



Enanta Pharmaceuticals Presents New Data for EDP-235, its Lead Oral Protease Inhibitor Designed for the Treatment of COVID-19, at the ISIRV–WHO Virtual Conference 2021

October 19, 2021

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- Demonstrated Highly Potent Antiviral Activity Against SARS-CoV-2 in Cellular Models -

- Once-Daily, Oral Dosing Supported by Optimized Pharmacokinetic Properties -

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 reported new preclinical data for EDP-235, its recently announced lead oral protease inhibitor specifically designed for the treatment of COVID-19. These data were presented in a poster titled “EDP-235, A Potential Oral, Once-Daily Antiviral Treatment and Preventative for COVID-19,” during the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV)–World Health Organization (WHO) Virtual Conference 2021.

“We are excited to present preclinical data for the first time on EDP-235, demonstrating potent inhibition of SARS-CoV-2 replication,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “As the respiratory tract is the initial site of SARS-CoV-2 infection, we are particularly pleased to see good distribution of EDP-235 into lung cells as well as other key target tissues. This combination of potent antiviral activity and a favorable pharmacokinetic profile positions EDP-235 to potentially be a best-in-class, once-daily oral therapy for the treatment and prevention of COVID-19.”

Dr. Luly added, “Despite the availability of effective vaccines against the virus, SARS-CoV-2 continues to persist worldwide, demonstrating a critical need for a conveniently dosed, oral antiviral therapy for COVID-19 that inhibits viral replication and reduces disease progression. We have designed EDP-235 to meet this need and look forward to advancing it into the clinic in early 2022.”

In a biochemical assay, EDP-235 inhibited the SARS-CoV-2 3CLpro protease with an IC₅₀ of 5.8 nM. Importantly, this activity was retained against proteases from SARS-CoV-2 variants. EDP-235 potently blocked the replication of SARS-CoV-2 in multiple cellular models, including primary human airway epithelial cells, where an EC₉₀ of 33 nM was observed. Additionally, EDP-235 was shown to have potent antiviral activity across other human coronaviruses. In comparison to preclinical data from other direct acting antivirals in development for COVID-19 today, EDP-235 appears to be among the most potent against SARS-CoV-2 in cellular assays.

EDP-235 showed good human Caco-2 cell permeability and a low plasma clearance in human liver microsomes. Consistent with this *in vitro* data, EDP-235 had robust plasma exposure with an oral bioavailability of 95% in rats. Moreover, EDP-235 had favorable *in vivo* penetration into multiple target tissues, including lung, kidney, liver, and heart. These results indicate that EDP-235 has good oral bioavailability and target tissue distribution compared to other antivirals in development for SARS-CoV-2 today. Based on allometric scaling, EDP-235 is projected to have a long half-life of 16 hours with an efficacious dose of 100 to 500 mg once-daily in humans. Taken together, these data indicate that EDP-235 has the potential for once-daily oral dosing with a low pill burden.

Enanta has completed IND-enabling preclinical studies of EDP-235 and plans to advance the candidate into the clinic in early 2022.

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 EDP-235 for the treatment of COVID-19. 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 disease areas such COVID-19; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for COVID-19; Enanta's limited clinical development experience; 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.



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Source: Enanta Pharmaceuticals, Inc.