Enanta Pharmaceuticals to Present New Preclinical Data on EDP-305, an FXR Agonist for NASH and PBC, at The Liver Meeting® 2017

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WATERTOWN, Mass.--(BUSINESS WIRE)--Oct. 20, 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 new data presentations on EDP-305, Enanta's lead Farnesoid X receptor (FXR) agonist being developed for non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC), will be presented at The Liver Meeting® 2017, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), taking place October 20-24, 2017 in Washington, D.C.

EDP-305 has demonstrated potency and efficacy in a variety of NASH, fibrosis and cirrhosis animal models. EDP-305 has completed a Phase 1 clinical study in healthy subjects and in subjects with presumed non-alcoholic fatty liver disease (obese, with or without pre-diabetes or type 2 diabetes mellitus). Further studies are planned in NASH and PBC patients.

EDP-305 is a potent agonist of FXR, a nuclear receptor that is the main regulator of bile acid levels in the liver and small intestine. FXR 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.

The following will be presented during The Liver Meeting® 2017:

Friday, October 20
Presidential Poster of Distinction, 8:00 am - 5:30 pm ET
Session: Basic Fibrosis Research and Stellate Cell Biology
#367 – "A novel FXR agonist EDP-305 potently suppresses hepatic stellate cell activation and hepatic fibrosis in chronic mouse models of biliary and metabolic liver disease"

- Data demonstrates that EDP-305 directly inhibits hepatic stellate cell proliferation *in vitro* and improved pre-established liver injury and hepatic fibrosis in biliary and metabolic models of liver disease in mice.

Monday, October 23
Oral Presentation, 8:00 - 9:30 am ET
Parallel Session 23: Steatosis and Steatohepatitis: Experimental I
#162 – "Significant anti-fibrotic efficacy of EDP-305, a highly potent and selective farnesoid X receptor (FXR) agonist, in a rat model of thioacetamide-induced liver fibrosis and cirrhosis"

- EDP-305 exhibits excellent anti-fibrotic efficacy in rats with ongoing TAA-induced fibrosis.

Monday, October 23
Presidential Poster of Distinction, 8:00 am - 5:30 pm ET
Session: Steatohepatitis: Experimental
#1988 – "EDP-305 favorably regulates lipoprotein mechanism *in vitro*"

- *In vitro* data demonstrates that EDP-305 maintains a positive effect on lipoprotein metabolism under steatotic conditions by not altering LDLR or SRB1 expression, without increasing ApoB secretion.

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, and that 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 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 and development 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 U.S. marketed regimens MAVYRET™ (glecaprevir/pibrentasvir) and VIEKIRA PAK® (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.

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