Enanta Pharmaceuticals Presents New Preclinical Data for EDP-235, its Oral, Direct-Acting Antiviral Protease Inhibitor Specifically Designed for the Treatment of COVID-19 at IDWeek™ 2022

October 19, 2022

WATERTOWN, Mass.--(BUSINESS WIRE)--Oct. 19, 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 new preclinical data supporting the potential of EDP-235 for the treatment of COVID-19, which are being presented at IDWeek 2022 in Washington, DC.

New data presented continue to highlight EDP-235's excellent penetration into SARS-CoV-2 target tissues and cells including macrophages and monocytes, suggesting it can possibly mitigate the macrophage-mediated cytokine storm that can occur in high-risk COVID-19 patients. Enanta is on schedule to begin a Phase 2 study of EDP-235 this quarter.

"We are encouraged by the growing body of data suggesting that EDP-235 is a differentiated, once-daily, oral antiviral for COVID-19. In particular, these data presented show that EDP-235 has the ability to penetrate into critical immune cells and eliminate viral replication." said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "Taken together with data from our Phase 1 study that demonstrated favorable safety, tolerability, and pharmacokinetics with strong exposure multiples over the EC_{90}, EDP-235 is well positioned to potentially be a best-in-class direct acting antiviral for COVID-19. We look forward to continuing the clinical development of EDP-235."

October 21, 2022, Oral Presentation from 12:15 – 12:45 PM ET, Poster# 1123 Presentation from 12:15 – 1:30 PM ET

"*EDP-235, A Potent and Once-Daily Oral Antiviral, Demonstrates Excellent Penetration into Macrophages and Monocytes, with the Potential for Mitigation of Cytokine Storm in High-Risk COVID-19 Patients*" Lisha Xu, United States

Intracellular uptake of EDP-235 compared to nirmatrelvir was evaluated in rat lung alveolar macrophages (AM), human monocytes and human macrophages. To determine the *in vivo* drug distribution into lung AM, rats were dosed orally with 25 mg/kg of EDP-235 or nirmatrelvir and plasma and AM drug levels were analyzed by liquid chromatography-tandem mass spectrometry. The ratios of intracellular to extracellular concentrations of EDP-235 in rat lung AM, human monocytes and human macrophages were 23.6, 22.7 and 30.5, respectively, compared to ratios of 0.6, 1.5 and 1.2 for nirmatrelvir in these cells. Consistent with the *in vitro* observations, EDP-235 showed favorable rat AM penetration with an $AUC_{0\text{-}24}$ ratio of 28.4 (AM over plasma), and nirmatrelvir had less rat AM penetration with an $AUC_{0\text{-}24}$ ratio of 0.5 (AM over plasma). EDP-235 had respective $AUC_{0\text{-}24}$ values of 9.6 and 271.9 h·µg/mL in rat plasma and AM, while the $AUC_{0\text{-}24}$ values of nirmatrelvir in rat plasma and AM were 2.7 and 1.2 h·µg/mL, respectively. These preclinical data demonstrate that EDP-235 achieved excellent penetration into monocytes and macrophages, including lung AM. EDP-235 has the potential to eliminate viral replication of SARS-CoV-2 in these critical immune cells, thus mitigating macrophage-mediated cytokine storm in high-risk COVID-19 patients.

About Enanta Pharmaceuticals
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 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 programs 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 COVID-19 program; 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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Source: Enanta Pharmaceuticals, Inc.