Enanta Announces 99 Percent SVR12 Rate in Chronic HCV Patients with Compensated Cirrhosis Treated with AbbVie's Investigational, Pan-Genotypic, Ribavirin-free Regimen of Glecaprevir/Pibrentasvir (G/P)

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- *New data demonstrated high SVR12 rates across compensated cirrhotic patients with genotype 1, 2, 4, 5 or 6 chronic hepatitis C virus infection with 12 weeks of treatment1*
- *No patients discontinued treatment due to adverse events in the Phase 3 EXPEDITION-1 study1*
- *Study results add to body of data for G/P in patients with compensated cirrhosis across all genotypes*
- *Glecaprevir is Enanta's second protease inhibitor being developed through its collaboration with AbbVie and is one of the two new direct-acting antivirals (DAAs) in G/P*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 20, 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 that 99 percent (n=145/146) of chronic hepatitis C virus (HCV) infected patients with genotype 1, 2, 4, 5 or 6 and compensated cirrhosis (Child-Pugh A) achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}) with AbbVie's investigational, pan-genotypic, ribavirin-free regimen of glecaprevir/pibrentasvir (G/P). This high SVR_{12} rate was seen following 12 weeks of G/P treatment without ribavirin. Patients with specific virus strains associated with resistance or with a high quantity of the virus in their bloodstream before treatment initiation were not excluded from the study. These new data, from the Phase 3 EXPEDITION-1 study, will be featured as an oral presentation today at The International Liver Congress™ (ILC) 2017 in Amsterdam, The Netherlands.

In the EXPEDITION-1 study, the majority of adverse events (AEs) were mild, and no patients discontinued treatment due to an AE. The most common (?10 percent) AEs were fatigue and headache.

Approximately 130 to 150 million people worldwide are living with chronic HCV, for whom the risk of cirrhosis of the liver is between 15-30% within 20 years.[2] Treatment guidelines around the world recommend that all patients with cirrhosis should be considered for treatment, yet the treatment of specific patients with HCV and compensated cirrhosis is still challenging.[3,4]

AbbVie is presenting additional data at ILC in patients with specific treatment challenges, including in those with chronic kidney disease (SAT-273), HIV-1 co-infection (LBP-522), post liver transplant, and post renal transplant (LBO-03), as well as in patients who did not achieve SVR_{12} with previous direct-acting antiviral treatment (PS-156). Additional information on the clinical trials for G/P is available at http://www.clinicaltrials.gov.

Authorization applications for G/P are currently under review by regulatory authorities around the world. G/P has been granted accelerated assessment by the European Medicines Agency, and priority review designations by the U.S. Food and Drug Administration and Japanese Ministry of Health, Labour and Welfare. G/P is an investigational regimen and its safety and efficacy have not been established.

About the EXPEDITION-1 Study
EXPEDITION-1 is a single arm, multicenter, open-label study evaluating the efficacy and safety of 12 weeks of G/P in adults with GT1, 2, 4, 5 or 6 chronic HCV infection and compensated cirrhosis (Child-Pugh A). The study enrolled 146 patients, including those new to treatment or those who had prior treatment experience with IFN-based treatments (IFN/pegIFN ± RBV, or sofosbuvir + RBV ± pegIFN). The primary endpoint was the percentage of patients achieving SVR_{12}. SVR_{12} was achieved by 145/146 (99 percent) patients, with one GT1a-infected patient experiencing relapse.

No patients experienced ALT elevations equal to or above Grade 3. Of the 11 patients (7.5 percent) who experienced serious AEs, none were considered treatment-related.

About G/P
G/P is an investigational, pan-genotypic regimen that is being evaluated by AbbVie as a potential cure in 8 weeks for HCV patients without cirrhosis and who are new to treatment with direct-acting antivirals (DAAs)*, who make up the majority of HCV patients. AbbVie is also studying G/P in patients with specific treatment challenges, such as patients with genotype 3 HCV, patients who were not cured with previous DAA treatment and those with chronic kidney disease, including patients on dialysis.

G/P is an investigational, once-daily regimen that combines two distinct antiviral agents in a fixed-dose combination of glecaprevir (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor. G/P is dosed once-daily as three oral tablets.

Additional information on AbbVie's clinical trials for G/P is available at www.clinicaltrials.gov.

*Patients who are treatment-naive or had prior treatment experience with IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).

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 the following 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 for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, part of AbbVie's currently marketed HCV regimens, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational, pan-genotypic HCV regimen of glecaprevir/pibrentasvir (G/P) now in registration in the U.S., the E.U. and Japan. Royalties and any further milestone payments from this collaboration will provide additional funding for Enanta's earlier development programs, including its Phase 1 FXR agonist program for NASH/PBC, and its preclinical programs for HBV and RSV. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

Forward Looking Statements

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's G/P regimen 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 efforts of AbbVie (our collaborator developing glecaprevir) to obtain regulatory approvals of its glecaprevir/pibrentasvir (G/P) combination and commercialize it successfully; the regulatory and marketing efforts of others with respect to competitive treatment regimens for HCV; regulatory and reimbursement actions affecting G/P, any competitive regimen, or both; the need to obtain and maintain patent protection for glecaprevir 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.

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[1] Forns, X et al. EXPEDITION-1: Efficacy and Safety of Glecaprevir/Pibrentasvir in Adults with Chronic Hepatitis C Virus Genotype 1, 2, 4, 5 or 6 Infection and Compensated Cirrhosis. Presented at The International Liver Congress™ (ILC) in Amsterdam, The Netherlands, April 19-23, 2017.

[2] Hepatitis C. World Health Organization. World Health Organization, July 2016. Web. http://www.who.int/mediacentre/factsheets/fs164/en/

[3] EASL Recommendations on Treatment of Hepatitis C 2016. J Hepatol (2016), http://dx.doi.org/10.1016/j.jhep.2016.09.001.

[4] Spach D, Scott J. Treatment of Hepatitis C in Patients with Cirrhosis. Hepatitis C Online. http://cdn.hepatitisc.uw.edu/pdf/special-populations-situations/treatment-cirrhosis/core-concept/all Published 2015. Accessed April 3, 2017.

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