



Terns Announces Initiation of Patient Dosing in AVIATION Phase 1b NASH Clinical Trial of VAP-1 Inhibitor TERN-201

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- *TERN-201 is a highly selective VAP-1 inhibitor intended to address chronic liver inflammation and fibrosis in NASH*
- *Sustained VAP-1 inhibition with TERN-201 may make it suitable for co-administration with other Terns therapies*
- *Topline TERN-201 NASH clinical data expected in first half of 2022*

FOSTER CITY, Calif., June 24, 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 the initiation of patient dosing in the AVIATION Trial, a Phase 1b clinical trial evaluating TERN-201, an orally-administered, highly selective inhibitor of vascular adhesion protein-1 (VAP-1) in patients with NASH.

The AVIATION Trial ([NCT04897594](#)) is a multi-center, randomized, double-blind, dose-ranging, placebo-controlled, proof of concept, adaptive, Phase 1b clinical trial to evaluate the safety, pharmacokinetics, pharmacodynamics, and efficacy of TERN-201 in patients with presumed non-cirrhotic NASH and a cT1 value of greater than 800ms. Corrected T1, or cT1, is a magnetic resonance-based imaging test measuring liver inflammation and fibrosis that has been associated with clinical outcomes and liver histology. The primary objective of the AVIATION Trial is to evaluate the safety and tolerability of TERN-201 versus placebo when given for 12 weeks in patients with NASH. The clinical trial will be conducted in two parts: Part 1 of the trial has begun with a dose of 10 mg as compared to placebo while Part 2 is expected to enroll additional dose cohorts of TERN-201 based on an interim assessment of the 10 mg cohort. Each part of the AVIATION Trial is planned to include approximately 20 patients receiving each of the designated doses of TERN-201 and approximately 10 patients receiving placebo. The clinical trial will also explore the effects of TERN-201 on NASH imaging biomarkers (such as cT1) and NASH blood biomarkers (such as CK-18). Preliminary topline 12-week data from Part 1 and Part 2 of the AVIATION Trial are expected in 1H 2022 and 2H 2022, respectively.

"Increasing evidence points to the role of VAP-1 in recruiting white blood cells to the liver as a key factor driving liver inflammation and fibrosis in people living with NASH," said Erin Quirk, M.D., President, Chief Medical Officer and Head of R&D at Terns, "We are excited by TERN-201's selective VAP-1 inhibition and its potential anti-inflammatory and anti-fibrotic effects which may complement the anti-steatotic activity seen with our other product candidates. Initiation of the AVIATION Trial is an important step towards a single once-daily pill as an effective NASH treatment."

About TERN-201

TERN-201 is a highly selective, irreversible, covalent inhibitor of vascular adhesion protein-1 (VAP-1). VAP-1 is a transmembrane protein highly expressed in hepatic vascular endothelial cells that binds to proteins on the surface of white blood cells to facilitate their deceleration, binding and transmigration from the blood stream into the liver. VAP-1 has been shown to be over-expressed in the livers of patients with NASH and fibrosis. In Terns' Phase 1 first-in-human (SAD/MAD) clinical trial across 61 healthy subjects, TERN-201 was shown to be well-tolerated and fully suppress the enzymatic activity of VAP-1 at all evaluated doses with suppression persisting up to 7 days after a single dose. In preclinical studies, TERN-201 showed significant dose-dependent reductions in liver inflammation and fibrosis in a model of liver injury. TERN-201 exhibits high selectivity for VAP-1, enhanced liver distribution and minimal potential for off-target inhibition of monoamine oxidases (MAO). The sustained activity of TERN-201, with its VAP-1 selectivity and anticipated low therapeutic dose, may make it suitable for co-administration with therapies directed at steatosis and other metabolic processes involved in NASH. Terns received Fast Track Designation from the FDA for TERN-201 for the treatment of NASH in August 2020.

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; the therapeutic potential of TERN-201; the potential for vascular adhesion protein-1 (VAP-1) to be a therapeutic target for NASH; the potential utility and progress of the Company's product candidates in NASH, including the clinical utility of the data from and the endpoints used in the Phase 1b AVIATION Trial of TERN-201; the Company's clinical development plans and activities, including the development plans for TERN-201 in combination with therapies directed at steatosis and other metabolic processes involved in NASH; the Company's expectations regarding the profile of its product candidates, including tolerability, safety, metabolic stability and pharmacokinetic profile; and the Company's ability to continue to execute on its clinical strategy and plans. 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 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 Report on form 10-Q for the three months ended March 31, 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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