Terns Pharmaceuticals Receives Fast Track Designation From the FDA for TERN-101, an FXR Agonist for the Treatment of NASH

FOSTER CITY, Calif. & SHANGHAI--(BUSINESS WIRE)-- Terns Pharmaceuticals, Inc., a global biopharmaceutical company focused on discovering and developing innovative therapies to treat non-alcoholic steatohepatitis (NASH) and cancer, today announced that TERN-101, an investigational farnesoid X receptor (FXR) agonist, has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of NASH.

“Receiving Fast Track Designation for TERN-101 is an important step in bringing this promising treatment to patients as soon as possible, and we look forward to working with the agency as we advance TERN-101 through clinical development," said Erin Quirk, M.D., Chief Medical Officer of Terns. “We are pleased the that the U.S. FDA recognizes the potential for TERN-101 to address the unmet treatment need for patients with NASH, who currently have no therapeutic options.”

In Phase 1 studies to date, TERN-101 demonstrated clinical pharmacokinetic properties consistent with once-daily dosing. At The International Liver Congress™ 2019 in Vienna, Terns presented preclinical data demonstrating that TERN-101 reduced liver steatosis, inflammation, ballooning, and fibrosis in a preclinical model of NASH.

TERN-101 and TERN-201, Terns’ semicarbazide-sensitive amine oxidase (SSAO) inhibitor, are both in development for the treatment of NASH and were initially discovered and developed by Eli Lilly and Company. Terns signed a global, exclusive license agreement with Eli Lilly in 2018 to develop, manufacture, and commercialize TERN-101 and TERN-201.

About FDA Fast Track Designation

Fast Track is a process designed to facilitate the expedited development and review of new drugs to treat serious or life-threatening conditions and which have demonstrated the potential to fill an unmet medical need. The purpose is to advance new drugs earlier for patients who need them. Fast Track addresses a broad range of serious conditions.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA[1].

About TERN-101 and Farnesoid X Receptor (FXR) Agonism

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.

About 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.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. 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.

For more information, visit www.ternspharma.com and www.ternspharma.com.cn

[1] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

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Source: Terns Pharmaceuticals, Inc.