FDA Grants Fast Track Designation to TTI-101 for Advanced Hepatocellular Carcinoma

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"We are pleased to receive fast track designation for TTI-101 in HCC from the FDA," Imran Alibhai, Ph.D., chief executive officer of Tvardi, said in a press release. "This designation provides validation of the compelling safety and efficacy we have seen in last-line HCC patients in our phase 1 trial [NCT03195699]. This comes at a perfect time as we look forward to enrolling patients imminently in our phase 2 HCC basket trial [NCT05440708] which will test TTI-101 as monotherapy and in combination with existing approved therapies across first-, second-, and last-line [patients with] HCC."

HCC is the most common form of liver cancer; however, treatment options for this patient population are limited and prognosis is poor, with a 5-year overall survival rate of 18%.

TTI-101 is an oral, small-molecule, STAT3 inhibitor. STAT3 is a regulatory protein that plays a key role in the proliferation of HCC.

In April 2022, the agent received an orphan drug designation from the FDA for the treatment of patients with HCC.2

In preclinical data, TTI-101 was shown to inhibit the growth of cancers of the breast, head and neck, lung, and liver in mice and was safe when administered at high doses to mice, rats, and dogs.3

TTI-101 is completing a first-in-human phase 1 trial in patients with advanced solid tumors who have failed all prior lines of therapy. Eligible patients must be between the ages of 18 and 65 years and have received a diagnosis of breast cancer, head, and neck squamous cell carcinoma, non–small cell lung cancer, HCC, colorectal cancer, gastric adenocarcinoma, melanoma, or other advanced cancer.
Additional eligibility criteria include an ECOG performance status of 0 or 1, adequate renal and liver function, and measurable disease per RECIST v1.1 criteria.

The primary objective is the determination of the maximum tolerated dose of the agent and its pharmacokinetic profile. Secondary objectives include the evaluation of pharmacodynamics and the best response in target and non-target lesions.

To date, TTI-101 monotherapy has been well-tolerated and has clinical activity defined by durable radiographic objective responses across a range of tumors.

The study has an estimated primary completion date of October 1, 2023.

Source: OncLive by Caroline Seymour

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2. Tvardi Therapeutics' TTI-101 receives orphan drug designation for hepatocellular carcinoma. News release. Tvardi Therapeutics, Inc. April 21, 2022. Accessed October 19, 2022. **bwnews.pr/3Fc3NWr**
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