Terns Pharmaceuticals Announces First Participant Dosed in Phase 1 Clinical Trial of TERN-601 Oral GLP-1 Receptor Agonist for Treatment of Obesity

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Phase 1 trial underway for Terns' first oral GLP-1R agonist candidate for obesity, with 28-day proof of concept data anticipated in 2H24

Oral GLP-1R agonist offers potential for weight loss and improved convenience compared to currently marketed injectables

FOSTER CITY, Calif., Nov. 02, 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 that the first participant has been dosed in the Phase 1 clinical trial of TERN-601, the Company's oral small-molecule glucagon-like peptide-1 receptor, or GLP-1R, agonist for the treatment of obesity.

"We are excited to initiate this first-in-human study of our oral GLP-1R agonist, TERN-601, as we believe it represents a potentially meaningful alternative to the currently marketed injectable GLP-1R agonist treatments," said Erin Quirk, MD, president and head of research and development at Terns. "TERN-601 represents our first internally discovered small molecule GLP-1R agonist, which is designed to be administered orally once daily with a competitive profile for weight loss, both as a monotherapy and as part of a potential all oral combination treatment for obesity."

"We are encouraged by the prospects for our obesity franchise and look forward to reporting initial 28-day weight loss proof of concept data from the Phase 1 trial of TERN-601, which is anticipated in the second half of 2024. We also have ongoing discovery efforts in obesity with our TERN-600 series of additional small molecule GLP-1R agonists and our TERN-800 series of small-molecule glucose-dependent insulinotropic polypeptide receptor (GIPR) modulators, which have the potential to be combined with GLP-1R agonists. These programs along with TERN-501, our highly selective THR-β agonist in development for the treatment of NASH, aim to meaningfully improve clinical outcomes for patients battling metabolic diseases, with better potential tolerability, accessibility and ease-of-use than currently available treatments," added Dr. Quirk.

Phase 1 Trial Design
The Phase 1 trial is a randomized, double-blind, placebo-controlled single and multiple-ascending dose (SAD and MAD) trial to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of TERN-601 in healthy adults with obesity or overweight. The trial will consist of two parts.

Part 1 (SAD) is a single ascending dose study that will evaluate up to six once-daily TERN-601 dose levels in approximately 40 healthy participants with a Body Mass Index (BMI) of ≥ 25 kg/m^2 and < 40 kg/m^2. The starting TERN-601 dose is 30 mg, with subsequent dose levels based on review of emerging safety and PK data from prior cohorts.

In Part 2 (MAD) of the trial, obese and overweight healthy adults will be enrolled in cohorts that will include titration of TERN-601 administered for 28-days at doses to be selected based on data from Part 1 (SAD). Part 2 will include approximately 72 healthy participants with a BMI of ≥ 27 kg/m^2 to < 40 kg/m^2.
The primary endpoint of the trial is safety and tolerability. Secondary endpoints include PK, efficacy as measured by body weight loss following 28-days of treatment with TERN-601, and other exploratory markers. Top-line, proof of concept 28-day weight loss data from Part 2 (MAD) are expected in the second half of 2024.

About TERN-601
TERN-601 is an oral, small-molecule glucagon-like peptide-1 receptor, or GLP-1R, agonist program for obesity. Obesity is a chronic disease that is increasing in prevalence in adults, adolescents and children and is often defined by having an elevated BMI of 30 or greater. GLP-1 agonism offers multiple benefits including improved glucose control, slowing of gastric emptying and increases in satiety. Terns' lead GLP-1R agonist, TERN-601, was designed through internal structure-based drug discovery efforts employing our proprietary three-dimensional QSAR model of the receptor, which was used to identify new GLP-1R agonist candidates. The ligands were further optimized based on in vitro activity, metabolic stability, and pharmacokinetic parameters. Through this process, we discovered TERN-601, a potent GLP-1R agonist biased towards cAMP generation. A Phase 1, first-in-human clinical trial for obesity is underway with top-line data expected in the second half of 2024. TERN-601's potential as a treatment for obesity is supported by preclinical data that were presented at the American Diabetes Association's 83 rd Annual Scientific Session in June 2023. The full poster is available on Terns' scientific publications website.

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, 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; 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; the Company's plans for and ability to continue to execute on its current development strategy, including potential combinations involving multiple product candidates; and the Company's expectations with regard to the sufficiency of its financial resources. 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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