Tvardi Therapeutics Provides Update on Preliminary Data from Phase 2 REVERT Trial in Idiopathic Pulmonary Fibrosis

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HOUSTON--(BUSINESS WIRE)--Oct. 13, 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 provided an update on preliminary data from the Phase 2 REVERT clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF).

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. After reviewing the preliminary safety data and exploratory efficacy results, including changes in Forced Vital Capacity (FVC), the Company concluded that the study did not meet its goals.

Overall, 88 patients were randomized to TTI-101 400mg per day (n=30), 800mg per day (n=29) or placebo (n=29), and stratified by nintedanib use, with 58% of patients receiving concomitant therapy. Preliminary data[1] demonstrated patients’ baseline characteristics were similar across treatment arms, with the exception of percent predicted FVC, which was lower in the placebo-treated patients (70.1%) compared to the TTI-101-treated arms (74.1% and 81.1%, respectively).

Discontinuation rates across treatment arms were imbalanced, with lower discontinuation rates observed in the placebo group (10.3%) compared to treated arms (400mg and 800mg; 56.7% vs 62.1%, respectively). Discontinuation rates among the TTI-101 population were primarily driven by gastrointestinal adverse events, with higher rates of events and discontinuations among patients on concurrent nintedanib.

The study was not powered to evaluate exploratory endpoints. The number of efficacy evaluable patients with at least one baseline and on-treatment FVC measurement was placebo (n=29), 400mg (n=23), and 800mg (n=27). The numbers, however, declined by the 12-week timepoint to placebo (n=24), 400mg (n=8), or 800mg (n=13). The preliminary analysis was performed on actual FVC values; values were not modeled or imputed.

Preliminary analysis of exploratory efficacy showed no statistically significant differences between placebo and treatment arms. Overall, from baseline to last visit on treatment, the proportion of patients who demonstrated FVC improvement from baseline was 41% for the placebo, and 39% and 44% for the 400mg and 800mg arms, respectively.

FVC change from baseline overlapped between treatment arms, with large variability within each cohort. Notably, the placebo-treated patients’ FVC decline was lower than expected compared to historical controls.

Preliminary Summary of Change from Baseline in FVC (mL) at 12 Weeks While on Treatment

	Placebo	TTI-101 – 400mg	TTI-101 – 800mg
n	24	8	13
Mean in mL (SD[2])	-22.2 (126.0)	-61.1 (190.7)	-102.8 (238.3)

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, “In the aggregate, we did not observe a benefit of TTI-101 treatment in this IPF study. The limited data set, high variability within treatment arms, and unexpected performance of the placebo arm make it difficult to provide more definitive conclusions at this time. We are conducting additional analyses to further understand the results and inform our next steps. I want to sincerely thank the patients, their families, investigators, and site staff for their commitment to this study.”

“Importantly, we remain on track to report preliminary topline data in the first half of 2026 from a healthy volunteer study on our next-generation STAT3 inhibitor, TTI-109, and from the Phase 2 trial of TTI-101 in hepatocellular carcinoma. 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. Once the healthy volunteer TTI-109 study is completed, we will assess the opportunity to expand into other STAT3-driven indications.”

As of June 30, 2025, the Company reported $41.0 million in cash, cash equivalents, and short-term investments, which is expected to fund operations into the fourth quarter of 2026.

Conference Call

Tvardi management will host a conference call today, Monday, October 13, 2025, at 8:30 am ET to discuss these preliminary results. To access the live conference call, please dial 1-877-704-4453 from the U.S., or 1-201-389-0920 internationally, Conference ID# 13756659. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at https://ir.tvarditherapeutics.com/events-presentations.

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 tvarditherapeutics.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. 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; the final results of its clinical trial of TTI-101 in IPF; its anticipated cash runway; 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 June 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. 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.

[1]Preliminary data; data not final and subject to change

[2]SD: Standard Deviation

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