-mediated fibrotic signaling that spans several fibrotic indications and significantly reduced fibrosis *in vitro* and in preclinical mouse models. MTX-463 is currently in Phase 1 clinical evaluation to assess its safety and tolerability in healthy participants (NCT06401213).

About Mediar Therapeutics

Mediar Therapeutics is pioneering a new approach to fibrosis treatment that aims to halt 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 progression. By combining novel targets with reliable, easily detectable blood biomarkers and familiar modalities, Mediar's goal is to bring forward novel anti-fibrotic therapies that potentially have a precision medicine approach. For more information, contact info@mediartx.com or follow us on LinkedIn.

Media Contact

Joan Bosisio, Deerfield Group
joan.bosisio@deerfieldgroup.com