



## Enanta Pharmaceuticals Announces Highlights of Business Overview and Update on its Research and Development Programs to be Presented at the 35th Annual J.P. Morgan Healthcare Conference

January 6, 2017

- Enanta to provide updates in all major therapeutic focus areas: NASH/PBC, RSV, HBV, HCV
- New *in vivo* data to be presented demonstrating EDP-305 improved pre-established liver injury and hepatic fibrosis in an MCD-induced model of steatohepatitis in mice<sup>1</sup>
- A potent non-fusion inhibitor, EDP-938, selected as a development candidate for RSV, and new *in vivo* efficacy data to be presented<sup>2</sup>

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 6, 2017-- 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 the highlights of its business overview and research and development program update that will be presented at the 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference on January 11, 2017 at 9:00 a.m. PT. The presentation will provide updates on Enanta's development programs in non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), hepatitis C virus, (HCV), hepatitis B virus (HBV) and respiratory syncytial virus (RSV), as well as an update on the company's HCV assets. In addition, new *in vivo* data will be presented on EDP-305, Enanta's lead FXR agonist for NASH and PBC and on EDP-938, Enanta's new non-fusion inhibitor development candidate for RSV.

The following are details of Enanta's research and development programs updates and expectations for the coming year.

### Research and Development Update:

#### EDP-305, FXR agonist for NASH:

- New *in vivo* data will be presented by Dr. Yury V. Popov at the NASH-TAG conference later today. In a poster presentation titled, "*A novel and highly potent FXR agonist EDP-305 suppresses liver injury and fibrosis in a murine model of steatohepatitis*" (Popov, *et al.*), therapeutic efficacy data in mice with steatohepatitis and fibrosis is presented in comparison with the first-in-class FXR agonist, obeticholic acid (OCA). The data demonstrate that treatment with EDP-305 improved pre-established liver injury and hepatic fibrosis in an MCD-induced model of steatohepatitis in mice. EDP-305 at both doses (10 and 30 mg/kg) had a strong inhibitory effect on liver fibrosis progression, with up to 70% reduction in hepatic collagen deposition ( $p < 0.05$ , ANOVA) as determined biochemically via hydroxyproline measurement. Histologically, MCD-fed control mice developed the advanced perisinusoidal fibrosis ("chicken wire") characteristic of NASH. Treatment with EDP-305 was associated with markedly reduced perisinusoidal fibrosis compared to the placebo group.<sup>1</sup>
- Data will be presented from a poster titled "*The Novel Farnesoid X Receptor (FXR) agonist, EDP-305, Reduces Fibrosis Progression in Bile Duct Ligated Rats*", (B. Fuchs, *et al.*). This data, previously presented at the American Association for the Study of Liver Disease (AASLD) meeting in November, demonstrated that EDP-305 reduced liver fibrosis in CDAHFD and BDL rodent models.<sup>3</sup>
- As previously announced on January 4, the U.S. Food and Drug Administration (FDA) granted EDP-305 Fast Track designation for the treatment of patients with NASH with liver fibrosis.
- Enanta expects to complete a phase 1 clinical study in healthy volunteers and presumptive NAFLD subjects by mid-2017, to initiate a phase 2 clinical study in patients with primary biliary cholangitis (PBC) and to perform NASH-enabling studies in the second half of 2017, and expects to initiate a phase 2 clinical study in patients with NASH in early 2018.

#### Respiratory Syncytial Virus (RSV):

- Enanta has selected EDP-938, a potent non-fusion inhibitor of both RSV-A and RSV-B activity, as its first development candidate for RSV. New pre-clinical data demonstrated a rapid reduction in viral load, below the limits of detection (LOD) in animals treated with EDP-938. A phase 1 clinical study is expected to begin in the fourth quarter of 2017.<sup>2</sup>

#### Hepatitis B Virus (HBV):

- 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 2017.

#### Hepatitis C Virus (HCV):

- Enanta's HCV collaboration partner, AbbVie, submitted a new drug application (NDA) for the investigational, pan-genotypic HCV regimen of glecaprevir/pibrentasvir (G/P) for the treatment of genotypes 1 through 6 of chronic HCV. Glecaprevir is Enanta's second protease inhibitor being developed through its collaboration with AbbVie and is one of the two new direct-acting antivirals in G/P. AbbVie has announced that it is planning for the commercial launch of G/P to begin in the U.S. in 2017.
- Enanta has concluded the proof-of-concept study of EDP-494, its cyclophilin inhibitor candidate, in patients with HCV genotypes 1 and 3. Given the high SVR rates in most of the underserved HCV populations demonstrated in phase 3 studies of treatment with G/P in our partnered HCV program, Enanta now believes that G/P has the best and most timely potential for Enanta to participate in the treatment of those HCV patients who have failed on other treatment regimens. Therefore, Enanta has decided to stop further development of EDP-494 and to focus its efforts on its wholly-owned programs in NASH/PBC, RSV and HBV.

#### Webcast Information

Enanta's presentation will take place on January 11, 2017 beginning at 9:00 a.m. PT. A live webcast and replay of the presentation, as well as the question and answer breakout session that follows the presentation will be accessible by visiting the "Calendar of Events" section on the "Investors" page of Enanta's website at [www.enanta.com](http://www.enanta.com). The replay webcasts will be available following the presentation and will be archived for approximately 60 days.

#### About Enanta

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development efforts are currently focused on three disease targets: non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

Enanta has discovered novel protease inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of an investigational, pan-genotypic, once-daily, ribavirin-free, fixed-dose combination (G/P) with pibrentasvir (ABT-530), AbbVie's second NS5A inhibitor.

Enanta has discovered EDP-305, an FXR agonist product candidate for NASH and PBC, currently in Phase 1 clinical development, and has identified a clinical candidate for RSV, EDP-938, now, in preclinical development. Enanta is also developing early lead candidates for HBV. Please visit [www.enanta.com](http://www.enanta.com) for more information on Enanta's programs and pipeline.

#### 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, the prospects for AbbVie's G/P regimen in HCV, and the prospects for further developments in Enanta's RSV and HBV programs. 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; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for NASH, PBC, RSV, HCV or HBV; regulatory and reimbursement actions affecting any competitive treatment for NASH, PBC, RSV, HCV or HBV; 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, 2016 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.

<sup>1</sup> Poster presentation: "A Novel and Highly Potent FXR agonist EDP-305 Suppresses Liver Injury and Fibrosis in a Murine Model of Steatohepatitis". (Popov, *et al.*), NASH-TAG conference, January 6, 2017

<sup>2</sup> Enanta internal data

<sup>3</sup> Poster presentation: "The Novel Farnesoid X Receptor (FXR) agonist, EDP-305, Reduces Fibrosis Progression in Bile Duct Ligated Rats", (B. Fuchs, *et al.*), American Association for the Study of Liver Disease (AASLD) meeting November 11, 2016

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