



Terns Pharmaceuticals Presents Late-Breaking Data from Phase 2a DUET Trial of THR- β Agonist TERN-501 in NASH at AASLD The Liver Meeting® 2023

November 13, 2023

TERN-501 treatment over 12 weeks significantly improved liver fat content and fibro-inflammation in NASH patients, with low rates of gastrointestinal and no cardiovascular adverse events

TERN-501 significantly increased SHBG, a marker of target engagement and predictor of histologic response in the THR- β class

Company to host in-person investor event following late-breaking data today at 4:00 p.m. ET in Boston

FOSTER CITY, Calif., Nov. 13, 2023 (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 the late-breaking oral presentation of top-line data from its Phase 2a DUET clinical trial of TERN-501, an investigational orally administered thyroid hormone receptor- β (THR- β) agonist for the treatment of NASH. TERN-501 was evaluated alone and in combination with the Company's liver-distributed farnesoid X receptor (FXR) agonist TERN-101. These data will be presented at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD), on Monday, November 13 at 2:00 p.m. ET in Boston, Massachusetts.

"NASH continues to be a serious, multi-faceted disease, and it is encouraging to see the additional evidence supporting the THR- β mechanism of action of TERN-501 to address these disease processes," said Mazen Nouredin, M.D., MHSc, Professor of Medicine, Academic Institute, Houston Methodist, Director of Houston Research Institute, study presenter and principal investigator in the DUET trial. "The efficacy of TERN-501, showing a significant impact on steatosis and fibro-inflammation markers in a short period of time, coupled with its convenient oral once-daily dosing and highly positive safety profile, indicate that TERN-501 is a promising candidate for NASH treatment, either as a monotherapy or in combination with other therapies."

Late-Breaking Oral Presentation

Date/Time: November 13, 2023 at 2:00 p.m. ET
Location: Auditorium
Session Title: Late Breaking Abstract #1

In the Phase 2a DUET trial, patients with phenotypic or prior histologic NASH were randomized to one of seven treatments: once-daily, orally administered TERN-501 (1, 3 or 6 mg), TERN-101 (10 mg), TERN-501 (3 or 6 mg) combined with TERN-101 (10 mg), or placebo. The primary endpoint was the relative change from baseline in magnetic resonance imaging proton density fat fraction (MRI-PDFF), a measure of liver fat content, at Week 12 for TERN-501 monotherapy versus placebo. The study also assessed liver fibro-inflammation as measured by MRI corrected T1 (cT1), sex hormone binding globulin (SHBG) levels, a marker of THR- β agonism in the liver, lipid levels, and other fibrosis biomarkers as well as safety and tolerability following treatment.

Late-Breaking Phase 2a DUET Top-line Data to be Presented at AASLD The Liver Meeting

- TERN-501 (6 mg) monotherapy demonstrated significant reductions in liver fat content as early as Week 6
- The study met its primary endpoint, with TERN-501 monotherapy demonstrating a mean relative reduction of 27% ($p=0.0036$) and 45% ($p<0.0001$) at 3 mg and 6 mg doses, respectively, versus a 4% reduction in the placebo group at Week 12
- A significantly higher percentage of patients achieved a $\geq 30\%$ MRI-PDFF reduction in TERN-501 arms and a $\geq 50\%$ reduction with TERN-501 (6 mg) monotherapy at Week 12
- TERN-501 (6 mg) monotherapy resulted in a significant and rapid decrease in cT1 with a significantly higher percentage of patients achieving a ≥ 80 ms reduction (recovering from an at-risk NASH category)
- TERN-501 combined with TERN-101 resulted in efficacy improvement or maintenance compared to TERN-501 monotherapy
- TERN-501 monotherapy arms demonstrated significant increases in SHBG and improved lipid levels, including significant reductions in apolipoprotein B (ApoB) and a decrease in low-density lipoprotein (LDL) levels, when combined with TERN-101
- TERN-501 was generally well tolerated, with treatment-related adverse events (AEs) similar to the placebo group
 - Overall, there were low rates of gastrointestinal AEs reported similarly across all treatment arms
 - No treatment-related cardiovascular AEs or serious AEs were reported

"The acceptance of this late-breaking analysis of our Phase 2a DUET study for patients with non-cirrhotic NASH at one of the most prestigious liver meetings in the world is further validation that we are advancing important research that has the potential to transform the treatment of this serious

disease,” said Erin Quirk, M.D., president and head of research and development at Terns. “These top-line data of TERN-501 are encouraging, with significant reductions in key biomarkers including liver fat content, MRI-PDFF, and cT1, a marker of fibro-inflammation. The positive efficacy and safety profile of TERN-501 supports our belief that it has the potential to become the THR- β monotherapy of choice and potentially a mainstay backbone of combination therapies for people living with NASH who are in desperate need of treatment options.”

The presentation will be made available on the Scientific Publications portion of the Terns website.

In-Person Investor Event Information

Terns will host an investor reception event during The Liver Meeting in Boston on Monday, November 13 at 4:00 p.m. ET. Interested investors may reach out to RSVP at investors@ternpharma.com.

About the Phase 2a DUET Trial

The Phase 2a DUET trial ([NCT05415722](https://clinicaltrials.gov/ct2/show/study/NCT05415722)) is a multicenter, randomized, double-blind, placebo-controlled clinical trial in non-cirrhotic NASH, designed to evaluate efficacy and safety of TERN-501 as a monotherapy and in combination with TERN-101. The trial enrolled over 160 adults with body mass index (BMI) ≥ 25 kg/m² and pre-cirrhotic NASH identified based on prior liver biopsy and/or imaging and clinical criteria. All participants had liver fat content measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF) of $\geq 10\%$, MRI corrected T1 (cT1) relaxation time of ≥ 800 msec and met other inclusion and exclusion criteria. The trial included a 12-week treatment period and a 4-week follow-up period. The primary endpoint was the relative change from baseline in MRI-PDFF at Week 12 for TERN-501 monotherapy compared to placebo. Secondary endpoints included assessments of relative change from baseline in MRI-PDFF for TERN-501+TERN-101 combination compared to placebo and change from baseline in cT1 for TERN-501 monotherapy compared to placebo as well as for TERN-501+TERN-101 combination therapy compared to placebo.

About Non-alcoholic Steatohepatitis (NASH)

NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) that affects up to 20 million people in the United States, and up to 5% of the global population, and for which there is currently no approved therapy in the United States or Europe. In a study published in *Hepatology* in 2018, lifetime costs of treating and managing NASH patients in the United States in 2017 were estimated to be over \$220 billion, in the absence of approved therapies. NASH is a multifaceted disease that involves three distinct pathogenic hepatic disease processes: accumulation of excess fat in the liver (steatosis), inflammation and fibrosis. In addition to these three disease processes, NASH patients often exhibit elevated levels of glucose and atherogenic lipids, are overweight or obese and accumulate excessive lipotoxic fat. Severe progression of NASH can lead to cirrhosis, decompensated liver disease and increased risk for hepatic carcinoma and liver-related mortality.

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 three clinical stage development programs including an allosteric BCR-ABL inhibitor, a small-molecule GLP-1 receptor agonist, and a THR- β agonist, and a preclinical GIPR modulator program. For more information, please visit: www.ternspharma.com.

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 clinical trials and other development activities of the Company and its partners; the potential indications to be targeted by the Company with its small-molecule product candidates; the therapeutic potential of the Company’s small-molecule product 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, including the results of any interactions with regulatory authorities on its programs; the Company’s expectations regarding the profile of its product candidates, including efficacy, 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 development strategy, including potential combinations involving multiple product candidates. 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, 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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