Enanta Pharmaceuticals Announces AbbVie's Investigational, Pan-Genotypic Regimen of Glecaprevir/Pibrentasvir (G/P) Shows High SVR Rates in Chronic Hepatitis C Patients with Severe Chronic Kidney Disease

November 15, 2016

- *98 percent of patients across all major HCV genotypes (GT1-6) with severe chronic kidney disease (CKD), including patients on dialysis, achieved SVR12 with 12 weeks of G/P in the primary intent-to-treat analysis, regardless of previous treatment status or presence of compensated cirrhosis*
- *100 percent of patients achieved SVR12 in a modified intent-to-treat analysis*
- *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. 15, 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 98 percent (n=102/104) of chronic hepatitis C virus (HCV) infected patients with severe chronic kidney disease (CKD) achieved sustained virologic response following 12 weeks of treatment (SVR_{12}) with AbbVie's investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) in the primary intent-to-treat (ITT) analysis. In a modified intent-to-treat (mITT) analysis, SVR_{12} was achieved in 100 percent (n=102/102) of severe CKD patients. The mITT analysis excludes patients who did not achieve SVR for reasons other than virologic failure. These new data from the Phase 3 EXPEDITION-4 study, evaluating patients with chronic HCV infection across all major genotypes (GT1-6) and severe CKD, will be presented as a late-breaker today at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

The EXPEDITION-4 results are the latest to be released from registrational studies in AbbVie's 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.

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.

HCV is common among people with severe CKD, reaching prevalence of up to 80 percent in some regions of the world.[1] In the U.S., it is estimated that over 500,000 people have both chronic HCV and CKD[2]. Some chronic HCV infected patients with severe CKD, particularly those with GT2 and GT3 HCV infection, currently don't have access to direct-acting antivirals (DAAs). The development of new, safe and effective regimens to treat HCV in these patients remains a critical unmet medical need.[3]

The EXPEDITION-4 study enrolled 104 patients with severe chronic kidney disease, including 85 patients (82 percent) who were receiving dialysis at enrollment and 20 patients (19 percent) who had compensated cirrhosis. The study also included those who were not cured with previous treatment with sofosbuvir (SOF) plus ribavirin (RBV) or with interferon (IFN) plus RBV, with or without SOF (44 patients, 42 percent).

The majority of treatment related adverse events (AEs) were mild or moderate. The most commonly reported AEs included pruritus, fatigue and nausea. Of the 24 percent of patients who experienced serious AEs, none were considered related to G/P. Four AEs (4 percent) led to the discontinuation of G/P and one patient died after achieving SVR_4 due to a serious AE (intracerebral hemorrhage) considered not-related to G/P.

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

About the EXPEDITION-4 Study
EXPEDITION-4 is a single-arm, open-label, Phase 3 study evaluating the safety and efficacy of 12 weeks of G/P in patients with GT1-6 chronic HCV infection and chronic kidney disease, including those on dialysis. The primary endpoint is SVR_{12}.

Patients in the study had severe or end stage kidney disease (stage 4 and 5 CKD), with an eGFR < 30 mL/min/1.73 m2 required at screening. Prior treatment in the study is defined as treatment with interferon (IFN)/pegIFN ± RBV, or sofosbuvir (SOF) + RBV ± pegIFN therapy.

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

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 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 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 develop its glecaprevir/pibrentasvir(G/P) combination and successfully obtain regulatory approval and 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; 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, 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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[1] Fabrizi F, Poordad FF, Martin P. Hepatitis C infection in the patient with end stage renal disease. Hepatology. 2002;36(1):3-10.

[2] IMS Health, July 2016. Parsippany, NJ; Medivo, July 2016. New York, NY (Estimate based on IMS Health Dx Medical Claims 12/2013-4/2016; IMS Health Life Link Patient Level Data 12/2013-4/2016; Medivo Lab Data 12/2013-4/2016).

[3] American Association for the Study of Liver Diseases. Recommendations for Testing, Managing, and Treating Hepatitis C, February 24, 2016, http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have. Accessed March 15, 2016.

View source version on businesswire.com: http://www.businesswire.com/news/home/20161115005983/en/

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