Enanta Pharmaceuticals Doses First Subject in a Phase 1 Clinical Study of EDP-235, its Oral 3CL Protease Inhibitor Specifically Designed for the Treatment and Prevention of COVID-19

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WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 16, 2022-- 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-235, a coronavirus 3CL protease inhibitor (also known as the main coronavirus protease, or Mpro) specifically designed as a once-daily, oral treatment for COVID-19.

“SARS-CoV-2 continues to infect millions of individuals worldwide and new variants are still emerging, highlighting the limitations of current therapies and vaccines for COVID-19. There remains an urgent need for highly potent, oral treatments designed specifically to treat and prevent COVID-19, and we believe that the profile of EDP-235 positions it to potentially be a best-in-class antiviral therapeutic,” said Jay R. Luly Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We are excited to reach this milestone and begin our EDP-235 clinical program, with the first subject being dosed in this Phase 1 study. Looking to the rest of the year, we plan to report data from this study in the second quarter of 2022 and, assuming positive findings, we expect to advance EDP-235 to the next stage of clinical development in the second half of 2022.”

This first-in-human Phase 1 study will evaluate the safety, tolerability, and pharmacokinetics of oral EDP-235 in single ascending doses (SAD), including a two-part food effect cohort, and multiple ascending doses (MAD) compared to placebo in healthy volunteers. All SAD and MAD cohorts will enroll eight participants who will be randomized to receive EDP-235 or placebo in a 3:1 ratio.

Preclinical data show that EDP-235 potently blocks the replication of SARS-CoV-2 in multiple cellular models, including primary human airway epithelial cells where an EC_{90} of 33 nanomolar was observed, positioning EDP-235 among the most potent direct-acting antivirals currently in development for SARS-CoV-2 infection. Preclinical studies demonstrate that EDP-235 has good oral bioavailability without ritonavir boosting and favorable distribution into lung cells as well as other key target tissues, with expected once-daily human dosing. Importantly, in addition to SARS-CoV-2, EDP-235 has potent antiviral activity against other human coronaviruses, enabling the potential for a pan-coronavirus treatment, including possibly coronaviruses that may infect human populations in the future.

About Enanta Pharmaceuticals, Inc.

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 programs include clinical candidates currently in development for the following disease targets: respiratory syncytial virus (RSV), SARS-CoV-2 (COVID-19) and hepatitis B virus (HBV). 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

This press release contains forward-looking statements, including statements with respect to the prospects for advancement of EDP-235 for 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 impact of development, regulatory and marketing efforts of others with respect to competitive treatments for COVID-19; the discovery and development risks of Enanta’s program for COVID-19; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; any continuing impact of the COVID-19 pandemic on business operations and clinical trials; Enanta’s lack of clinical development experience; Enanta’s need to attract and retain senior management and key research and development 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 Form 10-Q for the fiscal quarter ended December 31, 2021, and any 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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