Terns Pharmaceuticals Highlights Positive Clinical Data from Multiple NASH Programs at AASLD The Liver Meeting® Digital Experience 2021

November 12, 2021

Oral presentation of data from Phase 2a LIFT Trial of TERN-101, demonstrating differentiated safety and efficacy profiles

12 weeks of TERN-101 treatment significantly decreases cT1, a marker of liver inflammation and fibrosis, leading to study population shifts into cT1 categories associated with lower risk of clinical events

Phase 1 data show single doses of TERN-501 are generally well-tolerated, produce significant LDL decreases and increases in SHBG, a key pharmacodynamic marker of THR-β engagement linked to NASH histologic efficacy

FOSTER CITY, Calif., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Terns Pharmaceuticals, Inc. (“Terns” or the “Company”) (Nasdaq: TERN), 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 multiple presentations of positive results from clinical trials of TERN-101 and TERN-501 will be delivered at The Liver Meeting® Digital Experience 2021, the annual meeting of the American Association for the Study of Liver Diseases (AASLD), which will be held virtually from November 12-15, 2021.

An oral presentation titled “Liver-distributed FXR Agonist TERN-101 Demonstrates Favorable Safety and Efficacy Profile in NASH Phase 2a LIFT Study” will be delivered by Rohit Loomba, M.D., MHSc, director of the UC San Diego NAFLD Research Center and director of Hepatology at UC San Diego School of Medicine. This presentation will highlight the safety and efficacy of TERN-101 after 12 weeks of treatment in patients with NASH. TERN-101 was overall safe and well-tolerated at all doses studied with no discontinuations due to adverse events, including pruritus. In the TERN-101 5 and 10 mg groups, no differences from placebo in percentage change in low density lipoprotein (LDL) cholesterol or high density lipoprotein (HDL) cholesterol from baseline to Week 12 were observed. TERN-101 demonstrated numerical reductions in alanine transaminase (ALT) and MRI proton density fat fraction (MRI-PDFF) in the 10 and 15 mg groups, and significant reductions in gamma-glutamyl transferase (GGT) in all dose groups. Corrected T1 (cT1), a marker of liver inflammation and fibrosis, declined significantly as early as Week 6 with persistent decreases through Week 12 in all TERN-101 groups compared to placebo. These data support further clinical studies of TERN-101 for the treatment of NASH, either alone or in combination with other agents.

“These data add to the growing body of evidence supporting TERN-101 as a potential treatment for NASH, a complex and multi-faceted disease that currently has no available treatments targeting all of the different underlying causes,” said Dr. Loomba. “TERN-101 demonstrates a differentiated safety and efficacy profile, including the potential to decrease liver inflammation and fibrosis as measured by cT1, an increasingly recognized non-invasive biomarker of fibro-inflammation.”

A second clinical presentation titled “Liver-distributed FXR Agonist TERN-101 Leads to Corrected T1 (cT1) Response and a Population Shift to Lower cT1 Risk Categories in NASH Phase 2a LIFT Study” will be delivered by Eric Lawitz, M.D., director of the Texas Liver Institute and Clinical Professor of Medicine at University of Texas Health Science Center. This presentation will detail the cT1 responses observed during the Phase 2a LIFT Study. cT1 relaxation time, measured in milliseconds (msec), is a magnetic resonance imaging-based test that is a composite biomarker of inflammation and fibrosis. Mean cT1 values declined in a significant and dose-dependent manner from baseline to Week 12 for all TERN-101 doses. cT1 changes at Week 6 strongly correlated with changes at Week 12. A higher proportion of patients treated with TERN-101 for 12 weeks had a cT1 response (defined as a decrease ≥80 msec from baseline at Week 12) compared to placebo. TERN-101 treatment for 12 weeks also led to an increased proportion of cT1 low risk patients (where cT1<800msec), and a decreased proportion of high-risk patients (where cT1>875msec). cT1 may serve as a biomarker of TERN-101 treatment response as early as Week 6. Overall, cT1 declines in the LIFT Study indicate significant improvements in fibro-inflammation following TERN-101 treatment in NASH patients.

