



Tvardi Therapeutics Announces First Patients Dosed in its Phase 2 Idiopathic Pulmonary Fibrosis Trial using TTI-101, a Novel STAT3 Inhibitor

August 31, 2023 12:00 PM EDT

Houston, TX – August 31, 2023 – Tvardi Therapeutics, Inc., a privately held, clinical-stage biopharmaceutical company focused on the development of STAT3 inhibitors, announced that the first patients have been dosed in its ongoing REVERT_{IPF} trial. The trial is a 12-week, randomized, double-blind study evaluating both safety and clinical activity of TTI-101 at three different doses, alone or in combination with nintedanib (OFEV®), compared to placebo in patients with idiopathic pulmonary fibrosis (IPF).

IPF is a chronic, progressive, and debilitating lung disease with unknown etiology. This disease has a poor prognosis, with most patients experiencing worsening respiratory symptoms, declining lung function, and functional impairment. Currently approved treatments have been shown to slow progression; however, fail to reverse clinical decline or restore lung function. Although several ongoing efforts are underway to discover novel ways to treat IPF, none have interrogated STAT3, a key regulatory protein, that is the central node in the development of pulmonary fibrosis. TTI-101 is an orally delivered, small molecule, direct inhibitor of STAT3.

“The REVERT_{IPF} trial will expand our understanding of the impact of STAT3 inhibition beyond cancer into fibrotic diseases, which severely impair and burden hundreds of thousands of people globally. Interest in our IPF study continues to grow due to recently presented [clinical data](#) demonstrating TTI-101 was safe and effective in heavily pretreated cancer patients, [published preclinical work](#) highlighting TTI-101’s restorative effect in fibrosis, and the FDA’s [Orphan Drug Designation for TTI-101 in IPF](#),” said Imran Alibhai, PhD, CEO of Tvardi Therapeutics. “This is the third of three Phase 2 trials Tvardi has initiated to address diseases driven by STAT3.”

For more information about the REVERT_{IPF} trial currently enrolling at sites throughout the US, please visit [ClinicalTrials.gov \(NCT05671835\)](https://ClinicalTrials.gov/NCT05671835).

About Tvardi Therapeutics

Tvardi is a privately held, clinical-stage biopharmaceutical company developing small molecule inhibitors of STAT3, a key regulatory protein positioned at the intersection of many signaling pathways integral to the survival and immune evasion of cancer cells. STAT3 also plays a central role in the pathogenesis of many inflammatory and fibrotic diseases. The company has now initiated three Phase 2 clinical programs in hepatocellular carcinoma ([NCT05440708](#)), metastatic breast cancer ([NCT05384119](#)), and idiopathic pulmonary fibrosis ([NCT05671835](#)). To learn more, please visit the website for [Tvardi Therapeutics](#).

Contact:

Tvardi Investor Relations
Sara Manning
ir@tvardi.com