



Terns Pharmaceuticals Highlights Results from Phase 1 Clinical Trial of TERN-501 at AASLD The Liver Meeting® 2022

November 4, 2022

Data demonstrated treatment with TERN-501 resulted in time- and dose-dependent increases in sex hormone binding globulin (SHBG), a key marker linked to NASH histologic efficacy

Phase 2a DUET trial evaluating TERN-501 alone and in combination with TERN-101, the first trial assessing both THR-β and FXR agonists in NASH, is ongoing

FOSTER CITY, Calif., Nov. 04, 2022 (GLOBE NEWSWIRE) -- Terns Pharmaceuticals, Inc. ("Terns" or the "Company") (Nasdaq: TERN), a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology, obesity and non-alcoholic steatohepatitis (NASH), today announced that the company is presenting positive clinical data from its Phase 1 study of TERN-501, a thyroid hormone receptor beta (THR-β) agonist in development for the treatment of NASH. The results are being highlighted in a poster presentation at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD), taking place November 4-8, 2022.

The poster presentation, delivered by Cara Nelson, Ph.D., senior director of clinical pharmacology at Terns, highlights results from a Phase 1 study in which healthy participants with low-density lipoprotein (LDL) cholesterol levels of 100-190 mg/dL were randomized (3:1) to receive TERN-501 (1, 3, 6, or 10 mg) or placebo once daily for 14 days. Results showed that among the 24 treated participants TERN-501 was generally well tolerated and exhibited dose-dependent pharmacokinetics with low variability. TERN-501-treated participants also experienced increases in sex-hormone binding globulin (SHBG), a key pharmacodynamic marker of THR-β engagement linked to decreases in levels of atherogenic lipids and NASH histologic efficacy, which were time- and dose-dependent and highly associated with TERN-501 exposure. Results showed that 0%, 0%, 33.3%, 83.3%, and 100% of subjects in the placebo, TERN-501 1, 3, 6, and 10 mg groups, respectively, had ≥ 75% SHBG increases at Day 15 compared to baseline.

In TERN-501 recipients, results also showed dose-dependent decreases in levels of total cholesterol, LDL cholesterol and apolipoprotein-B, with greater median percent decreases at Day 15 in recipients who had ≥ 75% SHBG increases than those who had < 75% SHBG increases and placebo recipients.

"The data presented from our Phase 1 study reiterate that TERN-501 has a predictable pharmacokinetic profile with low variability and treatment results in robust SHBG increases and lipid-lowering effects. TERN-501 is a promising candidate for NASH treatment, either as a monotherapy or in combination with other agents," said Kerry Russell, M.D., Ph.D., chief medical officer at Terns. "We look forward to continued assessments of TERN-501 including our ongoing Phase 2a DUET trial of TERN-501, alone and in combination with our FXR agonist TERN-101, with top-line data anticipated in the second half of 2023."

Terns will review the ongoing Phase 2a DUET trial ([NCT05415722](https://clinicaltrials.gov/ct2/show/study/NCT05415722)) design and objectives in a second presentation at The Liver Meeting. DUET is the first trial assessing the safety and efficacy of a THR-β agonist and a farnesoid X receptor (FXR) agonist combination regimen in NASH patients. The DUET trial will evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of TERN-501 administered alone and in combination with TERN-101 in approximately 140 non-cirrhotic NASH patients for 12 weeks. The primary endpoint will be the relative change in liver fat content as measured by MRI protein density fat fraction (PDFF) at Week 12 for TERN-501 monotherapy compared to placebo.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology, obesity and NASH. Terns' pipeline includes four clinical stage development programs including an allosteric BCR-ABL inhibitor, a THR-β agonist, an FXR agonist, a VAP-1 inhibitor, and a preclinical small-molecule GLP-1 receptor agonist program. For more information, please visit: www.ternspharma.com.

About TERN-501

TERN-501 is a thyroid hormone receptor beta (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. Terns reported positive top-line single-ascending and multiple-ascending dose (SAD/MAD) [data](#) from Phase 1 proof of concept clinical trial in November 2021. The DUET Phase 2a clinical trial of TERN-501 alone and in combination with TERN-101 is ongoing, with top-line data expected in the second half of 2023.

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. Clinical studies of other FXR agonists have demonstrated significant histological NASH improvements but have also resulted in pruritus, adverse lipid changes and discontinuations. Terns reported positive top-line [results](#) from the Phase 2a LIFT Study of TERN-101 in June 2021.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about Terns Pharmaceuticals, Inc. (the “Company,” “we,” “us,” or “our”) within the meaning of the federal securities laws, including those related to the Company’s expectations of timing and potential results of the Company’s clinical trials and other development activities, such as the Phase 2a DUET trial of TERN-501 alone and in combination with TERN-101; the potential indications to be targeted by the Company with its product candidates; the therapeutic potential of the Company’s product therapy candidates; the potential for the mechanisms of action of the Company’s product candidates to be therapeutic targets for their targeted indications; the potential utility and progress of the Company’s product candidates in their targeted indications, including the clinical utility of the data from and the endpoints used in the Company’s clinical trials; the Company’s clinical development plans and activities; the Company’s expectations regarding the profile of its product candidates, including tolerability, safety, metabolic stability and pharmacokinetic profile and potential differentiation as compared to other products or product candidates; and the Company’s plans for and ability to continue to execute on its current clinical strategy. All statements other than statements of historical facts contained in this press release, including statements regarding the Company’s strategy, future financial condition, future operations, future trial results, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results and the implementation of the Company’s plans to vary materially, including the risks associated with the initiation, cost, timing, progress, results and utility of the Company’s current and future research and development activities and preclinical studies and clinical trials. These risks are not exhaustive. For a detailed discussion of the risk factors that could affect the Company’s actual results, please refer to the risk factors identified in the Company’s SEC reports, including but not limited to its Annual Report on Form 10-K for the year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the periods ended March 31, 2022 and June 30, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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