



## Tvardi Therapeutics Announces Further Phase 2 REVERT IPF Data, Expanding Clinical Insights

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*Pooled patients treated with TTI-101 demonstrated a 9.4% decrease from baseline in fibrosis score at week 12, compared to a 2.4% decrease for the placebo group*

*Topline healthy volunteer data from Phase 1 study of next-generation STAT3 inhibitor, TTI-109, on track for H1 2026*

HOUSTON, Jan. 08, 2026 (GLOBE NEWSWIRE) -- 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 provided further updates from its Phase 2 REVERT IPF clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF). Preliminary results were announced on October 13, 2025.

Additional analysis was conducted to interrogate the impact of STAT3 inhibition using TTI-101 on fibrosis, inflammatory markers and pulmonary function. In order to do so, the additional analysis was limited to patients who were exposed to study drug for 12 weeks. Upon interrogation of pharmacokinetics and adverse events, one patient was removed from the analysis due to receiving less than 60% of the expected dosing; two patients were removed due to no measurable TTI-101 observed in the blood as well as no reported adverse events; and one additional patient was removed as an outlier for the 12-week analysis as their pulmonary function initially improved on treatment, but was subsequently severely impacted by acute bronchitis deemed unrelated to study drug. This resulted in a dataset of 40 patients analyzed: 16 pooled patients treated with TTI-101, and 24 patients treated with placebo.

### Data highlights:

- Fibrosis: Fibrosis decline was greater in patients treated with TTI-101 compared to placebo, -9.4% vs -2.4%, respectively, in baseline-weighted high resolution CT lung fibrosis score (centrally read, blinded and independently assessed).
- Inflammation: A greater IL-6 decline was observed among TTI-101-treated patients vs placebo. In addition, greater reduction in IL-6 was observed among patients with higher baseline IL-6 in the TTI-101-treated patients. IL-6 is a key pro-inflammatory cytokine that signals through STAT3. Inhibition of STAT3 is expected to reduce downstream inflammatory signaling associated with disease.
- 63% of pooled patients treated with TTI-101 demonstrated an increase in FVC at 12 weeks, compared to 46% of the placebo group.
- Mean FVC change in TTI-101-treated patients was -15mL; less of a decline when compared to the REVERT placebo (-22mL) and historical placebo groups from comparable IPF trials.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "Our subsequent analyses of the REVERT IPF clinical trial data set revealed deeper insights into the impact of TTI-101 on the inhibition of STAT3 in fibrosis and inflammation. Notably, treatment with TTI-101 was associated with improvement in blinded fibrosis scores vs placebo and reductions in IL-6 levels consistent with STAT3 pathway inhibition. Further interrogation into FVC after 12 weeks of TTI-101 was encouraging despite the placebo-treated patients' FVC decline being lower than expected compared to historical controls.

"With these data in-hand, we eagerly await results from the ongoing healthy volunteer study of our next-generation STAT3 inhibitor, TTI-109. TTI-109 is designed to enhance TTI-101's ability to target STAT3 as a more efficient delivery vehicle with the potential to improve tolerability. If successful, we will move quickly to identify next steps for this promising, potentially disease modifying therapy across a range of fibrosis-driven diseases where STAT3 activation is implicated."

The REVERT IPF Phase 2 clinical trial was a randomized, double-blind, placebo-controlled clinical trial of TTI-101 alone or in addition to nintedanib (OFEV®) in patients with IPF. The study was designed to assess safety, pharmacokinetics, and exploratory outcomes related to lung function. Tvardi announced on October 13, 2025 that the study did not meet its goals after reviewing preliminary safety data and efficacy results.

### 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 clinical trials with TTI-101 in hepatocellular carcinoma (NCT05440708) and TTI-109 in healthy volunteers. To learn more, please visit [tvardi.com](http://tvardi.com) or follow us on LinkedIn and X (Twitter).

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**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. Examples of these forward-looking statements include statements concerning the anticipated benefits of Tvardi's product candidates; its ongoing clinical trials and anticipated timing of reporting data from such trials; potential indications for its product candidates; 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; 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 anticipated cash runway; 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 September 30, 2025, and Tvardi's other documents subsequently filed with or furnished to the SEC, all of which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). All forward-looking statements contained in this press release speak only as of the date on which they were made. The 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.