Enanta Pharmaceuticals Announces AbbVie's Submission of NDA for Investigational, Pan-Genotypic HCV Regimen of Glecaprevir/Pibrentasvir (G/P) for the Treatment of Genotypes 1 through 6 of Chronic Hepatitis C Virus (HCV)

December 19, 2016

- *If approved, G/P will provide an eight week once-daily, ribavirin-free treatment option for HCV patients without cirrhosis across all major genotypes*
- *AbbVie's investigational regimen was granted Breakthrough Therapy Designation by the FDA for genotype 1 (GT1) patients who failed previous therapy with direct-acting antivirals (DAAs)*
- *G/P includes Enanta's second protease inhibitor, glecaprevir (ABT-493)*
- *AbbVie is on track to submit Marketing Authorization Application for G/P in the European Union in early 2017*

WATERTOWN, Mass.--(BUSINESS WIRE)--Dec. 19, 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, today announced that AbbVie has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational, pan-genotypic, fixed-dose combination of glecaprevir (ABT-493) and pibrentasvir (ABT-530) (G/P), being evaluated for the treatment of chronic HCV. In Phase 3 clinical studies, eight weeks of therapy with G/P demonstrated high sustained virologic response (SVR) rates across all major genotypes (GT1-6) in patients without cirrhosis and who are new to treatment, which represent the majority of HCV patients. In patients with compensated cirrhosis, high SVR rates were achieved after 12 weeks of therapy. High SVR rates were also achieved in patients with limited treatment options, such as those with severe chronic kidney disease (CKD). In historically difficult to treat populations, including those not cured* by prior direct-acting antiviral (DAA) treatment regimens, high rates of SVR were achieved with durations as short as 12 weeks.

"We are pleased with the data that AbbVie has submitted with this NDA, and that once-daily G/P has the potential to bring an 8-week treatment option to treatment-naïve, non-cirrhotic HCV patients across all major genotypes," stated Jay R. Luly, Ph.D.

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. Patient populations studied included all major genotypes, new and experienced to treatment, those with and without cirrhosis and patients with specific treatment challenges, including those with severe CKD, and those who have failed a DAA-containing regimen.

AbbVie previously announced registrational data that show with eight weeks of treatment, 97.5 percent (n=693/711) of chronic HCV patients across all major genotypes (GT1-6) without cirrhosis and new to treatment achieved SVR_{12}. Additional data submitted show that with 12 weeks of treatment, 98 percent (n=102/104) of severe CKD patients achieved SVR_{12} in a primary intent-to-treat (ITT) analysis. In a modified intent-to-treat (mITT) analysis of severe CKD patients, 100 percent (n=102/102) of patients achieved SVR_{12}. The mITT analysis excludes patients who did not achieve SVR for reasons other than virologic failure. The most commonly reported adverse events (AEs) for severe CKD patients were pruritus, fatigue and nausea. The most commonly reported AEs for GT1-6 patients without cirrhosis and new to treatment were headache and fatigue. These data were presented at The American Association for the Study of Liver Diseases (AASLD) annual meeting in November 2016. Data for other registrational studies will be shared at future meetings.

On September 30, 2016, AbbVie announced that the FDA granted Breakthrough Therapy Designation (BTD) for G/P for the treatment of patients with HCV who failed previous therapy with DAAs in GT1, including therapy with an NS5A inhibitor and/or protease inhibitor. The BTD is supported by positive results seen in AbbVie's Phase 2 MAGELLAN-1 clinical study. According to the FDA, BTD is intended to expedite the development and review of therapies for serious or life threatening conditions.[1]

AbbVie has announced it is on track to submit a marketing authorization application for G/P in the European Union in early 2017.

About AbbVie's Clinical Development of G/P for HCV

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, who make up the majority of HCV patients. AbbVie is also studying G/P in patients with specific treatment challenges, such as genotype 3, patients who were not cured with previous DAA treatment and those with 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 (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor. G/P is dosed once-daily as three oral tablets.

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.

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

***Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR12) are considered cured of HCV.*

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 four disease targets: Hepatitis C Virus (HCV), Non-alcoholic Steatohepatitis (NASH), Respiratory Syncytial Virus (RSV) and Hepatitis B Virus (HBV).

Enanta has discovered novel protease inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie has developed in Phase 3 studies as part of an investigational, pan-genotypic, once-daily, ribavirin-free, fixed-dose combination (G/P) with pibrentasvir (ABT-530), AbbVie's second NS5A inhibitor. In addition to

the recent NDA filing with the FDA, AbbVie has announced it is on track to submit a marketing authorization application for G/P in the European Union in early 2017.

Enanta has also discovered EDP-305, an FXR agonist product candidate for NASH, currently in Phase 1 clinical development, as well as a cyclophilin inhibitor, EDP-494, a novel host-targeting mechanism for HCV, which is also in Phase 1 clinical development. In addition, Enanta has early lead candidates for HBV and RSV in preclinical development. 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 investigational G/P treatment 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 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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[1] U.S. Food and Drug Administration. Fact Sheet: Breakthrough Therapies. http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm. Accessed November 23, 2016.

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