Enanta Announces U.S. FDA Grants Priority Review for AbbVie's Investigational, All-Oral, Interferon-Free Treatment Regimen for Genotype 4 Chronic Hepatitis C Infection

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WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 23, 2015-- 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 AbbVie has stated that the U.S. Food and Drug Administration (FDA) has accepted AbbVie's New Drug Application (NDA) and granted priority review for its all-oral, interferon-free, two direct-acting antiviral (2-DAA) treatment regimen consisting of the fixed-dose combination of ombitasvir, paritaprevir, ritonavir (OBV/PTV/r), with ribavirin (RBV) for the treatment of adult patients with chronic genotype 4 (GT4) hepatitis C virus (HCV) infection.

The FDA grants priority review designation to investigational therapies that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. AbbVie's regimen was also granted a Breakthrough Therapy designation by the FDA on June 30, 2014, a status given to investigational treatments for serious or life-threatening conditions with preliminary clinical evidence that may demonstrate substantial improvement on at least one clinically significant endpoint compared to available therapy.[1]

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the two DAAs in AbbVie's treatment regimen included in the NDA for the treatment of GT4 chronic hepatitis C patients. AbbVie is responsible for all development and commercialization activities for regimens that contain paritaprevir. Paritaprevir is included in AbbVie's GT1 HCV treatment regimens approved in the U.S. in late 2014 and in the E.U. in early 2015. In addition, Enanta will be eligible to receive annually tiered royalties ranging from the low double digits up to twenty percent, on 45% of AbbVie's worldwide net sales of any 2-DAA paritaprevir-containing regimen.

The Centers for Disease Control and Prevention (CDC) estimates that in the United States, 3.2 million people are chronically infected with HCV.[2] While genotype 1 (GT1) is the most prevalent form of HCV in the U.S., accounting for approximately 73 percent of all cases, GT4 infection accounts for up to 6 percent of HCV infections in the U.S.[3,4] Hepatitis C is inflammation of the liver caused by an infection with the HCV virus.[5] It is transmitted when an infected person's blood enters the bloodstream of another person.[6] There are six major HCV genotypes (GT1-6).[7] Presently, there is no vaccine for HCV infection.[4]

Protease Inhibitor Collaboration with AbbVie
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. AbbVie is Abbott's successor under the agreement and is responsible for all development and commercialization activities for paritaprevir, as well as ABT-493, the collaboration's next-generation protease inhibitor.

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 is discovering, and in some cases developing, novel inhibitors designed for use against the hepatitis C virus (HCV). These inhibitors include members of the direct–acting-antiviral (DAA) inhibitor classes – protease (partnered with AbbVie), NS5A, and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and damage caused by a buildup of fat in the liver.

Forward Looking Statements Disclaimer
This press release contains forward-looking statements, including with respect to the prospects for AbbVie's paritaprevir-containing regimens for patients with GT4 HCV infection. Statements that are not historical facts are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our 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 that may affect actual results include the efforts of AbbVie (our collaborator on paritaprevir) regarding regulatory approval and commercialization of regimens containing paritaprevir; the level of market acceptance and the pricing and rate of reimbursement for those regimens; the impact of competitive products on the use and sales of those regimens; regulatory actions affecting clinical development of competitive product candidates; 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, 2014 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.

[1] U.S. Food and Drug Administration Online. Fact Sheet: Breakthrough Therapies. http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm329491.htm. Accessed March 20, 2015.

[2] Centers for Disease Control and Prevention (CDC). Hepatitis C FAQs for health professionals. http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed March 10, 2015

[3] O'Leary JG, Davis GL. Hepatitis C. In: Feldman M, Friedman LS, Brandt LJ, eds. Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management. 9th ed, Vol 1. Philadelphia, PA: Saunders Elsevier. 2010:1313-1335.

[4] Gower E, Estes C, Blach S, et al. Global epidemiology and genotype distribution of the hepatitis C virus infection. *J Hepatology.* 2014;61:S45-S57.

[5]Mayo Clinic. Hepatitis C: Definition. http://www.mayoclinic.org/diseases-conditions/hepatitis-c/basics/definition/con-20030618. Accessed November 2013.

[6]World Health Organization. Hepatitis C Fact Sheet 2014. http://www.who.int/mediacentre/factsheets/fs164/en/. Accessed April 2014.

[7] AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed March 9, 2015.

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