Enanta to Present New Data for Core Inhibitor for Hepatitis B Virus and FXR Agonist EDP-305 for NASH at The International Liver Congress™ 2018

April 12, 2018

- Oral presentation will demonstrate novel core inhibitor EP-027367 reduces hepatitis B virus DNA levels up to 3.0 logs from baseline in HBV viral titers with 4 weeks of treatment in a humanized mouse model.

WATERTOWN, Mass.-(BUSINESS WIRE)--Apr. 12, 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 data from Enanta’s wholly-owned development programs, including EP-027367, one of Enanta’s novel core inhibitors in preclinical testing targeting hepatitis B virus (HBV), and EDP-305, an FXR agonist in development for non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC), will be presented at The International Liver Congress™ (ILC) 2018 taking place this week in Paris, France.

The abstract titled, “Discovery of a novel HBV core inhibitor EP-027367 with potent antiviral activity both in vitro and in a humanized mouse model” will be presented today at 17:45 CET in an oral presentation. EP-027367 is one of several core inhibitors Enanta is evaluating for hepatitis B virus. Core inhibitors, sometimes referred to as capsid assembly modulators, are a new class of HBV inhibitors that can disrupt the assembly and replication of the virus at multiple steps in the virus lifecycle. Data being presented today will demonstrate that in a chimeric mouse model with human liver cells, EP-027367 reduced hepatitis B virus DNA levels by up to 3.0 logs from baseline in HBV viral titers with 4 weeks of treatment and demonstrated a favorable tolerability and pharmacokinetic profile. EP-027367 has also demonstrated potent, pan-genotypic, anti-HBV activity capable of preventing the establishment of cccDNA in vitro.

There will also be three posters on EDP-305, Enanta’s FXR agonist currently in a Phase 2 study for NASH and a Phase 2 study for PBC. One poster will highlight new preclinical data demonstrating EDP-305 favorably regulates the expression of key fibrogenic genes in vitro and in vivo and a second will show EDP-305 has distinct transcriptional and post-transcriptional regulatory mechanisms for LDLR and SRB1 expression. A third poster will present data from our previously released phase 1 study highlighting the pharmacokinetics, pharmacodynamics and safety of EDP-305 in healthy and presumptive NAFLD subjects. 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.

The full ILC 2018 scientific program as well as the abstracts can be found at http://ilc-congress.eu/. Further details will be available at the time of these presentations.

Oral Presentation:

- Thursday, April 12, 17:45 - 18:00 CET
  

Poster Presentations

Thursday, April 12, 09:00 - 17:00 CET

- THU-469 - “EDP-305 modulates lipoprotein metabolism via distinct chromatin and microRNA regulatory mechanisms” (M. Roqueta-Rivera, M.D. Chau, K. Garlick, Y. Li, G. Wang, Y.S. Or, and L.J. Jiang)

Friday, April 13, 09:00 - 17:00 CET

- FRI-084 - “EDP-305, a highly selective and potent farnesoid X receptor agonist, favorably regulates the expression of key fibrogenic genes in vitro and in vivo” (Y. Li, J.Y. Shang, M.D. Chau, M. Roqueta-Rivera, K. Garlick, P. An, K. Vaid, G. Wang, Y. Popov, Y.S. Or, and L.J. Jiang)

- FRI-489 - “Pharmacokinetics, pharmacodynamics, and safety of EDP-305, in healthy and presumptive NAFLD subjects” (A. Ahmad, K. Sanderson, D. Dickerson, N. Adda)

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 regimens marketed as MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir) and VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir) (U.S.) and VIEKIRAX® (paritaprevir/ritonavir/ombitasvir) (ex-U.S.).

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 Enanta’s further development of EDP-305 and EP-027367. 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 Enanta’s early stage discovery efforts in NASH, PBC and HBV; potential competition from the development efforts of others in these disease areas; Enanta’s lack of clinical...
development experience; Enanta's need to attract and retain senior management and key scientific personnel; the need to obtain and maintain patent protection for Enanta’s 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 December 31, 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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