



New Data from Enanta's Phase 2a Human Challenge Study of EDP-938 for RSV Demonstrates Highly Statistically Significant Reductions ($p < 0.001$) in Total Symptom Score, Mucus Weight and RSV Viral Load as Measured by RT-PCR Assay and by Plaque Assay

October 3, 2019

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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 new data from its Phase 2a Human Challenge Study of EDP-938 is being presented as a late-breaker oral presentation today at IDWeek™ 2019 in Washington, D.C. EDP-938 is Enanta's lead N-protein inhibitor being developed for the treatment of RSV infection.

Today's late-breaking oral presentation will include data demonstrating that in the RSV Challenge study EDP-938 administered once or twice daily achieved highly statistically significant reductions ($p < 0.001$) in RSV viral load by quantitative viral culture (plaque assay), as well as in mucus production. These data were consistent with the data for the primary efficacy endpoint of RSV viral load reduction by RT-PCR, as well as the secondary endpoint of reduction in RSV-associated total symptom score, both of which endpoints have been reported previously.

The results of the RSV quantitative viral culture assay (Log_{10} plaque forming units/mL) demonstrated highly statistically significant ($p < 0.001$) reductions in RSV viral load area under the curve (AUC) of 82.53% and 77.43%, in the QD and BID arms, respectively, compared to the placebo arm and without a significant difference between the dosing groups. These findings confirm the previously reported, highly statistically significant ($p < 0.001$) reductions in RSV viral load AUC by quantitative RT-PCR in the QD and BID arms of 74.43% and 71.46%, respectively, compared to placebo and without a significant difference between the dosing groups. Additionally, highly statistically significant reductions ($p < 0.001$) in RSV-associated nasal mucus production (mucus weight) of 72.06% and 77.67% in the QD and BID arms, respectively, compared to placebo and without a significant difference between the dosing groups.

These data support the further clinical evaluation of EDP-938. Enanta plans to initiate a Phase 2b clinical study of EDP-938 in adult out-patients with RSV by the end of 2019.

The double-blind, placebo-controlled, Phase 2a study being presented evaluated EDP-938 in adult volunteers inoculated with RSV-A Memphis 37b. EDP-938 was dosed for 5 days as 600mg once daily (QD arm) or a 500mg loading dose then 300mg twice daily (BID arm), or study subjects received placebo. A total of 115 subjects were randomized and inoculated; 86 were included in the analysis of the intent-to-treat-infected (ITT-I) population, which comprised all randomized and inoculated subjects who received at least one dose of study drug and who had confirmed RSV infection.

EDP-938 Presentations at IDWeek™ 2019 are listed below:

Late-Breaker Oral Presentation:

October 3, 2019

Time: 2:35 – 2:45 pm ET

#LB6: "EDP-938, a Novel RSV N-Inhibitor, Administered Once or Twice Daily Was Safe and Demonstrated Robust Antiviral and Clinical Efficacy in a Healthy Volunteer Challenge Study", Coakley, et.al.

Poster Presentation:

October 3, 2019

12:15 – 1:30 pm ET

#667: "Preclinical Pharmacokinetic and Pharmacodynamic Characterization of EDP-938, a Novel and Potent Non-Fusion Replication Inhibitor of Respiratory Syncytial Virus," Jiang, et.al.

These abstracts and further information about IDWeek™ 2019 can be found at <https://www.idsociety.org/events2/events/2019/October/idweek-2019/>.

About EDP-938

EDP-938, Enanta's lead N-protein inhibitor, is being developed for the treatment of RSV infection. Enanta believes EDP-938 is differentiated from fusion inhibitors currently in development by others for RSV because this N-protein inhibitor targets the virus' replication machinery and has 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, it is possible that N-protein inhibitors may be effective treatments at later stages of infection.

About Respiratory Syncytial Virus

Respiratory syncytial virus (RSV) is a virus that infects the lungs and represents a serious unmet medical need in infants and children. 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. 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 age 65 and older. Recent estimates suggest that approximately 200,000 hospitalizations in the U.S. and EU occur each year in children under the age of two and approximately 170,000 hospitalizations in these regions occur in each year in adults aged 65 and older. There is currently no safe and effective therapy for already established RSV infection.

About Enanta

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 efforts are currently focused on the

following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta's research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its 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). 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 further development with respect to EDP-938 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 development risks of early stage discovery efforts in the disease areas in Enanta's research and development pipeline, such as RSV; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV; Enanta's limited 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 fiscal quarter ended June 30, 2019 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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