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Terns Pharmaceuticals initiates Ph1 clinical trial of TERN 101

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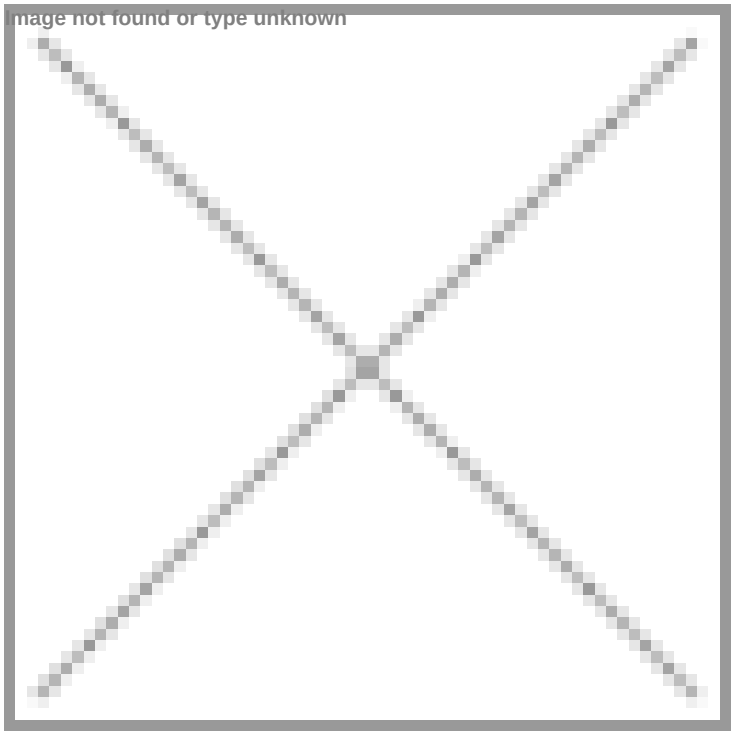
Phase 1 study will evaluate the safety and tolerability of TERN-101, an FXR agonist in development for the treatment of NASH.



Terns Pharmaceuticals has announced the initiation of Phase 1 clinical trial of TERN-101, a farnesoid X receptor (FXR) agonist, being developed for the treatment of non-alcoholic steatohepatitis (NASH). Initiation of the study in the US follows US Food and Drug Administration (FDA) clearance of the Investigational New Drug application for TERN-101 filed earlier this year.

“We’ve made significant progress this year, advancing the development of our lead program, TERN-101, as part of our dedicated approach to NASH, a condition with no existing treatment options,” said Erin Quirk, M.D., Chief Medical Officer of Terns. “We look forward to evaluating data from this trial later this year as we assess the potential benefits of TERN-101 in the treatment of NASH."

The Phase 1 trial of TERN-101 is a randomized, double-blind, placebo-controlled study designed to evaluate safety, pharmacokinetics, and plasma biomarkers of FXR pathway activation in participants receiving placebo or TERN-101 at various dose levels for 7 days.

Initially discovered and developed by Eli Lilly and Company, TERN-101 was previously advanced through a Phase 1 study and demonstrated clinical pharmacokinetic properties consistent with once daily dosing. In 2018, Terns announced a global, exclusive agreement with Eli Lilly to develop, manufacture, and commercialize TERN-101 for the treatment of NASH. Terns

previously presented preclinical data at The International Liver Congress™ 2019 in Vienna demonstrating that TERN-101 reduces liver steatosis, inflammation, ballooning, and fibrosis in a diet-induced obese mouse model of NASH. In addition to the Phase 1 trial now ongoing in the US, Terns also plans studies in China as part of the TERN-101 development plan.

TERN-101 is a potent non-bile acid FXR agonist being developed as a therapeutic for NASH. FXR is a nuclear receptor that is highly expressed in the liver and small intestine. Bile acids (BA) are natural ligands of FXR, and their binding with and activation of FXR is critical to the regulation of cellular pathways that modulate BA synthesis, lipid metabolism, inflammation, and fibrosis. FXR agonism and activation has demonstrated improvement over placebo in regression of histological liver fibrosis without progression to NASH in a late-stage study, demonstrating the potential for FXR agonists to be a new treatment modality for NAFLD and NASH.

Non-alcoholic steatohepatitis (NASH) is a severe form of non-alcoholic fatty liver disease (NAFLD), which is caused by the accumulation of excess fat in the liver. NASH is associated with chronic liver inflammation and liver cell injury, and it can lead to fibrosis, cirrhosis, and eventually liver cancer or liver failure. Global rates of NAFLD and NASH are increasing rapidly, in tandem with rising rates of obesity. There is currently no approved medication for the treatment of NASH.

Terns Pharmaceuticals is a clinical-stage pharmaceutical company that is focused on the discovery and development of medicines for chronic liver disease and cancer. Based in China and the United States, the company is advancing a pipeline of drug candidates for the treatment of non-alcoholic steatohepatitis (NASH) and cancer, across multiple modalities. Terns leverages world-class expertise in disease biology, medicinal chemistry, and clinical development in order to bring promising new therapies to patients in China and other global markets.