Enanta Pharmaceuticals to Provide Updates on its Research and Development Programs and 2024 Outlook at the 42nd Annual J.P. Morgan Healthcare Conference

January 4, 2024

- *Expansion into Immunology with New Discovery Program of Oral KIT Inhibitors Addressing High Unmet Need in Chronic Spontaneous Urticaria (CSU); Development Candidate Selection Targeted for 2024*
- *Expect Topline Data from at Least One Phase 2 Study of Zelicapavir (EDP-938), an N-Protein Inhibitor in Development to Treat Respiratory Syncytial Virus (RSV), in 3Q 2024, Pending Continuation of a Normal Northern Hemisphere RSV Season*
- *Anticipate Challenge Study Data for EDP-323, an L-Protein Inhibitor in Development to Treat RSV, in 3Q 2024*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 4, 2024-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs with an emphasis on indications in virology and immunology, today announced that Jay R. Luly, Ph.D., Enanta's President and Chief Executive Officer, will provide an update across its pipeline and plans for 2024 during Enanta's presentation at the 42nd Annual J.P. Morgan Healthcare Conference on Wednesday, January 10, 2024 at 9:45 a.m. PT.

"Entering 2024, Enanta is poised to achieve significant value creation, starting with advancement of our robust RSV program which has multiple clinical catalysts expected over the year, and continuing with our expansion into immunology. Our foundational capabilities in virology and small molecule drug development transition well to immunology, an adjacent field where we can leverage our core strengths. We are excited to announce our first immunology program developing oral KIT inhibitors for the treatment of CSU, a severely debilitating chronic inflammatory skin disease characterized by hives, with limited effective treatment options" said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "This program has the potential to bring an efficacious oral treatment to the millions of patients affected by CSU worldwide, and potentially other mast cell driven indications, and we are eager to make an impact in this field. Additionally, we are progressing our RSV program of zelicapavir, also known as EDP-938, with enrollment ongoing in RSVPEDs, a Phase 2 study in pediatric RSV patients, and RSVHR, a Phase 2 study in high-risk adults with RSV. Assuming the Northern Hemisphere RSV season continues on a more normal course, we expect to have data in one or both of these trials in the third quarter of this year. We are also advancing EDP-323, our L-protein inhibitor, in a human challenge study and are targeting topline data in the third quarter of this year. Finally, with our strong cash reserves, we are well-positioned to build value by delivering highly differentiated oral therapeutics through innovative drug discovery."

Pipeline Updates

Virology

Respiratory Syncytial Virus

- Enanta is progressing multiple clinical programs targeting populations at high-risk for serious outcomes from RSV infection. Its lead candidate, zelicapavir, an oral, N-protein inhibitor, is being evaluated in two ongoing Phase 2 clinical trials, RSVPEDS and RSVHR.
    - RSVPEDs is a Phase 2, randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients, and RSVHR is a Phase 2b randomized, double-blind, placebo-controlled study in adults with RSV infection who are at high risk of complications, including the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease, or asthma.
    - Enanta expects to complete enrollment in one or both of these ongoing Phase 2 studies of EDP-938 and to report data in the third quarter of 2024, if this winter continues to be a more normal RSV season in the Northern Hemisphere.
- Enanta's second RSV candidate, EDP-323, an oral, L-protein inhibitor, is on track to report topline data from its ongoing Phase 2a challenge study in the third quarter of 2024. This randomized, double-blind, placebo-controlled, human challenge study is designed to assess safety, pharmacokinetics (PK), and changes in viral load measurements and baseline symptoms in up to 114 healthy adult subjects who will be infected with RSV. The advancement of EDP-323 into a challenge study follows positive Phase 1 data which demonstrated favorable safety, tolerability, and PK supportive of once-daily dosing, with high exposure multiples.

COVID-19

- Enanta plans to pursue any future COVID-19 efforts in the context of a collaboration, including the development of EDP-235, an oral, once-daily, Phase-3-ready, 3CL protease inhibitor which has been granted Fast Track designation by the FDA.

Hepatitis B Virus

- Enanta's goal is to achieve a functional cure for chronic Hepatitis B infection by identifying additional mechanisms for development in a combination regimen with EDP-514, its potent core inhibitor which has Fast Track designation from the FDA. Advancing this program depends upon accessing an additional mechanism through a licensing or partnership agreement.

Immunology

Chronic Spontaneous Urticaria

- Today, Enanta announced its expansion into immunology with its first program in chronic spontaneous urticaria (CSU), a severely debilitating, chronic inflammatory skin disease. CSU is estimated to affect 0.5% to 1% of the global population, and there is a substantial unmet need for an efficacious oral agent.[1] Currently, approximately half of patients are not controlled with antihistamines, and a minority of those patients are treated with one indicated biologic.[2] Enanta's approach is to treat CSU by depleting mast cells through KIT inhibition, addressing a primary driver of the disease. The company has developed novel, potent and selective oral inhibitors of KIT, which are now being optimized in preclinical development. Enanta's prototype inhibitors potently inhibit activity in both binding and cellular function assays and are highly selective for KIT versus other kinases. These inhibitors also demonstrate strong *in vitro* and *in vivo* ADME properties.
- Enanta will present new preclinical data on its prototype KIT inhibitor at the J.P. Morgan Conference and is targeting the selection of a development candidate in 2024.

The Company expects the following milestones across its pipeline in 2024:

- 3Q 2024:
  - Report topline data for one or both of the Phase 2 studies of zelicapavir, if this winter continues to be a more normal RSV season in the Northern Hemisphere
  - Report topline data from the Phase 2a challenge study of EDP-323
- 2024:
  - Select a KIT inhibitor development candidate for CSU
  - Introduce a second immunology program

Webcast Information

Enanta's presentation will take place on Wednesday, January 10, 2024 at 9:45 a.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 with an emphasis on indications in virology and immunology. Enanta's research and development programs are focused on respiratory syncytial virus (RSV) and chronic spontaneous urticaria (CSU).

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic hepatitis c virus infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations. 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 CSU. 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 CSU; the discovery and development risks of Enanta's programs in RSV and CSU; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; 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-K for the fiscal year ended September 30, 2023, 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.

1. Maurer M et al. Unmet Clinical Needs in Chronic Spontaneous Urticaria. A GA^{2}LEN Task Force Report. *Allergy* 2011.
2. Clarivate Treatment Algorithms: Claims Data Analysis - Chronic spontaneous urticaria, February 2023. ©2023 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission. Clarivate makes no representation or warranty as to the accuracy or completeness of the data ("Clarivate

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