TERNS COMPLETES ENROLLMENT IN PHASE 2A CLINICAL TRIAL OF TERN-101 IN NASH PATIENTS

January 12, 2021

-Top-line results expected in third quarter 2021 -

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 the completion of patient enrollment in the LIFT study, a Phase 2a NASH clinical trial of TERN-101, a liver-distributed non-bile acid farnesoid X receptor (FXR) agonist that has demonstrated a differentiated tolerability profile and improved target engagement in the liver.

“I would like to thank the clinical study team and investigators who worked tirelessly despite the COVID-19 pandemic to fully enroll the LIFT study and to express particular gratitude to the NASH patients who are participating in the trial. Together we continue to make great progress towards a key data milestone in the third quarter of this year,” said Erin Quirk, M.D., President and Chief Medical Officer of Terns. “In all four Phase 1 clinical trials of TERN-101, none of the 119 subjects who received TERN-101 reported pruritus, and the serum lipid profiles among TERN-101 recipients were similar to placebo recipients even at high doses. We believe this favorable tolerability profile stems from the differentiated characteristics of TERN-101, including high liver-distribution, which limits the potential for systemic and intestinal FXR activation. We believe this differentiation could give TERN-101 significant advantages over other FXR agonists in development.”

About LIFT

TERN-101 is currently being evaluated in the LIFT Study, a Phase 2a, 12-week, randomized, placebo-controlled clinical trial in approximately 96 patients with phenotypic or biopsy-diagnosed NASH, identified either by prior biopsy or clinical diagnosis (liver stiffness measured by transient elastography of 7.6—25 kPa and controlled attenuation parameter (CAP) > 300). Terns initiated this clinical trial in June 2020, and top-line data are now expected in the third quarter of 2021. Clinical trial participants receive once-daily oral administration of placebo or TERN-101 tablet doses of 5 mg, 10 mg or 15 mg for 12 weeks. TERN-101 plasma concentrations resulting from these tablet doses are expected to fall within a comparable range as the plasma concentrations observed in Phase 1 studies of prior capsule formulation doses of 25 mg to 150 mg. The primary endpoint for the LIFT Study is the incidence of adverse events. Key secondary and exploratory outcome measures for the LIFT Study are percent change from baseline in ALT and change from baseline in hepatic fat fraction assessed by magnetic resonance imaging derived proton density fat fraction, or MRI-PDFF, key biomarkers that have been associated with histologic improvements in NASH patients.

About TERN-101

TERN-101 is a liver-distributed, non-bile acid FXR agonist that has demonstrated a differentiated tolerability profile and improved target engagement, likely due to its sustained FXR activation in the liver but only transient FXR activation in the intestine. FXR is a nuclear receptor primarily expressed in the liver, intestine and kidneys. FXR regulates hepatic expression of various genes involved in lipid metabolism, inflammation and fibrosis. Studies have demonstrated that there is minimal overlap between liver and intestine FXR binding sites, indicating potentially a high degree of tissue-specific FXR function. Clinical studies of other FXR agonists have demonstrated significant histological NASH improvements but have also resulted in pruritus and adverse lipid changes. These tolerability issues have generally been observed in Phase 1 clinical trials of other FXR agonists in development and have been regarded as dose-limiting toxicities, which are suboptimal for patients and can lead to treatment discontinuation. However, in all four Phase 1 clinical trials of TERN-101, none of the 119 subjects who received TERN-101 reported pruritus, and the serum lipid profiles among TERN-101 recipients were similar to placebo recipients even at high doses.

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.

Contacts

US Media Contact:
Investor Relations Contact:
Mark Vignola
investors@ternspharma.com

Media Contact:
Cory Tromblee
media@ternspharma.com