Enanta Pharmaceuticals Announces Data Presentations at the 2018 NASH-TAG Conference

December 21, 2017
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WATERTOWN, Mass.--(BUSINESS WIRE)--Dec. 21, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a chemistry-driven biotechnology company dedicated to creating and developing small molecule drugs for viral infections and liver diseases, today announced that two presentations on EDP-305, Enanta's FXR agonist for non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC), will be presented at the NASH-TAG conference January 4-6, 2018 in Park City, Utah.

Data will be presented 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.

Also, new preclinical data to be presented will demonstrate that treatment with EDP-305 had a significant therapeutic effect on NASH progression in NASH mouse models, and resulted in decreased liver steatosis, hepatocyte ballooning, and total non-alcoholic fatty liver disease score (NAS).

The following data will be presented during the conference:

Poster Presentation:

- **Pharmacokinetics (PK), pharmacodynamics (PD), and safety/tolerability effects of EDP-305, a novel, once-daily, oral farnesoid X receptor (FXR) agonist in healthy subjects and in subjects with presumptive nonalcoholic fatty liver disease (NAFLD)**Alaa Ahmad, Kristen Sanderson, Daniel Dickerson, Nathalie Adda, Enanta Pharmaceuticals, Inc., Watertown, MA USA

Oral Presentation:

- **EDP-305, a highly selective and potent farnesoid X receptor (FXR) agonist, reduces liver steatosis, ballooning, and non-alcoholic fatty liver disease activity score (NAS) in two murine models of non-alcoholic steatohepatitis (NASH)** Li-Juan Jiang, Mary Chau, Yang Li and Yat Sun Or, Enanta Pharmaceuticals, Inc., Watertown, MA, USA

For more information, visit https://www.nash-tag.org/.

About Enanta's EDP-305 Development Program
Enanta is developing EDP-305, its lead farnesoid X receptor agonist, for the treatment of patients with non-alcoholic steatohepatitis (NASH) and for patients with primary biliary cholangitis (PBC). Data from a Phase 1 clinical study demonstrated that EDP-305 was generally safe and well tolerated over a broad range of single and multiple doses, with pharmacokinetic (PK) data supporting once daily oral dosing. Results also support the ability to administer EDP-305 in future trials at doses that neither elicit clinically significant changes in lipids nor result in pruritus. EDP-305 has been granted Fast Track Designation by U.S. Food and Drug Administration for the treatment of patients with PBC and for NASH patients with liver fibrosis. Enanta plans to initiate a Phase 2 dose-ranging study in PBC patients by the end of 2017 and a Phase 2 dose-ranging study in NASH patients in early 2018.

About EDP-305, a Farnesoid X Receptor (FXR) Agonist
EDP-305 is a potent FXR agonist and Enanta's lead product candidate being developed for the treatment of NASH and PBC. EDP-305 represents a new class of FXR agonists that has been designed to take advantage of increased binding interactions with the receptor. Further, this non-bile acid class contains steroidal and non-steroidal components, and does not contain the carboxylic acid group that can lead to the formation of taurine and glycine conjugates normally associated with bile acids, which may also be present in other classes of FXR agonists.

About NAFLD, NASH, and FXR
Non-alcoholic fatty liver disease (NAFLD) is the accumulation of excessive fat in the form of triglycerides in patients' liver cells (steatosis) that is not caused by alcohol. NAFLD is widely considered to be the liver expression of metabolic disease associated with type 2 diabetes, insulin resistance, obesity, and hyperlipidemia. A subgroup of NAFLD patients has liver cell injury and inflammation in addition to excessive fat (steatohepatitis). Progression of this condition leads to non-alcoholic steatohepatitis (NASH). Patients with NASH can develop fibrosis and ultimately cirrhosis of the liver, potentially leading to hepatocellular carcinoma (HCC) or requiring a liver transplant. Farnesoid X receptor (FXR) is a nuclear receptor and a main regulator of bile acid levels in the liver and small intestine. It responds to bile acids by regulating gene transcription of key enzymes and transporters, many of which play important roles in lipid metabolism, insulin resistance, inflammation, and fibrosis.

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, paritaprevir and glecaprevir, 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

This press release contains forward-looking statements, including statements with respect to the prospects for the development of EDP-305 for the treatment of NASH and/or PBC. 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 discovery and development risks of early stage development efforts in disease areas such as NASH that currently have no therapeutic treatment; potential competition from the development efforts of others in NASH and PBC; Enanta's level 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-K for the fiscal year ended September 30, 2017 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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