Enanta Pharmaceuticals Initiates SPRINT, a Phase 2 Clinical Trial of EDP-235, its Oral, Direct-Acting Antiviral Protease Inhibitor Specifically Designed for the Treatment of COVID-19

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WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 9, 2022-- Enanta Pharmaceuticals, Inc. (NASDAQ: ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections, today announced the initiation of SPRINT (**S**ARS-Cov-2 **PR**otease **IN**hibitor **T**reatment), a Phase 2 clinical trial of EDP-235, Enanta's lead oral, 3CL protease inhibitor, in non-hospitalized, symptomatic adults with mild or moderate COVID-19. The study is designed to evaluate the safety, tolerability, and antiviral activity of 200mg and 400mg once-daily doses of EDP-235 compared to placebo.

"The initiation of SPRINT is an important milestone in advancing the clinical development of EDP-235 as a once-daily antiviral treatment for COVID-19. Our recent encouraging Phase 1 data for EDP-235 demonstrated that 200mg and 400mg once-daily doses were safe and well-tolerated and provided plasma drug levels that were 7-fold and 13-fold, respectively, over the plasma protein adjusted EC_{90} for the Omicron variant, without the need for a boosting agent such as ritonavir and its associated drug-drug interactions," said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "EDP-235 has the potential to be a best-in-class, one pill, once-a-day antiviral treatment for COVID-19 that can be easily prescribed and administered to reduce the burden of this disease on patients and our healthcare systems. As COVID-19 continues to present significant challenges worldwide, we remain confident in our expertise in infectious disease to combat this virus with a much-needed antiviral treatment that is active against all COVID-19 variants of concern. We look forward to reporting data from SPRINT in the first half of 2023."

The randomized, double-blind, placebo-controlled study will enroll approximately 200 non-hospitalized, symptomatic patients with mild to moderate COVID-19, who are not at increased risk for developing severe disease. Patients will be eligible to participate if they have had symptoms for five days or less and have not received a SARS-CoV-2 vaccine or been infected with SARS-CoV-2 within 90 days of enrollment.

Patients will receive EDP-235 orally at a dose of 200mg or 400mg or placebo once daily for five days. The primary objective of the study includes evaluation of safety and tolerability, and secondary objectives include the evaluation of virologic endpoints, clinical symptoms and outcomes, and pharmacokinetics.

EDP-235 is supported by positive topline data from a Phase 1 study which assessed the safety, tolerability, and pharmacokinetics of orally administered single and multiple ascending doses of EDP-235 in healthy adult subjects. In the Phase 1 study, EDP-235 demonstrated favorable safety, tolerability, and pharmacokinetics with strong exposure multiples over the EC_{90}, supporting its potential as a once-daily antiviral therapy without ritonavir.

About EDP-235

EDP-235, Enanta's lead 3CL protease inhibitor (also known as main protease or Mpro), which has Fast Track designation from the U.S. Food and Drug Administration, was specifically designed for the treatment of COVID-19. Preclinical data show that EDP-235 potently blocks the replication of SARS-CoV-2 in multiple cellular models. For example, in Vero cells, an EC_{90} of 11 and 5 nanomolar were observed for the Alpha and Omicron variant, respectively, positioning EDP-235 among the most potent direct-acting antivirals currently in development for SARS-CoV-2 infection. Preclinical studies also show that EDP-235 has favorable distribution into lung cells as well as other key target tissues. 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

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. 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 part of one of the leading treatment regimens for curing chronic HCV infection and is sold by AbbVie 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

This press release contains forward-looking statements, including statements with respect to the prospects for advancement of Enanta's clinical program in 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 this disease area; 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 June 30, 2022, 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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