Terns Pharmaceuticals Announces Initiation of Patient Dosing in the LIFT Study, a Phase 2a Clinical Trial of TERN-101 in Development for NASH

-Trial is evaluating the safety and efficacy of farnesoid X receptor (FXR) agonist TERN-101 in NASH patients -

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 that it has dosed the first patient in the LIFT study, a Phase 2a clinical trial of TERN-101, a liver-selective farnesoid X receptor (FXR) agonist, the company's lead development candidate for the treatment NASH.

“TERN-101 is a potent and highly selective FXR agonist that has demonstrated significant suppression of 7α-C4, a liver FXR activation biomarker, as well as a favorable safety profile, and we believe it can become the backbone of a combination therapy that can meaningfully benefit patients living with NASH,” said Erin Quirk, M.D., President and Chief Medical Officer of Terns. “We look forward to LIFT study data next year for TERN-101 monotherapy in NASH and subsequently to testing TERN-101 in combination with our potentially best-in-class THR- β agonist TERN-501, which is on track to enter clinical trials later this year.”

Initiation of screening in the 12-week Phase 2a LIFT study was announced in June 2020, and the first patient was dosed on July 21, 2020. “I am extremely proud of our team for collaborating with our investigator sites and vendors to safely initiate this study during the ongoing COVID-19 pandemic," said Weidong Zhong, Ph.D., Chief Executive Officer of Terns. "We will continue to monitor the situation to minimize study disruption while maintaining the safety of the patients and site staff."

About LIFT

The LIFT study is a multi-center, randomized, double-blind, placebo-controlled Phase 2a clinical trial designed to evaluate efficacy, safety, and pharmacokinetics in 96 NASH patients who receive placebo or TERN-101 at various dose levels for 12 weeks. The primary objective for the trial is assessing safety, with a secondary objective of assessing change in alanine aminotransferase levels with TERN-101. The study, which is ongoing in the United States, will also evaluate standardized biomarkers of tissue fat concentration (MRI-derived proton density fat fraction) and NASH-associated fibrosis.

TERN-101 Phase 1 Clinical Trial Results Summary

Four Phase 1 studies of TERN-101 have been completed. Oral dose administration of TERN-101 resulted in 74% to 91% dose-dependent reductions in 7α-C4, a fluid biomarker whose production is inhibited by FXR activation in the liver. FGF19, a biomarker of intestinal FXR agonism, increased between 6- to 8-fold from baseline after TERN-101 dosing. TERN-101 was well tolerated in each of the studies. No subjects who were dosed with TERN-101 reported pruritus in any of these initial Phase 1 trials.

About TERN-101 and Farnesoid X Receptor (FXR) Agonism

TERN-101 is a potent, liver-selective, non-bile acid FXR agonist being developed for the treatment of NASH. FXR is a nuclear receptor that is highly expressed in the liver and small intestine. Bile acids (BA) are natural ligands of FXR, and their binding with and activation of FXR is critical to the regulation of cellular pathways

that modulate BA synthesis, lipid metabolism, inflammation, and fibrosis. FXR agonism has demonstrated improvement over placebo in regression of histological liver fibrosis without progression of NASH in a late-stage study, demonstrating the potential for FXR agonists to be a new treatment modality for non-alcoholic steatohepatitis (NASH). TERN-101 has been granted FastTrack Designation by the U.S. Food and Drug Administration (FDA) for the treatment of NASH.

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), primary biliary cholangitis (PBC), 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.

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

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