Enanta Pharmaceuticals Doses First Subject in a Phase 1 Clinical Study of EDP-323, its Novel, Oral L-Protein Inhibitor in Development for the Treatment Respiratory Syncytial Virus

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WATERTOWN, Mass.--(BUSINESS WIRE)--Oct. 17, 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 it has dosed the first subject in its Phase 1 clinical trial of EDP-323, a novel, oral L-protein inhibitor in development for the treatment of respiratory syncytial virus (RSV).

“This first-in-human study of EDP-323, our selective, direct-acting antiviral specifically targeting the RSV L-protein, is an important milestone for Enanta as we mark the continued expansion of our clinical RSV portfolio. Compelling preclinical data show that EDP-323 potently blocks RSV replication and pathology across all RSV genotypes positioning EDP-323 as a potentially best-in-class potent oral antiviral treatment for RSV,” said Scott T. Rottinghaus, M.D., Senior Vice President and Chief Medical Officer of Enanta Pharmaceuticals. “EDP-323 could be used as a monotherapy or in combination with other RSV mechanisms, such as EDP-938, to broaden the addressable patient populations or treatment windows. As we continue to build upon our leadership in the RSV space, we believe having two unique mechanisms to treat the virus could potentially provide additional benefit to patients.”

This randomized, double-blind, placebo-controlled, first-in-human Phase 1 study will enroll approximately 80 healthy subjects ranging in age from 18 to 65 years old to evaluate the safety, tolerability and pharmacokinetics of EDP-323 with a single-ascending dose (SAD) phase, including a two-part food-effect (FE) cohort, and a multiple-ascending dose (MAD) phase. All SAD and MAD cohorts will enroll eight participants who will be randomized to receive EDP-323 or placebo in a 3:1 ratio. The SAD/FE cohort will enroll 10 subjects randomized in a 4:1 ratio.

EDP-323 is supported by *in vitro* data demonstrating a significant reduction in RSV replication with picomolar potency in primary human bronchial epithelial cells against RSV A and B, with consistent potency across a range of RSV clinical isolates in various cell types. In a mouse model of RSV infection, EDP-323 treatment was associated with dose-dependent decreases in viral load in the lung, reduced lung immunopathology and decreases in pro-inflammatory cytokines, including IFNγ, TNFα, and IL1β. Additionally, EDP-323 has favorable oral bioavailability with good plasma exposures across preclinical species and pharmacokinetic properties supporting once-daily oral dosing in humans. These data indicate that EDP-323 is a potent inhibitor of RSV replication and has the potential to be a best-in-class, broad spectrum, once daily, oral antiviral treatment for RSV.

About Respiratory Syncytial Virus

RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under one year of age in the United States and a significant cause of respiratory illness in older adults and immunocompromised individuals.[1] According to the Centers for Disease Control and Prevention, virtually all children in the United States get an RSV infection by the time they are two years old and one to two out of every 100 children younger than six months of age with an RSV infection may need to be hospitalized.[2] Globally, there are an estimated 33 million cases of RSV annually in children less than five years of age, with about 3 million hospitalized and up to approximately 120,000 dying each year from complications associated with the infection.[3] RSV represents a significant health threat for adults older than 65 years of age, with an estimated 177,000 hospitalizations and 14,000 deaths associated with RSV infections annually in the United States.[4]

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 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 program in RSV. 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 discovery and development risks of Enanta’s program in RSV; the competitive impact of development and regulatory efforts of others in this disease area; any continuing impact of the COVID-19 pandemic on Enanta’s 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.

1. Centers for Disease Control & Prevention – Respiratory Syncytial Virus
2. Centers for Disease Control & Prevention – RSV in Infants and Young Children
3. Shi et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. *Lancet*. 2017 Sep 2; 390(10098): 946–958:
4. Falsey AR, et al. Respiratory syncytial virus infection in elderly and high-risk adults. *New Engl J Med*. 2005;352(17):1749-59.

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Media and Investor Contact:
Jennifer Viera
617-744-3848
jviera@enanta.com

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