



Terns Pharmaceuticals Announces Positive Interim Results From Ongoing Phase 1 Clinical Trial of TERN-201, a SSAO Inhibitor in Development for NASH

- *Results from single-ascending dose cohorts demonstrate that TERN-201 is generally safe and well tolerated and results in sustained inhibition of plasma SSAO activity*
- *The trial has now progressed to the multiple-ascending dose phase*

FOSTER CITY, Calif. & SHANGHAI--([BUSINESS WIRE](#))-- Terns Pharmaceuticals, Inc., a global biopharmaceutical company focused on discovering and developing innovative therapies to treat non-alcoholic steatohepatitis (NASH) and cancer, today announced the interim results of an ongoing Phase 1 clinical trial of TERN-201, a semicarbazide-sensitive amine oxidase (SSAO) inhibitor, being developed for the treatment of NASH.

Interim data from the first-in-human clinical study of TERN-201 demonstrate that single, oral administrations of TERN-201 were well tolerated with no significant safety findings or adverse events observed that led to discontinuation. Each dose level studied resulted in decreases from baseline in plasma SSAO activity that were maintained up to one week after single dose administrations of TERN-201. Based on these results, the study has progressed to the multiple-dose phase.

"The data observed to date from the Phase 1 clinical study of TERN-201 are encouraging and show that TERN-201 has the potential to be a promising new therapy to treat NASH and liver fibrosis," said Erin Quirk, M.D., Chief Medical Officer of Terns. "Terns has advanced two compounds into clinical development in 2019 with both TERN-201 and TERN-101, an FXR agonist, in ongoing studies. We look forward to seeing further results from the Phase 1 studies of TERN-101 and TERN-201 later in the year as we progress toward our goal of introducing safe and effective combination therapies for NASH."

The first-in-human trial of TERN-201 is a multiple phase, single- and multiple-ascending dose study in healthy human participants. In the first phase, study volunteers receive a single dose of TERN-201 or placebo in ascending dose cohorts. In the second phase of the study, healthy participants receive repeat doses of TERN-201 or placebo, also in ascending dose cohorts. The primary endpoint for each phase of the trial is safety and tolerability. Secondary endpoints include pharmacokinetics (PK) and pharmacodynamic (PD) biomarker assessments of SSAO target engagement.

TERN-201 was initially discovered and developed by Eli Lilly and Company. Terns signed a global, [exclusive agreement](#) with Eli Lilly in 2018 to develop, manufacture, and commercialize TERN-201 for the treatment of NASH. At The International Liver Congress™ 2019 in Vienna, Terns presented [preclinical data](#) demonstrating that TERN-201 improves the NAFLD Activity Score (NAS) and fibrosis in rodent models of NASH.

About Semicarbazide-Sensitive Amine Oxidase (SSAO) Inhibition and TERN-201

SSAO, also known as VAP-1 (Vascular Adhesion Protein-1), is a dual-function amine oxidase which increases oxidative stress through the generation of H₂O₂ and promotes recruitment of white blood cells in the liver, which results in increased oxidative stress, inflammation and hepatic fibrosis. The level of surface SSAO is upregulated in the vasculature of inflamed tissues, and soluble SSAO levels are elevated in patients with NASH. Inhibition of SSAO is believed to have therapeutic benefit for the treatment of NAFLD, NASH and other chronic fibrotic liver diseases. TERN-201 is a potent SSAO inhibitor which provides an additional treatment mechanism for NASH by reducing oxidative stress and recruitment of white blood cells to the liver.

About NASH

Non-alcoholic steatohepatitis (NASH) is a severe form of non-alcoholic fatty liver disease (NAFLD), which is caused by the accumulation of excess fat in the liver. NASH is associated with chronic liver inflammation and liver cell injury, and it can lead to fibrosis, cirrhosis, and eventually liver cancer or liver failure. Global rates of NAFLD and NASH are increasing rapidly, in tandem with rising rates of obesity. There is currently no approved medication for the treatment of NASH.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company that is focused on the discovery and development of medicines for chronic liver disease and cancer. Based in China and the United States, the company is advancing a pipeline of drug candidates for the treatment of non-alcoholic steatohepatitis (NASH) and cancer, across multiple modalities. Terns leverages world class expertise in disease biology, medicinal chemistry, and clinical development in order to bring promising new therapies to patients in China and other global markets.

For more information, visit www.ternspharma.com and www.ternspharma.com.cn

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