# Enanta Announces U.S. FDA Grants Priority Review to AbbVie's Investigational HCV Regimen of Glecaprevir/Pibrentasvir (G/P) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6)

February 2, 2017

- *If approved, G/P may provide an eight-week, once-daily, ribavirin-free cure* for HCV patients new to treatment who have any of the major HCV genotypes, without cirrhosis*
- *G/P includes Enanta's second protease inhibitor, glecaprevir (ABT-493)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 2, 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 the U.S. Food and Drug Administration (FDA) has accepted AbbVie's New Drug Application (NDA) for its investigational, pan-genotypic regimen of glecaprevir/pibrentasvir (G/P) being evaluated for the treatment of all major genotypes (GT1-6) of chronic hepatitis C virus (HCV), and has granted the NDA priority review. 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.

The FDA grants priority review designation to medicines that it determines have the potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease. The NDA is supported by data from eight registrational studies in AbbVie's G/P clinical development program, which evaluated more than 2,300 patients in 27 countries across major HCV genotypes and special populations.

**About AbbVie's G/P HCV Clinical Development Program**

AbbVie's glecaprevir/pibrentasvir (G/P) clinical development program was designed to investigate a faster path to virologic cure* for all major HCV genotypes (GT1-6) and with the goal of addressing treatment areas of continued unmet need.

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

G/P is a once-daily regimen that combines two distinct antiviral agents in a fixed-dose combination of glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor. G/P (300/120mg) 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 achieve a sustained virologic response at 12 weeks post treatment ($SVR_{12}$) are considered cured of hepatitis C.

**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, currently marketed in AbbVie's HCV regimens, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational HCV regimen of glecaprevir/pibrentasvir (G/P) currently under regulatory review in the U.S. and the E.U. Royalties and any further milestone payments from this collaboration will provide 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 Disclaimer**

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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