



## **Enanta Pharmaceuticals Announces New R&D Initiatives in Hepatitis B Virus and Respiratory Syncytial Virus and Plan to Provide Data Updates on Programs in NASH and HCV at the 34th Annual J.P. Morgan Healthcare Conference**

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- **Updates on Enanta's wholly-owned programs to be presented on Wednesday, January 13 at 11:00 a.m. PT at the 34th Annual J.P. Morgan Healthcare Conference**
- **First subject dosed in phase 1 clinical study with cyclophilin inhibitor EDP-494 for hepatitis C virus infection**

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 11, 2016-- Enanta Pharmaceuticals, Inc., (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, announced today that it has expanded its research and development programs within the company's core focus areas of virology and liver disease to include new programs to treat hepatitis B virus (HBV) and respiratory syncytial virus (RSV) infections. Enanta also announced that the first subject was dosed in a phase 1 clinical study with EDP-494, its cyclophilin inhibitor for the treatment of hepatitis C virus (HCV).

Enanta has ongoing internal research and development in four disease areas: HCV, HBV, RSV, and non-alcoholic steatohepatitis (NASH). Updates on all four wholly-owned programs will be presented on Wednesday, January 13 at 11:00 a.m. PT at the 34th Annual J.P. Morgan Healthcare Conference in San Francisco.

"Our successful HCV collaboration, our drug discovery expertise and our experience in virology resulted in our first marketed product with AbbVie, paritaprevir, which is part of the VIEKIRA PAK® combination HCV therapy," commented Jay R. Luly, Ph.D. President and Chief Executive Officer. "We are now in a position to diversify and grow beyond HCV and to expand our research into other areas where we can develop new therapies for patients with limited treatment options."

### **New Programs in Respiratory Syncytial Virus (RSV) and Hepatitis B Virus (HBV)**

Building on Enanta's knowledge and experience in developing treatments for virological diseases such as HCV, Enanta has initiated programs in two new areas where there is a large opportunity and an unmet medical need; RSV and HBV.

RSV is a viral lung infection that is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age in the United States. Each year, 75,000 to 125,000 children in this age group are hospitalized due to RSV infection.<sup>1</sup> RSV also causes serious complications in immune-compromised populations and the elderly.<sup>2</sup> There are currently no safe and effective treatments available.

HBV is a potentially life-threatening liver infection. It is estimated that 15-25% of patients with chronic HBV infection will develop chronic liver diseases including cirrhosis, hepatocellular carcinoma, or liver decompensation, with more than 780,000 deaths every year due to these complications.<sup>3</sup>

Significant progress has been made in discovering, characterizing, and seeking patent protection for new core inhibitors for HBV and new non-fusion inhibitors for RSV. Enanta expects to initiate phase 1 clinical development in at least one of the new programs in 2017.

### **EDP-494, a Cyclophilin Inhibitor for Hepatitis C Virus (HCV) Infection**

In anticipation of resistance arising due to direct-acting antiviral HCV therapies currently on the market, Enanta has developed an alternative approach to HCV that targets the human host protein cyclophilin. Since cyclophilin inhibitors act as host-targeted antivirals (HTAs), the viral mutation resistance that arises from direct-acting antiviral (DAA) treatments would not be expected for this mechanism, and thus cyclophilin inhibitors may have the highest barrier to resistance of any class of HCV treatments. As the number of patients treated with the current HCV regimens on the market increases, the treatment failure population will continue to represent an important unmet medical need in hepatitis C and may require new mechanisms of therapy such as cyclophilin inhibition. Enanta recently initiated a phase 1 clinical study of EDP-494, Enanta's lead cyclophilin candidate. Enanta anticipates that cyclophilin inhibitors may be combined with direct-acting antivirals (such as nucleot(s)ide inhibitors of the NS5B HCV target) to provide highly effective new combination treatments for HCV.

### **Non- Alcoholic Steatohepatitis (NASH)**

NASH is a condition that results in liver inflammation and liver damage caused by a buildup of fat in the liver. Currently there are no approved therapies. The US prevalence is estimated to be approximately 3%-5% (~9 to 15 million) of the population, 20% of whom are expected to develop cirrhosis.<sup>4</sup> Enanta's initial preclinical work in NASH has generated several promising leads with excellent potency and activity against the clinically validated NASH target, FXR. Enanta is in the process of conducting preclinical studies and is on track to initiate clinical development of an FXR agonist later in 2016. In addition, a safe and effective FXR agonist may prove to be effective in the treatment of primary biliary cholangitis, or PBC (formerly known as primary biliary cirrhosis), a chronic liver disease resulting from progressive destruction of the bile ducts in the liver.

### **Protease Inhibitor Collaboration with AbbVie (formerly the research-based pharmaceutical business of Abbott Laboratories)**

In December 2006, Enanta and Abbott announced a worldwide agreement to collaborate on the discovery, development and commercialization of HCV NS3 and NS3/4A protease inhibitors and HCV- protease-inhibitor-containing drug combinations. Paritaprevir and ABT-493 are protease inhibitors identified through the collaboration. Under the agreement, AbbVie is responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir, as well as for ABT-493, the collaboration's next-generation protease inhibitor. Enanta is eligible to receive annually tiered, double-digit royalties on AbbVie's worldwide net sales allocable to any of the collaboration's protease inhibitor products and is eligible to receive up to \$80 million in approval milestones for ABT-493.

#### **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 is currently focused on four disease targets: Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

Enanta has developed novel protease inhibitors and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). Enanta's protease inhibitors, developed through its collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's next-generation protease inhibitor which AbbVie is developing in phase 3 studies in combination with ABT-530, AbbVie's next-generation NS5A inhibitor. Enanta has also discovered a cyclophilin inhibitor, EDP-494, a novel host-targeting mechanism for HCV, which is now in a phase 1 clinical development. Please visit [www.enanta.com](http://www.enanta.com) for more information on our programs and pipeline.

#### **Forward-Looking Statements Disclaimer**

This press release contains forward-looking statements, including statements with respect to the prospects for Enanta's growth and expansion into new research areas and development of new therapies, the prospects for developing EDP-494 for resistance-associated variants of HCV and initiating clinical development of Enanta's programs in NASH, HBV and RSV, and the potential for new mechanisms of action for HCV. 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 discovery efforts in new disease areas and new mechanisms of action; potential competition from the development efforts of others in those new disease areas; Enanta's lack 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, 2015 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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<sup>1</sup> <http://www.cdc.gov/hepatitis/hbv/bfaq.htm>

<sup>2</sup> <http://www.cdc.gov/rsv/about/infection.html>

<sup>3</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5750a3.htm>

<sup>4</sup> Rinella, Hepatology, 2011

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