# Enanta Pharmaceuticals Receives FDA Fast Track Designation for EDP-323, its Oral, L-Protein Inhibitor in Development for the Treatment of Respiratory Syncytial Virus

April 6, 2023

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 6, 2023-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for EDP-323, Enanta's L-protein inhibitor in development for the treatment of respiratory syncytial virus (RSV).

"Receiving Fast Track designation from the FDA underscores EDP-323's potential as a once-daily, oral therapeutic for the treatment of this deadly virus and reflects the pressing need for a highly potent, direct antiviral to treat RSV, particularly for high-risk populations," said Scott T. Rottinghaus, M.D., Senior Vice President and Chief Medical Officer of Enanta Pharmaceuticals. "Given that EDP-323 has shown sub-nanomolar potency against several RSV-A and RSV-B strains *in vitro* and is not expected to have cross-resistance to other classes of inhibitors, we believe it could be used as a monotherapy or in combination with other RSV mechanisms to potentially broaden the addressable RSV patient populations or the treatment window. We believe this designation will be a valuable component of our clinical and regulatory strategy as we progress EDP-323 in development."

The Fast Track program is designed to accelerate the development and review of products such as EDP-323, 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.

EDP-323 is being evaluated in a Phase 1 double-blind, placebo-controlled study designed to assess its safety, tolerability, and pharmacokinetics (PK). Enanta plans to present new preclinical PK data at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in April and expects to report topline data from the Phase 1 study this quarter.

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, 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. Enanta's research and development programs include clinical candidates for the following disease targets: respiratory syncytial virus (RSV), SARS-CoV-2 (COVID-19) and hepatitis B virus (HBV). Enanta is also conducting research on a single agent targeting both RSV and 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 EDP-323 for 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 impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV; the discovery and development risks of Enanta's RSV program ; the competitive impact of development, regulatory and marketing efforts of others in this disease; any continuing impact of the COVID-19 pandemic on incidence of RSV; 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, 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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