Enanta Pharmaceuticals Doses First Subject in a Phase 1 Clinical Study of EDP-721, Its Oral Hepatitis B Virus RNA Destabilizer

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- Initial Data Expected in the First Half of 2022 -

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 that it has dosed the first subject in its Phase 1 clinical trial of EDP-721, a novel, oral hepatitis B virus (HBV) RNA destabilizer being developed for use in an all-oral combination regimen for chronic HBV patients.

“We are pleased to advance our HBV program by dosing the first subject in our Phase 1 clinical study of EDP-721, an orally administered HBV RNA destabilizer that has the potential to reduce S antigen. As we believe that achieving a functional cure for HBV will involve a combination approach, this milestone brings us closer to our vision of developing an all-oral regimen for HBV,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “The current standard of care for chronic HBV involves nucleoside reverse transcriptase inhibitors, or NUCs, which can suppress HBV replication. In addition, EDP-514, our potent core inhibitor inhibits several stages of HBV replication, from uncoating and nuclear import of the virus, to capsid assembly and recycling. Now, with EDP-721, we have an oral compound that has demonstrated preclinically the ability to destabilize HBV RNAs, leading to a reduction in viral proteins, including S antigen, which we believe is essential for the treatment of HBV. With this triple combination of a NUC, EDP-514, and EDP-721, we see the potential for an all-oral functional cure and look forward to progressing this study.”

This two-part Phase 1a/b study will initially evaluate the safety, tolerability, and pharmacokinetics of EDP-721 in single and multiple ascending oral doses in healthy volunteers. The second part, in chronic HBV patients, will evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of multiple ascending oral doses of EDP-721 with or without a...
NUC, and then in combination with EDP-514. Data from the first part of the study are expected in the first half of 2022.

In a recent poster presentation at the European Association for the Study of the Liver (EASL) Digital International Liver Congress™ 2021, EDP-721 was shown to be a selective inhibitor of the non-canonical poly(A) polymerases, PAPD5 and PAPD7, which are host factors critical to the post-transcriptional stabilization of HBV RNA. Inhibition of PAPD5/7 results in potent and pangenotypic reduction in HBsAg production with minimal effects on the host transcriptome in uninfected primary human hepatocytes. Oral administration of EDP-721 demonstrated HBsAg reductions of up to 3 log10 IU/mL following 14 days of once-daily dosing in the AAV-HBV mouse model. EDP-721 was also shown to exhibit synergistic antiviral activity in vitro when combined with nucleos(t)ide reverse transcriptase inhibitors or the HBV core inhibitor EDP-514.

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. Current approaches to treatment include interferon therapy and/or nucleos(t)ide reverse transcriptase inhibitors. Treatment with interferon offers poor cure rates and is accompanied by serious side effects. Nucleos(t)ide 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), hepatitis B virus (HBV), non-alcoholic steatohepatitis (NASH), 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-721 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 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 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. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5401664/

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