Enanta Pharmaceuticals Announces Positive Phase 1 Results and Initiation of Phase 2a Clinical Study of EDP-938 for Respiratory Syncytial Virus

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WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced that dosing has begun in a Phase 2a study to evaluate the safety, pharmacokinetics and antiviral activity of multiple doses of orally administered EDP-938 against respiratory syncytial virus infection in a human challenge study.

“RSV is an infection for which there is no safe and effective treatment,” stated Jay R. Luly, Ph.D., President and CEO, Enanta. “Infants, the elderly, and immune compromised individuals are at the highest risk for this severe respiratory tract infection. EDP-938 is the only N-protein inhibitor in development today and represents a new approach by targeting viral replication of RSV. We are pleased to announce the initiation of our Phase 2a challenge study, and we are targeting preliminary Phase 2a results in calendar 3Q19.”

EDP-938 Phase 2a Design
In this randomized, double-blind, placebo-controlled, human challenge study, up to 114 healthy adult subjects will be randomized into 1 of 3 arms (1:1:1) and will be dosed for 5 days. All subjects will be infected with RSV-A Memphis 37b virus, and approximately 76 subjects will receive EDP-938 and 38 subjects will receive placebo. Arm 1 will receive placebo, Arm 2 will receive a single 500 mg loading dose of EDP-938 followed by 300 mg BID, and Arm 3 will receive a daily 600 mg dose. Primary and secondary outcome measures include changes in viral load measurements and change of baseline symptoms.

EDP-938 Phase 1 Results
Details of this Phase 1 study will be presented on November 1 at the 11th International Respiratory Syncytial Virus Symposium in Asheville, North Carolina.

The Phase 1 randomized, double-blind, placebo (PBO)-controlled, first-in-human study was conducted to evaluate the safety, tolerability, and pharmacokinetics (PK) of single- and multiple- (7 days) ascending doses (SAD: 50 - 800 mg and MAD: 100 - 600 mg once daily and 300 mg twice daily) and food effect (FE) of EDP-938 in healthy subjects. In the SAD phase, 50 subjects [EDP-938 (n=38) and PBO (n=12)] were enrolled into 6 dose cohorts; in the MAD phase, 40 subjects [EDP-938 (n=30) and PBO (n=10)] were enrolled into 5 dose cohorts.

Overall, no safety concerns have been reported in 68 healthy subjects receiving a broad range of single and multiple doses of EDP-938. Headache was the most frequently reported AE during the SAD and MAD phases. There were no SAEs, and AEs were of mild intensity, with none leading to study drug discontinuation.

EDP-938 was rapidly absorbed and exposure increased with increasing single and multiple dosing, resulting in a PK profile suitable for once or twice daily oral dosing regardless of food. In the MAD phase, half-life ranged from 12.9 to 17.6 hours, and at doses comparable to those under study in the Phase 2a trial, mean trough levels were approximately 30x higher than the EC90 of EDP-938 against RSV-infected human cells.

Data at the 11th International Respiratory Syncytial Virus Symposium in Asheville, North Carolina, October 31 to November 4, 2018:

- **Poster Presentation**
  Nov. 1, 11:30 am to 12:30 pm ET, Nathalie Adda, MD
  “EDP-938, a Novel, Non-Fusion Replication Inhibitor of Respiratory Syncytial Virus: Preliminary Results of a Phase 1 Study in Healthy Subjects (HS)”

- **Oral Presentation**
  Nov. 2, 12:45 to 13:00 pm ET, Michael Rhodin, Ph.D.
  “EDP-938, a Novel Non-Fusion Replication Inhibitor of RSV, Displays a High Barrier to Resistance In Vitro”

About EDP-938
EDP-938, Enanta’s lead non-fusion N-inhibitor, is being developed for the treatment of RSV infection. Enanta believes a non-fusion approach differentiates this compound from fusion inhibitors currently in development for RSV because non-fusion inhibitors target the virus’ replication machinery and have demonstrated high barriers to resistance against the virus *in vitro.* EDP-938 has also been shown to reduce viral load below the level of detection *in vivo*. Additionally, non-fusion inhibitors have the potential of being effective at later stages of infection.

About RSV
Respiratory syncytial virus (RSV) is a virus that infects the lungs and represents a serious unmet medical need in infants and children, as well as immune-compromised individuals and the elderly. RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age in the United States. Each year, 57,000 to 125,000 children in this group are hospitalized due to RSV infection. Also, at increased risk of a severe RSV infection, are children with compromised (weakened) immune systems due to a medical condition or medical treatment, adults with compromised immune systems and those 65 and older. There is currently no effective treatment available for treating RSV infection.

About Enanta
Enanta Pharmaceuticals 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. Glecaprevir, a protease inhibitor discovered by Enanta, has been developed by AbbVie, and is now approved in numerous countries, as part of AbbVie's newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen is sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir).

Royalties from the AbbVie collaboration are helping to fund Enanta's research and development efforts, which are currently focused on the following disease targets: non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV). Please visit www.enanta.com for more information.

FORWARD LOOKING STATEMENTS DISCLAIMER
This press release contains forward-looking statements, including statements with respect to the prospects for EDP-938 and Enanta's RSV program. 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 development risks of early stage development efforts in disease areas such as RSV; potential competition from the development efforts of others in RSV; Enanta's lack of clinical development experience; Enanta's need to attract and retain senior management and key scientific 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 most recent Form 10-Q for the quarter ended June 30, 2018 and 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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