FDA Grants Fast Track Designation to Tvardi Therapeutics' TTI-101 for Hepatocellular Carcinoma

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Houston, TX – October 19, 2022 – Tvardi Therapeutics, Inc. ("Tvardi"), a privately held, clinical-stage biopharmaceutical company focused on the development of STAT3 inhibitors, today announced that its lead product, TTI-101, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of relapsed/refractory locally advanced, unresectable, or metastatic hepatocellular carcinoma (HCC).

The FDA has the authority to grant Fast Track designation to aid in expedited development and review of any drug or biological product that shows promise in serious conditions with unmet need. 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 is an orally delivered, small molecule, direct inhibitor of STAT3. 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 completing a first-in-man Phase 1 trial of patients with advanced solid tumors who have failed all lines of therapy. 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.

"We are pleased to receive Fast Track designation for TTI-101 in HCC from the FDA," said Imran Alibhai, PhD, CEO of Tvardi. "This designation provides validation of the compelling safety and efficacy we have seen in last-line HCC patients in our Phase 1 trial. This comes at a perfect time as we look forward to enrolling patients imminently in our Phase 2 HCC basket trial which will test TTI-101 as monotherapy and in combination with existing approved therapies across first-, second-, and last-line HCC patients."

The Fast Track designation will provide the opportunity for early and frequent communication and meetings with the FDA, ensuring that any questions and issues are resolved quickly. The designation will also facilitate a rolling review of clinical data, allowing data to be shared as it becomes available, ultimately leading to a shortened application review for approval of TTI-101 in patients with HCC.

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 clinical programs in HCC, breast cancer, and idiopathic pulmonary fibrosis. To learn more about Tvardi, please visit **Tvardi Therapeutics**. To learn more about the ongoing clinical trial in HCC please visit **ClinicalTrials.gov**.

Contact:
Tvardi Investor Relations
Sara Manning
ir@tvardi.com