Enanta Announces High SVR12 Rates Achieved in Genotype 1 Chronic HCV Infected Japanese Patients with Eight Weeks of Treatment with AbbVie's Investigational, Pan-Genotypic, Ribavirin-free Regimen of Glecaprevir/Pibrentasvir (G/P)

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- *In the CERTAIN-1 study, 99 percent (n=105/106) of genotype 1 (GT1) chronic hepatitis C virus (HCV)-infected Japanese patients without cirrhosis achieved SVR_{12} with 8 weeks of G/P treatment*
- *Japan has one of the highest rates of hepatitis C infection in the industrialized world affecting approximately 1 million people, 60 to 70 percent of those are GT1*[1,2,3]
- *G/P includes Enanta's second protease inhibitor, glecaprevir (ABT-493)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 9, 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 results from AbbVie's Phase 3 CERTAIN-1 study of 8 weeks of treatment with AbbVie's investigational, pan-genotypic, ribavirin (RBV)-free regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) in Japanese patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection without cirrhosis. Top-line results from the study demonstrated 99 percent (n=105/106) of patients without cirrhosis, who represent the majority of HCV patients, and without the Y93H variant, achieved sustained virologic response at 12 weeks after treatment (SVR_{12}). The one patient who did not reach SVR_{12} in this intent to treat (ITT) population was lost to follow-up. All 23 patients with the Y93H variant were assigned to the G/P arm of this comparator study, and 100% achieved SVR_{12}.

These data are the first to be released by AbbVie from registrational studies in Japan as part of its global G/P clinical development program, designed to investigate a faster path to virologic cure* for all major HCV genotypes and with the goal of addressing treatment areas of continued unmet need. The results demonstrated from the CERTAIN-1 study are consistent with recently announced 8-week, GT1 data from AbbVie's global registration studies of G/P.

Approximately 1 million people are living with hepatitis C in Japan, with 60 to 70 percent of those infected with GT1 chronic HCV.[1,3] Patients participating in the CERTAIN-1 study were further representative of the HCV-infected patient population in Japan, where the prevalence of HCV infection increases with age, because a majority of patients in the study were over 65 years of age.[4]

The CERTAIN-1 study compared the safety and efficacy of 8 weeks of treatment with the investigational G/P regimen to 12 weeks of treatment with ombitasvir/paritaprevir/ritonavir (OBV/PTV/r), in GT1 chronic HCV-infected patients. The primary endpoint of the study was met, as 8 weeks of G/P was shown to be non-inferior to 12 weeks of OBV/PTV/r (100 percent SVR_{12}; n=52).

Additionally, in sub-study 1 evaluating GT1 patients (treated with G/P) without cirrhosis and who were new to treatment with direct-acting antivirals (DAA), no patients discontinued treatment due to adverse events (AEs). In patients treated with OBV/PTV/r, there was one who discontinued treatment due to AEs. In patients receiving the G/P regimen, the most common AEs, occurring at a rate greater than 5 percent, were nasopharyngitis (inflammation of the throat and nasal passages) and pruritus (itchiness).

About the CERTAIN-1 Study

The CERTAIN-1 study is a Phase 3, multicenter study evaluating the efficacy, safety and pharmacokinetics (PK) of G/P in Japanese adults. Sub-study 1 is a randomized, open-label and active-controlled study in genotype 1 (GT1) chronic HCV-infected patients without cirrhosis who are new to DAA treatment. Patients who tested negative for the Y93H resistance associated variant received either 8 weeks of G/P or 12 weeks of OBV/PTV/r (2:1 randomization ratio). All Y93H positive patients were assigned to receive 8 weeks of G/P and all (n=23/23) achieved SVR_{12}. The primary objectives were safety and non-inferiority of G/P compared to OBV/PTV/r.

Sub-study 2 is a non-randomized, open-label study evaluating GT1-6 HCV patients with specific treatment challenges, including those with compensated cirrhosis (Child-Pugh A), chronic kidney disease (CKD) and those who were not cured with previous DAA treatment.

AbbVie plans to present additional data at an upcoming scientific congress.

About AbbVie's G/P 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. In Japan, AbbVie studied the G/P regimen in additional dedicated clinical trials due to patient and viral characteristics specific to the Japanese HCV patient population.

G/P is an investigational, pan-genotypic regimen that is being evaluated as a potential cure in 8 weeks for HCV patients without cirrhosis who are new to treatment with direct-acting antivirals (DAA). Patients with these characteristics constitute 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.

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.

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.

G/P is an investigational product and its safety and efficacy have not been established in Japan.

*Patients with 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 three 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 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 is developing as part of an investigational, pan-genotypic, once-daily, ribavirin-free, fixed-dose combination with pibrentasvir (ABT-530), (G/P), AbbVie's second NS5A inhibitor.

Enanta has discovered EDP-305, an FXR agonist product candidate for NASH and PBC, currently in Phase 1 clinical development, and has identified a clinical candidate for RSV, EDP-938, now, in preclinical development. Enanta is also developing early lead candidates for HBV. 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 in 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]National Center for Global Health and Medicine. Hepatitis C. Assessed January 2017. Available from: http://www.kanen.ncgm.go.jp/cont/010/c_gata.html

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