In addition, a third clinical presentation titled “Single Doses of the THR-β Agonist TERN-501 are Well Tolerated and Result in Dose-dependent Changes in LDL Cholesterol and Sex Hormone Binding Globulin in a First-in-Human Clinical Trial” will be delivered by Barry Crittenden, M.D., Executive Director, Clinical Research and Medical Affairs at Terns. This presentation will highlight data from the single ascending dose (SAD) cohort of TERN-501 up to 60 mg. All SAD doses of TERN-501 were overall safe, well-tolerated and exhibited dose-proportional plasma exposures with low variability. Significant decreases in LDL cholesterol, total cholesterol, and apolipoprotein B were observed by Day 3 following single dose administration of TERN-501 in one or more dose groups with dose-dependent reductions on Day 4. TERN-501 also demonstrated significant effects on sex hormone binding globulin (SHBG). SHBG is a protein produced in the liver following activation of the thyroid hormone receptor in hepatocytes and is a marker of THR-β target engagement linked to NASH histologic efficacy. Significant increases in SHBG were observed following a single dose of ≥10 mg TERN-501 with dose dependent increases through 30 mg, indicating potent target engagement at all evaluated dose levels. Importantly, increases in SHBG have been associated with robust reductions in MRI-PDFF and NAFLD Activity Score in a precedent late-stage clinical NASH trial.

“Altogether, the multiple clinical data presentations at The Liver Meeting demonstrate the tremendous progress made in the advancement of Terns’ NASH pipeline. The data presented from our Phase 2a LIFT study of TERN-101 continue to support the potential of TERN-101 as a backbone of Terns’ combination strategy and the utility of cT1 as an effective, non-invasive biomarker. Data from our proof of concept Phase 1 clinical trial of TERN-501 released earlier this week also demonstrated a potentially best-in-class THR-β agonist profile, based on its significant increases in SHBG, which has been shown to be linked to NASH histologic efficacy,” said Erin Quirk, M.D., president, chief medical officer and head of R&D at Terns. “We are pleased to share our TERN-101 and TERN-501 data at The Liver Meeting as we look forward to Phase 1b top-line data for TERN-201 in NASH patients in the first quarter of 2022 and the initiation of Terns’ first FXR / THR-β agonist combination trial of TERN-101 with TERN-501 in NASH

patients in the first half of 2022."

Oral Presentation:

Title: Liver-distributed FXR Agonist TERN-101 Demonstrates Favorable Safety and Efficacy Profile in NASH Phase 2a LIFT Study
Publication Number: 143
Session Title: Parallel 21: NAFLD and NASH: Clinical Trials of Novel Therapeutics
Presenting Author: Rohit Loomba
Date and Time: Sunday, November 14, 6:30 p.m. ET

Clinical Poster Presentations:

Title: Liver-distributed FXR Agonist TERN-101 Leads to Corrected T1 (cT1) Response and a Population Shift to Lower cT1 Risk Categories in NASH Phase 2a LIFT Study
Publication Number: 1875
Session Title: NAFLD and NASH: Experimental: Clinical
Presenting Author: Eric Lawitz

Title: Single Doses of the THR-β Agonist TERN-501 are Well Tolerated and Result in Dose-dependent Changes in LDL Cholesterol and Sex Hormone Binding Globulin in a First-in-Human Clinical Trial
Presentation Number: 1889
Session Title: NAFLD and NASH: Experimental: Clinical
Presenting Author: D. Barry Crittenden

A full list of presentations can be found on The Liver Meeting Digital Experience™ 2021 website

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.

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. 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. Terns reported positive top-line results from the proof of concept Phase 1 clinical trial of TERN-501 in November 2021.

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' pipeline includes three clinical stage development programs including an FXR agonist, a VAP-1 inhibitor and a THR-β agonist, and a preclinical GLP-1 receptor agonist program. Terns is focused on developing combination therapies 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. 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 Company's clinical trials and other development activities and the potential utility and progress of the Company's product candidates in NASH. 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, 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 and results of the Company's current and future research and development activities and preclinical studies and clinical trials. In particular, the impact of the COVID-19 pandemic on the Company's ability to progress with its research, development, manufacturing and regulatory efforts, including the Company's clinical trials for its product candidates, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. 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, 2020 and its Quarterly Reports on Form 10-Q for the periods ended March 31, 2021

and June 30, 2021. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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