Enanta Pharmaceuticals to Provide Updates on its Research and Development Programs and 2023 Outlook at the 41st Annual J.P. Morgan Healthcare Conference

January 6, 2023

- *Progresses Phase 2 SPRINT Trial of EDP-235, an Oral, 3CL Protease Inhibitor for COVID-19, With Data Expected in 1H 2023*
- *Presents New Preclinical In Vivo Data Demonstrating EDP-235's Efficacy and Prevention of COVID-19 Transmission*
- *Expands Robust COVID-19 Antiviral Portfolio With a New Research Program Developing SARS-CoV-2 Papain-Like Protease Inhibitors*
- *Introduces New Research Program Targeting Human Metapneumovirus (hMPV) and Respiratory Syncytial Virus (RSV) with a Single Agent; Clinical Candidate Selection Targeted for 4Q 2023*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 6, 2023-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections, today announced that Jay R. Luly, Ph.D., Enanta's President and Chief Executive Officer, will provide an update across its pipeline of virology programs and plans for 2023 during Enanta's presentation at the 41 st Annual J.P. Morgan Healthcare Conference on Tuesday, January 10, 2023 at 3:00 p.m. PT.

"Building upon the advancements in both our COVID-19 and RSV programs during this past year, we enter 2023 poised for success by expanding our pipeline and executing against several important milestones to pursue our goal of developing curative therapies for viral infections," said Jay R. Luly, President & Chief Executive Officer at Enanta Pharmaceuticals. "In particular, we are encouraged that we are on track to announce data in the first half of 2023 from SPRINT, our ongoing Phase 2 study of EDP-235, an oral, 3CL protease inhibitor specifically designed for the treatment of COVID-19. We are also excited to present new preclinical *in vivo* data demonstrating EDP-235's robust antiviral treatment effect and its ability to prevent the transmission of COVID-19 in a ferret model. We are also enthusiastic about expanding our COVID-19 treatment program by developing SARS-CoV-2 Papain-Like Protease (PLpro) inhibitors. We believe that having multiple mechanisms to treat COVID-19, either alone or in combination, will allow us to bring best-in-class options to market for a range of patients suffering from this debilitating and deadly virus. In RSV, we continue to expect top-line data from the Phase 1 study of EDP-323, our L-protein inhibitor, in the first half of 2023. Additionally, we are pleased to build out our respiratory virology treatment portfolio with the addition of a new program to develop a broader spectrum antiviral that targets both hMPV and RSV with a single agent and plan to select a clinical candidate in the fourth quarter of 2023. Overall, we look to continue to leverage our expertise and previous successes in virology to deliver on our goal of providing effective treatments for respiratory infections to all vulnerable patient populations."

During the presentation, Dr. Luly will highlight Enanta's pipeline program updates and expectations for 2023.

Pipeline Updates

COVID-19 (SARS-CoV-2)

- Enrollment is ongoing in SPRINT (**S**ARS-Cov-2 **PR**otease **IN**hibitor **T**reatment), a Phase 2 clinical study of EDP-235, an oral, 3CL protease inhibitor, which received Fast Track designation from the U.S. Food and Drug Administration (FDA). The randomized, double-blind, placebo-controlled study is designed to evaluate the safety, tolerability, and antiviral activity of once-daily doses of EDP-235 compared to placebo. SPRINT will enroll approximately 200 non-hospitalized, symptomatic patients with mild to moderate COVID-19, who are not at increased risk for developing severe disease. During the study, patients will receive EDP-235 orally at a dose of 200 mg or 400 mg or placebo, once daily for five days, and will be assessed for a further 28 days. The primary objective of the study includes evaluation of safety and tolerability, and key secondary objectives include analysis of multiple virology measures and pharmacokinetics (PK) to guide dose selection for future trials. Enanta expects to report data from this Phase 2 study in the first half of 2023.
- Enanta today announced new preclinical *in vivo* data on EDP-235 highlighting the robust antiviral treatment effect and prevention of COVID-19 transmission in a ferret model. In a study, ferrets were infected with SARS-CoV-2 and then subsequently received either EDP-235 or vehicle. Results demonstrated that EDP-235 treatment of SARS-CoV-2 infected animals resulted in a rapid, robust and sustained decline in viral replication. To understand the effect of EDP-235 on transmission, cohorts of infected animals who had been treated with EDP-235 were co-housed with healthy and untreated animals and monitored for infection. Results showed that healthy animals did not contract COVID-19 when co-housed with infected animals that were treated with EDP-235, whereas the healthy animals co-housed with vehicle-treated infected animals did contract the virus. This study continues to support the potential of EDP-235 as an efficacious therapy for COVID-19, and also demonstrates its potential to reduce transmission of the virus.
- Enanta also today announced a new research program focused on the discovery and development of inhibitors of the SARS-CoV-2 PLpro for the oral treatment of COVID-19. PLpro is an essential enzyme, which, along with the 3CL protease (3CLpro, or Mpro), plays an important role in viral replication and also acts to suppress the innate immune response.

