



Enanta Pharmaceuticals Announces Clinical Trial Progress for EDP-514, its Lead Core Inhibitor for Hepatitis B Virus

July 9, 2020

- *Initiated Phase 1b Study Evaluating EDP-514 in Viremic HBV Patients; Preliminary Data Anticipated in 1H 2021*
- *Resumed Phase 1b Study Assessing Safety and Antiviral Activity of EDP-514 in NUC-Suppressed HBV Patients; Topline Results Anticipated in 2Q 2021*

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced advancements in its hepatitis B virus (HBV) program evaluating EDP-514 across different patient populations. Enanta initiated, as planned, a Phase 1b clinical trial in viremic HBV patients, and resumed its ongoing Phase 1b study in HBV patients treated with a nucleos(t)ide reverse transcriptase inhibitor (NUC-suppressed patients), which was previously paused due to the COVID-19 pandemic. EDP-514 is a novel class II HBV core inhibitor that has Fast Track Designation from the FDA.

"HBV is a potentially life-threatening liver infection, affecting over 250 million people worldwide for which there is no functional cure. We are pleased to continue to advance our HBV program with two clinical studies evaluating EDP-514 in chronic HBV patients – one in viremic patients not currently on therapy and the second in patients with HBV infection that is NUC-suppressed," said Jay R. Luly, President and Chief Executive Officer of Enanta Pharmaceuticals. "EDP-514, a novel core inhibitor of HBV replication, leverages our strength in compound optimization and targeted rational design, enabling potent anti-HBV activity at multiple steps in the HBV lifecycle. We are excited to further investigate EDP-514 in viremic HBV patients, and look forward to reporting preliminary safety and virologic data in the first half of 2021, while also completing our study in NUC-suppressed patients with topline data expected in the second quarter of 2021. As we look toward these catalysts, we are continuing to monitor any impact of the COVID-19 pandemic on our clinical progress."

The randomized, double-blind, placebo-controlled Phase 1b study in viremic chronic HBV subjects not currently on therapy is designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of orally administered EDP-514 over a 28-day period. The study is planned to enroll 24 subjects who will be randomized to receive one of three multiple ascending doses of EDP-514 or placebo.

The randomized, double-blind, placebo-controlled Phase 1b study in NUC-suppressed subjects with chronic HBV infection is Part 2 of a Phase 1a/1b study. Part 2 of the study is designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of orally administered EDP-514 over a 28-day period. The study is planned to enroll 24 subjects who will be randomized to receive one of three multiple ascending doses of EDP-514 or placebo.

In Part 1 of the Phase 1a/1b study, EDP-514 was studied in healthy subjects who received single or multiple doses for up to 14 days. EDP-514 was well tolerated with a favorable safety profile. Treatment-emergent adverse events were infrequent and mild in intensity. No patients discontinued EDP-514 due to an adverse event. Additionally, the pharmacokinetic profile was supportive of once-daily dosing. Enanta plans on presenting additional data from Part 1 of the Phase 1a/1b study in healthy volunteers in a poster presentation at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, August 27-29, 2020.

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 HBV 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 a nucleos(t)ide reverse-transcriptase inhibitor (NRTI), the current anti-viral therapy for HBV, or with 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 is a viral infection that attacks the liver and can cause both acute and chronic disease. The virus is most commonly transmitted from mother to child during birth and delivery, as well as through contact with blood or other body fluids. It is estimated that over 250 million people have chronic HBV infection. According to the World Health Organization, there are approximately 887,000 deaths from HBV infection per year mostly from cirrhosis and hepatocellular carcinoma or primary liver cancer. As of 2016, of the people living with HBV infection, only 27 million were aware of their infection, and only 4.5 million of those received treatment.¹

Current approaches to treatment include interferon therapy and/or inhibitors of HBV reverse transcriptase. Treatment with interferon offers poor cure rates and is accompanied by serious side effects. Reverse transcriptase inhibitors can be very effective at suppressing the virus but rarely result in full eradication of the virus from the liver.

About Enanta

Enanta 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 have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH), hepatitis B virus (HBV), human metapneumovirus (hMPV) and SARS-CoV-2 (COVID-19).

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with

AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection 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 of 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 quarter ended March 31, 2020 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.

¹ <https://www.who.int/news-room/fact-sheets/detail/hepatitis-b>



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