



Tvardi Therapeutics Announces Completion of Enrollment in Phase 2 Clinical Trial of TTI-101 in Idiopathic Pulmonary Fibrosis

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Topline data from the REVERT IPF trial anticipated in 4Q 2025

HOUSTON--(BUSINESS WIRE)--May 27, 2025-- Tvardi Therapeutics, Inc. ("Tvardi") (NASDAQ: TVRD), a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat fibrosis-driven diseases, today announced that it has completed enrollment for its lead program in a Phase 2 clinical trial of TTI-101 for patients with idiopathic pulmonary fibrosis (IPF). The REVERT IPF Phase 2 clinical trial is a randomized, double-blind, placebo-controlled clinical trial of TTI-101 in patients suffering from IPF. Key endpoints include safety and lung function (FVC).

TTI-101, is an oral, small molecule inhibitor of STAT3. STAT3 is a central mediator across critical fibrotic signaling pathways that drive uncontrolled deposition, proliferation, survival and immune suppression.

IPF is a chronic, progressive, and debilitating lung disease with unknown etiology. Patients diagnosed with IPF have a poor prognosis, with most patients experiencing worsening respiratory symptoms, declining lung function, and functional impairment. Although several ongoing efforts are underway to discover novel ways to treat IPF, none have interrogated STAT3. STAT3 plays a critical role as a central mediator underlying the pathogenesis of fibrosis in IPF.

Dr. Imran Alibhai, Chief Executive Officer of Tvardi, stated, "We are thrilled to announce the completion of enrollment in our Phase 2 trial of TTI-101 for idiopathic pulmonary fibrosis, our lead clinical indication. This marks a major milestone in our mission to address a disease with high unmet need—where current therapies only slow progression but fall short of halting or reversing fibrosis. TTI-101 has demonstrated a unique and powerful dual mechanism of action: inhibiting STAT3-driven proliferation while activating T-cells, resulting in reduced lung fibrosis and restored lung function in preclinical studies. We are energized by the potential of TTI-101 and are eager to see whether preclinical study results translate into our Phase 2 REVERT IPF trial. Topline data is expected in Q4 of this year."

About Tvardi Therapeutics

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. STAT3 is a central mediator across critical fibrotic signaling pathways that drive uncontrolled deposition, proliferation, survival and immune suppression. STAT3 is also positioned at the intersection of many signaling pathways integral to the survival and immune evasion of cancer cells. The company is conducting Phase 2 clinical trials in fibrosis-driven diseases with high unmet need: idiopathic pulmonary fibrosis ([NCT05671835](#)) and hepatocellular carcinoma ([NCT05440708](#)). To learn more, please visit varditherapeutics.com or follow us on [LinkedIn](#) and [X \(Twitter\)](#).

Cautionary Statement Regarding Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "will," "anticipate," "potential," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of these forward-looking statements include statements concerning the anticipated benefits of Tvardi's product candidates; its ongoing clinical trials, including the expected timing for topline data readouts; and other statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are subject to a number of risks, including, among other things: the uncertainties associated with Tvardi's product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the completion of clinical trials; preclinical results may not be indicative of results that may be observed in clinical trials; the significant net losses Tvardi has incurred since inception; Tvardi's ability to initiate and complete ongoing and planned preclinical studies and clinical trials and advance its product candidates through clinical development; the timing of the availability of data from Tvardi's clinical trials; the outcome of preclinical testing and clinical trials of the Tvardi's product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; Tvardi's plans to research, develop and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of Tvardi's product candidates; the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all;

Tvardi's ability to attract, hire, and retain skilled executive officers and employees; Tvardi's ability to protect its intellectual property and proprietary technologies; Tvardi's reliance on third parties, contract manufacturers, and contract research organizations; the possibility that Tvardi may be adversely affected by other economic, business, or competitive factors; risks associated with changes in applicable laws or regulations; those factors discussed in Tvardi's filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the Securities and Exchange Commission (the "SEC") on May 13, 2025, and Tvardi's other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The combined company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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