



TERNs ANNOUNCES FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG (IND) APPLICATION FOR FIRST-IN-HUMAN PHASE 1 TRIAL OF TERN-501, ITS THR-BETA AGONIST IN DEVELOPMENT FOR THE TREATMENT OF NASH

January 19, 2021

*-Initiation of Phase 1 trial expected in the first half of 2021 and top-line data expected in the second half of 2021–
-TERN-501 will be Terns' third NASH candidate to enter clinical trials in the United States-*

FOSTER CITY, Calif.--([BUSINESS WIRE](#))--Terns Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis (NASH) and other chronic liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug application (IND) for TERN-501, a selective thyroid hormone receptor beta, or THR- β , agonist with enhanced metabolic stability and liver distribution, characteristics that are intended to improve safety and efficacy in NASH patients. Terns expects to initiate a Phase 1 clinical trial for TERN-501 in the first half of 2021, with top-line data anticipated in the second half of 2021.

"TERN-501 is our third NASH program to enter clinical trials, and we are proud of our team's ability to advance our entire NASH pipeline," said Erin Quirk, M.D., President and Chief Medical Officer of Terns. "We believe the data on TERN-501 support its potential as an attractive candidate for fixed-dose combinations and we expect to initiate a Phase 2a clinical proof-of-concept trial evaluating a combination of TERN-101 and TERN-501 in the first half of 2022."

The Phase 1 clinical trial is expected to be a multi-part study enrolling approximately 90 healthy participants. The trial is designed to incorporate both single ascending dose and multiple ascending dose cohorts to assess the safety, tolerability and pharmacokinetics of TERN-501, as well as the reduction in serum lipid levels as an early marker of target engagement.

About TERN-501

TERN-501 is a THR- β agonist with high metabolic stability, enhanced liver distribution and greater selectivity for THR- β compared to other THR- β agonists in development. Agonism of THR- β increases fatty acid metabolism via mitochondrial oxidation and affects cholesterol synthesis and metabolism. As a result, THR- β stimulation has the ability to reduce hepatic steatosis and improve serum lipid parameters including LDL cholesterol and triglycerides. *In vivo* NASH studies in a rodent model have demonstrated that low-doses of TERN-501 achieved complete resolution of steatosis and reductions in serum lipids, hepatic inflammation and fibrosis. TERN-501 has high liver distribution and is 23-fold more selective for THR- β than for THR- α activation in a cell free assay, thereby minimizing the risk of cardiotoxicity and other off-target effects associated with non-selective THR stimulation. Finally, TERN-501 has been designed to be metabolically stable and is therefore expected to have little pharmacokinetic variability and a low clinical dose, making it an attractive candidate for use in fixed-dose combinations for NASH treatment.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis, or NASH, and other chronic liver diseases. Terns' programs are based on clinically validated and complementary mechanisms of action to address the multiple hepatic disease processes of NASH in order to drive meaningful clinical benefits for patients. Terns' investors include Decheng Capital, Deerfield Management Company, Eli Lilly and Company, Lilly Asia Ventures, OrbiMed Advisors, Samsara Capital, Suvretta Capital Management, and Vivo Capital.

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