Enanta Announces Eight Weeks of Treatment with AbbVie's Investigational, Pan-Genotypic, Ribavirin-Free HCV Regimen of Glecaprevir/Pibrentasvir (G/P) Achieved High SVR Rates in Challenging-to-Treat Genotype 3 Chronic HCV Patients

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- *95 percent of patients infected with genotype 3 (GT3) chronic hepatitis C virus (HCV), without cirrhosis and who are new to treatment achieved SVR_{12} with 8 weeks of treatment*
- *Together with previously reported data, these study results support the potential of G/P as an 8-week treatment for the majority of people living with HCV across all genotypes*
- *GT3 is the second most common genotype worldwide and the most challenging to treat[2,3]; limited treatment options exist for newly diagnosed patients*
- *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. 21, 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 reported that AbbVie announced high SVR rates were achieved with 8 weeks of treatment with its investigational, once daily, ribavirin-free, pan-genotypic regimen of glecaprevir/pibrentasvir (G/P) in patients with challenging-to-treat genotype 3 (GT3) chronic hepatitis C virus (HCV) infection. In results from AbbVie's Phase 3 ENDURANCE-3 study, 95 percent (n=149/157) of GT3 chronic HCV-infected patients without cirrhosis and who were new to treatment achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}) following 8 weeks of treatment with G/P.[1] These results will be featured as an oral presentation today at The International Liver Congress™ (ILC) 2017 in Amsterdam, The Netherlands.

In addition to evaluating 8 weeks of treatment with G/P, the ENDURANCE-3 study was designed to evaluate whether 12 weeks of G/P treatment is non-inferior to 12 weeks of sofosbuvir plus daclatasvir (SOF+DCV), a current standard of care for GT3 chronic HCV-infected patients.[1] SVR_{12} rates of 95 percent were seen in both 8 weeks (n=149/157) and 12 weeks (n=222/233) of treatment with G/P.[1] Additionally, 12 weeks of treatment with G/P was demonstrated to be non-inferior to 12 weeks of treatment with SOF+DCV (97 percent, n=111/115).[1]

GT3 is the second most common genotype globally, accounting for 18 percent of patients worldwide and 26 percent of patients in Europe.[2] Patients with GT3 HCV have more rapid disease progression, with the highest rates of associated fibrosis, steatosis (fatty liver), and hepatocellular carcinoma (HCC).[3] Treatment guidelines with current standards of care recommend 12 weeks of treatment in GT3 patients without cirrhosis and who are new to treatment.[4]

Full results from ENDURANCE-3 are the latest to be released from AbbVie's registrational studies in its G/P clinical development program, designed to investigate a faster path to virologic cure* for all major HCV genotypes (GT1-6) and with the goal of addressing areas of continued unmet need.

In the ENDURANCE-3 study, no patients who received 8 weeks of G/P discontinued treatment due to adverse events (AEs).[1] AEs were mostly mild (71 percent) in patients receiving both 8 and 12 weeks of G/P. The most common AEs (≥10 percent) in patients receiving 8 weeks and 12 weeks of G/P were headache (20 and 26 percent), fatigue (13 and 19 percent) and nausea (12 and 14 percent), respectively and with patients receiving 12 weeks of SOF+DCV treatment (headache 20 percent, fatigue 14 percent and nausea 13 percent).[1]

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.

The ENDURANCE-3 study will be featured in the official ILC press conference on Friday, April 21 from 11:30 a.m. - 12:30 p.m. local time.

About the ENDURANCE-3 Study
ENDURANCE-3 is a Phase 3, open-label, active-controlled study evaluating patients who are new to treatment with HCV GT3 infection without cirrhosis. The study included 505 patients who were randomized to receive either 12 weeks of G/P (Arm A, n= 233) or 12 weeks of SOF+DCV (Arm B, n=115), with subsequently enrolled patients receiving 8 weeks of G/P (Arm C, n=157). The primary endpoint was the percentage of patients achieving SVR12. The rate of virologic failure was 1.7 percent (n=4/233) in Arm A, 0.8 percent (n=1/115) in Arm B and 3.8 percent (n=6/157) in Arm C.

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

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.

*Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR_{12}) are considered cured of hepatitis C.

**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] Foster, GR et al. ENDURANCE-3: safety and efficacy of glecaprevir/pibrentasvir compared to sofosbuvir plus daclatasvir in treatment-naïve HCV genotype 3-infected patients without cirrhosis. Presented at The International Liver Congress™ (ILC) in Amsterdam, The Netherlands, April 19-23, 2017.

[2] Petruzziello, A. et al. Global epidemiology of hepatitis C virus infection: An up-date of the distribution and circulation of hepatitis C virus genotypes. World J Gastroenterol. 2016; 22(34): 7824-7840

[3] Asselah T, Thompson AJ, Flisiak R, Romero-Gomez M, Messinger D, Bakalos G, et al. (2016) A Predictive Model for Selecting Patients with HCV Genotype 3 Chronic Infection with a High Probability of Sustained Virological Response to Peginterferon Alfa-2a/Ribavirin. PLoS ONE 11(3): e0150569. doi:10.1371/journal.pone.

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

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