Enanta Pharmaceuticals Receives FDA Fast Track Designation for EDP-235, its Oral 3CL Protease Inhibitor Specifically Designed for the Treatment and Prevention of COVID-19

March 29, 2022

WATERTOWN, Mass.--(BUSINESS WIRE)--Mar. 29, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for EDP-235, its coronavirus 3CL protease inhibitor (also known as the main coronavirus protease, or Mpro) specifically designed as a once-daily, oral treatment for COVID-19.

"Despite the broad availability of vaccines, there remains a need for highly potent, oral treatments specifically designed to target SARS-CoV-2, a virus that continues to persist and mutate globally. Receiving Fast Track designation from the FDA underscores EDP-235's potential as a once-daily, oral therapeutic for the treatment and prevention of SARS-CoV-2 infection and as another option in the global fight against the ongoing pandemic," said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "We believe that the profile of EDP-235 positions it as a potential best-in-class antiviral therapeutic and we remain on track to report data from our ongoing Phase 1 study of EDP-235 next quarter. We look forward to working with the FDA to continue to advance EDP-235 as expeditiously as possible."

The Fast Track program is designed to accelerate the development and review of products such as EDP-235, which are intended to treat serious diseases and for which there is an unmet medical need. Fast Track designation enables more frequent communication with the FDA and eligibility for FDA programs such as priority review and rolling review, if relevant criteria are met.

Currently, EDP-235 is in a first-in-human Phase 1 study to 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.

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 this disease; 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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Source: Enanta Pharmaceuticals, Inc.