



## **Tvardi Therapeutics Announces First Patients Dosed in its Phase 2 Liver Cancer Trial Using TTI-101, a Novel STAT3 Inhibitor**

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### **The REVERT LIVER CANCER Trial is Evaluating STAT3 Inhibitor, TTI-101, Alone and in Combination with Current Standard of Care for Liver Cancer Patients**

Houston, TX – June 22, 2023 – Tvardi Therapeutics, Inc., a privately held, clinical-stage biopharmaceutical company focused on the development of STAT3 inhibitors, today announced that the first patients have been dosed in each arm of its ongoing REVERT LIVER CANCER trial. The trial is evaluating safety and clinical activity of TTI-101 as monotherapy and in combination with standard of care therapy in patients with locally advanced or metastatic, and unresectable hepatocellular carcinoma (HCC)

The REVERT LIVER CANCER trial is currently enrolling HCC patients at top US cancer research institutes and is designed to evaluate TTI-101 across multiple lines of therapy:

- TTI-101 alone for patients previously treated with up to three prior lines of systemic therapy
- TTI-101 in combination with pembrolizumab (Keytruda®) for patients previously treated with immunotherapy
- TTI-101 in combination with atezolizumab (Tecentriq®) and bevacizumab (Avastin®) for treatment naïve patients

Liver cancer is the sixth most commonly diagnosed cancer and the third most common cause of cancer death. HCC is the most common form of liver cancer; however, treatment options for the disease are limited and overall prognosis for survival is poor, with a 5-year survival rate of 18%. TTI-101's target, STAT3, is a key regulatory protein which plays a critical role in the pathogenesis of HCC by initiating tumorigenesis as well as promoting an immunosuppressive tumor microenvironment. TTI-101 is an orally delivered, small molecule, direct inhibitor of STAT3.

"Enthusiasm for our HCC study continues to expand with recently presented [clinical data](#) demonstrating TTI-101 monotherapy has robust efficacy in heavily pretreated patients with HCC, [published preclinical work](#) highlighting TTI-101's synergy with immunotherapy, and the FDA's [Fast-Track Designation for TTI-101 in HCC](#)," said Imran Alibhai, PhD, CEO of Tvardi Therapeutics. "This is the second of three Phase 2 trials Tvardi has initiated to address diseases driven by STAT3."

For more information about the REVERT LIVER CANCER trial currently enrolling at sites throughout the US, please visit [ClinicalTrials.gov \(NCT05440708\)](https://clinicaltrials.gov/ct2/show/study/NCT05440708).

### **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's lead product, TTI-101, completed enrollment in its first-in-man Phase 1 trial conducted in patients with relapsed/refractory solid tumors. To date, TTI-101 monotherapy has been well-tolerated and has clinical activity across a broad range of tumors including multiple durable radiographic objective responses. 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 [Tvardi Therapeutics](#).

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