

NEWS RELEASE

Enanta Pharmaceuticals Reports Positive Final Data from its Phase 1b Studies of EDP-514, a Novel Hepatitis B Virus Core Inhibitor

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EDP-514 is Safe and Well-Tolerated up to 800 mg

Robust Antiviral Activity Demonstrated in Chronic Hepatitis B Virus Patients at All Doses

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 final Phase 1b data for EDP-514, a novel pangenotypic class II hepatitis B virus (HBV) core inhibitor, in conjunction with two posters presented at The Liver Meeting® 2021, hosted by the American Association for the Study of Liver Diseases (AASLD).

"We are excited to present final data for EDP-514 from our Phase 1b studies in viremic and NUC-suppressed chronic HBV patients, giving us continued confidence in EDP-514 as a potential treatment for HBV," said Jay R. Luly, PhD, President and Chief Executive Officer of Enanta Pharmaceuticals. "At 800 mg, EDP-514 continues to demonstrate that it is safe and well-tolerated up to 28 days when dosed alone or in combination with NUC, as shown in the NUC-suppressed patients. Importantly, EDP-514 has robust antiviral activity across all dose groups, as best illustrated in the viremic patients where up to a 3.5 log decline in HBV DNA was observed. These data are supportive of a once-daily oral dosing regimen that could provide a foundation for a combination therapy approach to achieve functional cures for chronic HBV patients."

822: "EDP-514, a Novel Pangenotypic Class II Hepatitis B Virus Core Inhibitor: Results of a 28-day Phase 1b Study in NUC-Suppressed CHB Patients"

Jordan J. Feld, MD, MPH, Toronto Centre for Liver Disease, University Health Network, Toronto, Canada

The poster highlights data from Part 2 of a Phase 1a/1b randomized, double-blind, placebo-controlled study assessing the safety, tolerability, pharmacokinetics and antiviral activity of three doses of EDP-514 in 24 NUC-suppressed chronic HBV patients who were either HBeAg-positive or HBeAg-negative. Patients were randomized to receive 200 mg (n=6), 400 mg (n=6), 800 mg (n=6) of EDP-514 or placebo (n=6) daily for 28 days.

Overall, EDP-514 was generally safe and well-tolerated at 200 mg, 400 mg, and 800 mg doses for 28 days. EDP-514 was rapidly absorbed and its exposure increased with increasing multiple doses. EDP-514 exhibited pharmacokinetics suitable for once daily oral dosing, with C_{trough} concentrations reaching up to ~20-fold above the protein-adjusted EC₅₀. At Day 28, mean HBV RNA changes of -0.81, -1.12, 0.10, and -0.19 logs were observed in the 200 mg, 400 mg, 800 mg and placebo groups, respectively. EDP-514 led to a maximum HBV RNA reduction of 2.3 log in HBeAg-negative and 2.8 log in HBeAg-positive subjects in EDP-514 arms compared to 1.2 log in the placebo arm. In the EDP-514 800 mg arm, five of six subjects had either non-detectable or very low levels of HBV RNA at baseline; consequently, the effect of EDP-514 on HBV RNA could not be assessed in these subjects. As expected in this NUC-suppressed patient population, there were no discernible changes in HBV DNA, HBeAg, HBcrAg, and HBsAg, and no instances of virologic failure were reported.

823: "EDP-514, a Novel Pangenotypic Class II Hepatitis B Virus Core Inhibitor Demonstrates Significant HBV DNA and HBV RNA Reductions in a Phase 1b Study in Viremic, Chronic Hepatitis B Infected Patients"

Man Fung Yuen, MBBS, MD, PhD, DSc, Department of Medicine, Queen Mary Hospital, The University of Hong Kong, Hong Kong.

Data in this poster details results from a randomized, double-blind, placebo-controlled Phase 1b study evaluating the safety, pharmacokinetics and antiviral activity of three doses of EDP-514 in viremic chronic HBV patients, either HBeAg-positive or HBeAg-negative, and without cirrhosis. Patients were randomized to receive 200 mg (n=6), 400 mg (n=6), or 800 mg (n=6) of EDP-514 or placebo (n=6) daily for 28 days with an 8-week follow-up period.

Results demonstrated that EDP-514 was safe and well-tolerated through 28 days of treatment, displayed pharmacokinetics supportive of once-daily dosing, and resulted in mean HBV DNA reductions of 2.9, 3.3, and 3.5 logs at 28 days for the 200 mg, 400 mg, and 800 mg cohorts, respectively, compared to 0.2 log in placebo. HBV RNA was undetectable at Day 28 in 11 patients in the three EDP-514 cohorts as compared to none in placebo. Mean HBV RNA reductions were 2.9, 2.4, and 2.0 logs for the 200 mg, 400 mg, and 800 mg cohorts, respectively, compared to 0.02 log in placebo.

About EDP-514

EDP-514 is Enanta's lead HBV 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 de novo formation of new HBV covalently-closed circular DNA (cccDNA) in primary human hepatocytes when given early during HBV infection. In vitro data also show that EDP-514 is pangenotypic, and that combinations of EDP-514 with a nucleoside reverse transcriptase inhibitor (NUC), 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 a greater than 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 290 million people worldwide have chronic HBV infection.¹ Current approaches to treatment include interferon therapy and/or NUCs. Treatment with interferon offers poor cure rates and is accompanied by serious side effects.² NUCs can be very effective at suppressing the virus but rarely result in full eradication of the virus from the liver.³

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 currently in development for the following disease targets: respiratory syncytial virus (RSV), hepatitis B virus (HBV) and SARS-CoV-2 (COVID-19). Enanta is also conducting research in human metapneumovirus (hMPV).

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 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 risks of early stage development 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 June 30, 2021 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. Polaris Observatory Collaborators. "Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study." *The Lancet. Gastroenterology & Hepatology* vol. 3,6 (2018): 383-403. doi:10.1016/S2468-1253(18)30056-6
2. Woo, Aaron Shu Jeng et al. "Alpha-interferon treatment in hepatitis B." *Annals of Translational Medicine* vol. 5,7 (2017): 159. doi:10.21037/atm.2017.03.69
3. Yeo, Yee Hui et al. "Factors Associated with Rates of HBsAg Seroclearance in Adults with Chronic HBV Infection: A Systematic Review and Meta-analysis." *Gastroenterology* vol. 156,3 (2019): 635-646.e9. doi:10.1053/j.gastro.2018.10.027

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