Enanta Pharmaceuticals to Provide Updates on its Research and Development Programs and Business Outlook for 2018 during the 36th Annual J.P. Morgan Healthcare Conference

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- Phase 2 clinical study “INTREPID” of EDP-305 in patients with primary biliary cholangitis initiated
- Phase 1 clinical study of EDP-938 for respiratory syncytial virus initiated
- Strong cash balance of $294M as of September 30, 2017 to support advancing R&D programs

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 5, 2018-- 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 Jay R. Luly, Ph.D., Enanta’s President and Chief Executive Officer, will provide an update on its research and development programs in non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), respiratory syncytial virus (RSV), and hepatitis B virus (HBV) and its business outlook for 2018 during Enanta’s presentation at the 36 th Annual J.P. Morgan Healthcare Conference on January 9, 2018 at 4:00 p.m. PT.

“Enanta has executed well on its stated goals and as a result has achieved significant clinical progress,” stated Jay R. Luly, Ph.D. President and CEO Enanta. “We begin the year with two wholly-owned clinical programs ongoing for RSV and PBC, with a third for NASH to initiate soon. In addition, ongoing royalties from our HCV collaboration, along with our strong cash position at the end of our fiscal year of approximately $294 million, provide us a source of non-dilutive funding for these programs.”

The following are details of Enanta’s research and development program updates and expectations for 2018.

Research and Development Update:

EDP-305, FXR agonist for NASH/PBC:

- A Phase 2 dose-ranging clinical study of EDP-305, Enanta’s lead FXR agonist, has been initiated in patients with PBC. The Phase 2 clinical study, “INTREPID”, is a 12-week, randomized, double blind, placebo-controlled study evaluating the safety, tolerability, pharmacokinetics and efficacy of EDP-305 in subjects with PBC, with or without an inadequate response to ursodeoxycholic acid. The efficacy of EDP-305 will be assessed by evaluating reductions in levels of alkaline phosphatase versus placebo.
- Enanta plans to initiate a Phase 2 dose-ranging clinical study of EDP-305 in NASH patients in early 2018.
- The U.S. Food and Drug Administration has granted EDP-305 Fast Track designation for the treatment of NASH patients with liver fibrosis and Fast Track designation for the treatment of patients with PBC.
- Data is being presented at the 2018 NASH-TAG conference in Park City, Utah, January 4-6, 2018, from Enanta’s Phase 1 study of EDP-305 in healthy subjects and in subjects with presumptive non-alcoholic fatty liver disease (NAFLD). Top line results were first announced on October 23, 2017, and data from this trial studying the safety, pharmacokinetic, and pharmacodynamic properties of EDP-305 support further clinical evaluation of EDP-305 in NASH and PBC patients.

Respiratory Syncytial Virus:

- A Phase 1 clinical study of EDP-938, a potent non-fusion inhibitor of both RSV-A and RSV-B activity, has been initiated. The objective of the study is to evaluate the safety, tolerability and pharmacokinetics of single ascending dose (SAD) and multiple ascending dose (MAD) levels of EDP-938 in healthy volunteers. Upon successful completion of this study, a Phase 2 proof-of-concept challenge study in RSV-infected humans is expected to begin later in 2018.

Hepatitis B Virus:

- Enanta’s current research efforts in HBV are focused on core inhibitors, with the aim of developing a functional cure. Preclinical lead optimization continues to progress, with the goal of identifying a development candidate in 2018.

Licensed Products Update

Glecaprevir and paritaprevir, protease inhibitors for Hepatitis C Virus (HCV):

- Glecaprevir, Enanta's second protease inhibitor developed through its collaboration with AbbVie, is one of the two new direct-acting antivirals in AbbVie's new pan-genotypic glecaprevir/pibrentasvir combination for chronic HCV treatment now being marketed in the U.S., EU, Japan, and other jurisdictions under the tradenames MAVYRET™ (U.S.) or MAVIRET™ (ex-U.S.).
- Enanta has earned all of the clinical and regulatory milestones for two products, paritaprevir and glecaprevir, within the Enanta/AbbVie HCV collaboration, and continues to receive royalties on both products. Total cash received from AbbVie under the collaboration through December 31, 2017 totaled approximately $526 million dollars.

Webcast Information

Enanta's presentation will take place on January 9, 2018 beginning at 4:00 p.m. PT. A live webcast of the presentation, as well as the question and answer breakout session that follows 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 webcasts will be available following the presentation and will be archived for approximately 60 days.

About Enanta

Enanta Pharmaceuticals has used its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery of small molecule drugs for the treatment of viral infections and liver diseases. Two protease inhibitors, glecaprevir and paritaprevir, discovered and developed through Enanta's collaboration with AbbVie, have now been approved in jurisdictions around the world as part of AbbVie's direct-acting antiviral (DAA) regimens for the treatment of hepatitis C virus (HCV) infection, including the marketed regimens MAVYRET™ (U.S.) /MAVIRET™(ex-U.S.) (glecaprevir/pibrentasvir) and VIEKIRA PAK® (U.S.)(paritaprevir/ritonavir/ombitasvir/dasabuvir). Royalties and milestone payments 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 Enanta's further development of EDP-305 and EDP-938, the prospects for AbbVie's MAVYRET™ /MAVIRET™ (glecaprevir/pibrentasvir) regimen for HCV generating additional royalties for Enanta, and the prospects for further development in Enanta's HBV 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 discovery efforts in new disease areas in Enanta's research and development efforts, such as NASH, PBC, RSV and HBV; Enanta's revenues in the short-term are dependent upon the success of AbbVie's continuing commercialization efforts for its new MAVYRET/MAVIRET regimen; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for NASH, PBC, RSV, HCV or HBV; reimbursement actions affecting any competitive treatment for HCV; 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-K for the fiscal year ended September 30, 2017 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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