Enanta Announces Eight Weeks of Treatment with AbbVie's Investigational, Pan-Genotypic Regimen of Glecaprevir/Pibrentasvir (G/P) Achieved High SVR Rates Across All Major Genotypes of Chronic Hepatitis C

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- *97.5 percent of chronic HCV infected patients without cirrhosis and new to treatment across all major genotypes (GT1-6) achieved SVR12 with 8 weeks of G/P treatment*
- *Across the 8-week arms of three registrational studies, only 1 percent of patients experienced virologic failure, and no patients discontinued treatment due to adverse events*
- *G/P is an investigational, pan-genotypic, once-daily, ribavirin-free, fixed-dose combination for the treatment of chronic HCV*
- *G/P includes Enanta's second protease inhibitor glecaprevir (ABT-493)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 11, 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 published high SVR_{12} rates across all major chronic hepatitis C virus (HCV) genotypes with 8 weeks of treatment with its investigational, pan-genotypic regimen consisting of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P). In more than 700 chronic HCV patients without cirrhosis who were infected with one of genotypes 1-6 (GT1-6) and were new to treatment, 97.5 percent (n=693/711) achieved sustained virologic response at 12 weeks post treatment (SVR_{12}), regardless of baseline viral load. The rate of virologic failure was 1 percent (n=9/711).

Glecaprevir (GLE), an NS3/4A protease inhibitor, is Enanta's second protease inhibitor being developed through its collaboration with AbbVie. G/P is a once-daily regimen that combines two distinct antiviral agents. G/P is a fixed-dose combination of glecaprevir (300mg) and pibrentasvir (120mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

These new top-line data comprise results from the eight week arms of three registrational clinical trials evaluating the efficacy and safety of G/P – the ENDURANCE-1, ENDURANCE-3 and SURVEYOR-2 (Part 4) studies. Across the eight week arms of all three studies, there were no discontinuations due to adverse events (AEs). The most common AEs, occurring at a rate greater than 10 percent across these arms were headache and fatigue; and there were no AEs in any study arm at a rate greater than 20 percent. No clinically relevant laboratory abnormalities, including ALT changes, were observed.

"The SVR rates in these studies are an important step toward providing an 8-week treatment option to HCV-infected patients without cirrhosis who are new to treatment," commented Jay R. Luly, Ph.D. "We look forward to AbbVie's regulatory approval filings planned in the U.S. by the end of this year and in Europe and Japan in early 2017."

Overview of preliminary results across the three studies of G/P:

Study Name	Patient Population	Treatment Duration	Treatment Regimen	SVR12 Rate
ENDURANCE-1	GT1 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN +/- RBV or SOF/RBV +/- pegIFN), and patients co-infected with HIV-1	8 week	G/P	99% (n=348/351)
ENDURANCE-3	GT3 without cirrhosis, new to treatment	8 week	G/P	95% (n=149/157)
SURVEYOR-2 (Part 4)	GT2, 4, 5, or 6 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN, SOF/RBV or pegIFN/SOF)	8 week	G/P	97% (n=196/203)

G/P is an investigational, pan-genotypic regimen currently being evaluated in a registrational clinical development program, and its safety and efficacy have not been established. Additional data from the ENDURANCE-1 and SURVEYOR-2 (Part 4) studies will be presented at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston. Additional information on the clinical trials for G/P is available at www.clinicaltrials.gov.

G/P is an investigational, pan-genotypic regimen that is being evaluated as a potential cure with 8 weeks of treatment for HCV patients without cirrhosis and 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 chronic kidney disease, including patients on dialysis.

AbbVie's clinical development program for (G/P) was designed to investigate a faster path to virologic cure for all major HCV genotypes (GT1-6), with the goal of addressing treatment areas of continued unmet medical need. Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR_{12}) are considered cured of hepatitis C.

About the ENDURANCE and SURVEYOR Studies

ENDURANCE-1, ENDURANCE-3 and SURVEYOR-2 (Part 4) are open-label, multi-center, registrational studies evaluating the safety and efficacy of G/P across all major chronic HCV genotypes (GT1-6). The primary efficacy endpoint for all studies is SVR_{12}.

ENDURANCE-1 is a randomized study designed to evaluate the safety and efficacy of 8 and 12 week treatment durations of G/P in patients with GT1 chronic HCV infection without cirrhosis and new to treatment or not cured with previous IFN-based treatments (pegIFN +/- RBV or SOF/RBV +/- pegIFN), including patients co-infected with HIV-1.

ENDURANCE-3 is a partially randomized study designed to evaluate the safety and efficacy of 8 and 12 week treatment durations of G/P in patients with GT3 chronic HCV infection without cirrhosis and new to treatment. The study has an additional active comparator arm of 12 weeks of sofosbuvir + daclatasvir (SOF+DCV). Additional data from study arms will be presented at an upcoming scientific congress.

SURVEYOR-2 (Part 4) is a single-arm study evaluating 8 week treatment duration of G/P in patients with GT2, 4-6 chronic HCV infection without cirrhosis and new to treatment or not cured with previous IFN-based treatments (pegIFN, SOF/RBV or pegIFN/SOF).

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), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

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 in a fixed-dose combination (G/P) with pibrentasvir (ABT-530), AbbVie's second NS5A inhibitor, and is preparing for regulatory approval filings in the U.S., Europe and Japan.

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 our programs and pipeline.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for regulatory approval filings for AbbVie's investigational HCV treatment regimen containing glecaprevir (ABT-493). 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 approval of its glecaprevir/pibrentasvir(G/P) regimen containing glecaprevir and successfully commercialize it; 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; Enanta's need to obtain and maintain patent protection for its product candidates 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, 2015 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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