Inhibition of PLpro blocks viral replication and has the potential to restore the dysregulated immune response to SARS-CoV-2 infection. As this mechanism is distinct from 3CL protease inhibition, it has the potential to be used alone or in combination with 3CL protease inhibitors such as EDP-235 or other compounds to provide a range of treatment regimens for different patient populations suffering from COVID-19.

Respiratory Syncytial Virus (RSV)

- EDP-938, an N-protein inhibitor with Fast Track designation from the FDA, is being evaluated in a broad clinical development program in multiple high-risk patient groups, including pediatric and high-risk adult populations.
    - Ongoing studies include RSVHR, a Phase 2b randomized, double-blind, placebo-controlled study recently initiated in adults with acute RSV infection who are at high risk of complications, including the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease (COPD) or asthma; RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients; and RSVTx, a Phase 2b, randomized, double-blind, placebo-controlled study in adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection.
    - Enanta will continue to monitor RSV infection trends during the Northern Hemisphere season to evaluate the impact on trial enrollment and timing for data readouts in its ongoing RSV studies.
- Enanta is also currently evaluating EDP-323, a novel, oral, direct-acting antiviral selectively targeting the RSV L-protein, for the treatment of RSV, in a Phase 1 study. This double-blind, placebo-controlled, first-in-human study will enroll approximately 80 healthy subjects to evaluate the safety, tolerability, and PK of EDP-323. Enanta expects to report data from this Phase 1 study in the first half of 2023.
    - EDP-323 has shown sub-nanomolar potency against RSV-A and RSV-B *in vitro* and is not expected to have cross-resistance to other classes of inhibitors. EDP-323 could be used as a monotherapy or in combination with other RSV mechanisms, such as EDP-938, to potentially broaden the addressable patient populations or the treatment window.

Human Metapneumovirus (hMPV)/RSV

- Enanta today announced a new research program with broader spectrum antiviral activity, targeting hMPV and RSV with a single agent, which Enanta refers to as a dual-inhibitor. In preclinical studies, these dual-inhibitors maintained activity against multiple genotypes and strains of hMPV and RSV in a range of cell types. Enanta expects to select a clinical dual hMPV/RSV candidate in the fourth quarter of 2023.

Hepatitis B Virus (HBV)

- Enanta remains committed to developing a cure for HBV patients and is currently focused on identifying additional compounds with different mechanisms of action to combine with EDP-514, its potent core inhibitor, and a nucleoside reverse transcriptase inhibitor. EDP-514, which received Fast Track designation from the FDA, has displayed a good safety profile and robust antiviral activity in multiple HBV patient populations, with significant declines in HBV DNA among the best published to date for core inhibitors.

Webcast Information
Enanta's presentation will take place on Tuesday, January 10, 2023 at 3:00 p.m. PT. A live webcast of the presentation will be accessible by visiting the "Events and Presentations" section on the "Investors" page of Enanta's website at www.enanta.com. A replay of the webcast will be available following the presentation and will be archived for approximately 60 days.

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. Enanta's research and development programs include clinical candidates 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 RSV, SARS-CoV-2 and HBV and its preclinical program in hMPV. 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 vaccines and competitive treatments for RSV, SARS-CoV-2, HBV and hMPV; the discovery and development risks of Enanta's programs in RSV, SARS-CoV-2, HBV and hMPV; 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 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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Media and Investor:
Jennifer Viera
617-744-3848
jviera@enanta.com

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