Enanta Pharmaceuticals Initiates Phase 1 Clinical Study of EDP-514, its Lead Core Inhibitor for the Treatment of Hepatitis B Virus (HBV)

July 8, 2019
Download this Press Release

- ***EDP-514 HBV Lead Asset Granted Fast Track Designation from FDA***

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced that it has initiated part 1 of a Phase 1a/b clinical study of EDP-514, Enanta's lead core inhibitor for the treatment of hepatitis B virus (HBV).

The randomized, double-blind, placebo-controlled Phase 1a/b study is designed to evaluate first the safety, tolerability and pharmacokinetics (PK) of single ascending doses (SAD) and multiple ascending doses (MAD) of EDP-514 in healthy subjects (Part 1), and then the antiviral activity of EDP-514 in nucleos(t)ide-reverse-transcriptase (NUC)-suppressed patients with chronic HBV infection (Part 2). The study plans to enroll approximately 98 subjects and to evaluate up to 6 dose cohorts, with EDP-514 administered orally, once daily. Following the completion of the SAD and MAD portion in healthy subjects, the study will evaluate safety, PK and antiviral data of EDP-514 in NUC-suppressed patients with chronic HBV infection.

"Our diverse pipeline continues to advance, with clinical trials ongoing in all of our wholly-owned programs in NASH, PBC, RSV and now HBV," stated Jay R. Luly, Ph.D., President and Chief Executive Officer. "EDP-514 is a promising core inhibitor that we look forward to developing as a potential cure for the critical unmet need in HBV, either as a single agent or in combination with other therapeutics. Receipt of Fast Track designation from the FDA emphasizes the large unmet need of patients with chronic HBV infection."

About EDP-514

EDP-514, a novel class II hepatitis B virus (HBV) core inhibitor, is Enanta's lead core inhibitor candidate. Core inhibitors, also known as capsid assembly modulators or core protein allosteric modulators, are a novel class of replication inhibitors that have been shown to act at multiple steps in the HBV lifecycle. Preclinical data demonstrate that EDP-514 is a potent inhibitor of HBV replication and prevents the *denovo* formation of new cccDNA in primary human hepatocytes when given early during HBV infection. *In vitro* data also show that EDP-514 is pan-genotypic, and that combinations of EDP-514 with nucleoside reverse-transcriptase inhibitors (NRTIs, current anti-viral therapies for HBV) or a class I core inhibitor result in additive to synergistic antiviral effects. *In vivo* models of EDP-514 demonstrate excellent efficacy with >4-log viral load reduction in HBV-infected PXB mice.

About Hepatitis B Virus

Hepatitis B virus, or HBV, can cause a potentially life-threatening liver infection. The virus is transmitted through contact with the blood or other bodily fluids of an infected person. It is estimated that approximately 250 million people worldwide are chronically infected with HBV, and 15-25% of these patients develop chronic liver disease, including cirrhosis, liver cancer and/or liver decompensation. Current treatments for HBV offer modest cure rates and are accompanied by serious side effects. New treatments that can provide functional cures to chronically infected patients are urgently needed.

About Enanta

Enanta Pharmaceuticals is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases. Enanta's research and development efforts are currently focused on the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta's research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen is sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir) Please visit www.enanta.com for more information.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for further development with respect to EDP-514 for hepatitis B virus (HBV). Statements that are not historical facts, are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the development risks of early stage discovery efforts in the disease areas in Enanta's research and development pipeline, such as HBV; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for HBV; Enanta's limited clinical development experience; Enanta's need to attract and retain senior management and key scientific personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-Q for the fiscal quarter ended March 31, 2019 and

other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190708005167/en/

Investor Contact
Carol Miceli
617-607-0710
cmiceli@enanta.com

Media Contact:
Kari Watson
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com

Source: Enanta Pharmaceuticals, Inc.