

Enanta Pharmaceuticals Announces Update to its Hepatitis B Virus (HBV) Program

11/18/2021

Discontinuing Clinical Development of EDP-721, an Oral HBV RNA Destabilizer

Continuing to Focus on Development of EDP-514 in Combination Regimens as a Functional Cure for HBV

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 it is discontinuing development of EDP-721, an oral HBV RNA destabilizer, based on emerging safety observations in the single ascending dose part of a Phase 1 study in healthy volunteers.

"Despite the clean preclinical safety profile demonstrated in comprehensive toxicology studies, safety signals were seen in healthy subjects after administration of EDP-721. Patient safety is our top priority, and we have therefore decided to discontinue further development of this compound," said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "We are committed to developing a functional cure for chronic hepatitis B patients, and remain confident in EDP-514, our HBV core inhibitor, which has demonstrated safe and robust antiviral activity in Phase 1b studies of viremic and NUC-suppressed patients with chronic HBV infection. We believe core inhibitors will be an important component of a successful combination regimen, and we will look to advance our HBV program with additional mechanisms from internal discovery efforts, external opportunities, or both. Importantly, we are grateful to our Principal Investigator and his study team, and the participants in the Phase 1 study for their commitment to HBV research, and to our team for all their efforts in supporting the development and clinical evaluation of EDP-721."

[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.¹ It is estimated that over 290 million people worldwide have chronic HBV infection.² 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.³ 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.⁴

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 part of AbbVie's leading treatment for chronic HCV infection that it sells in numerous countries 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 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>
2. <https://pubmed.ncbi.nlm.nih.gov/29599078/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5401664/>
4. <https://pubmed.ncbi.nlm.nih.gov/30342034/>

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