Enanta Announces EMA Grants Accelerated Assessment, Validates Marketing Authorization Application for AbbVie's Investigational HCV Regimen of Glecaprevir/Pibrentasvir (G/P) for the Treatment of All Major Genotypes (GT1-6) of Chronic Hepatitis C

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- *If approved, G/P may provide a shorter, eight-week, once-daily, ribavirin-free treatment option for the majority of HCV patients without cirrhosis*
- *MAA is supported by data from global registrational clinical development program across all major HCV genotypes and in patients with specific treatment challenges*
- *If approved, AbbVie's G/P regimen could become available for marketing in the European Union (EU) in the second half of 2017.*
- *G/P includes Enanta's second protease inhibitor, glecaprevir (ABT-493)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 24, 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 AbbVie's marketing authorization application (MAA) for its investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) for the treatment of all major chronic hepatitis C virus (HCV) genotypes, has been validated by the European Medicines Agency (EMA) and is now under accelerated assessment. If approved, G/P may provide shorter treatment duration for patients infected with any of HCV genotypes 1-6 (GT1-6) and without cirrhosis, who represent the majority of HCV patients. G/P is also intended to provide an additional treatment option to patients with compensated cirrhosis (Child Pugh A) and to address the needs of patients with specific treatment challenges, including those with severe chronic kidney disease (CKD) and those not cured with previous direct-acting-antiviral (DAA) treatment.

The Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the EMA, will review the G/P regimen under accelerated assessment, which is the EMA's designation for new medicines of major public health interest and therapeutic innovation, and is designed to bring new treatments to patients more quickly. Validation of the MAA confirms that the submission is complete and starts the EMA's centralized review process. If approved, AbbVie's G/P regimen could become available for marketing in the European Union (EU) in the second half of 2017.

The MAA 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 all major HCV genotypes and several special populations. Patient populations studied included GT1-6, those new and experienced to treatment, those with compensated cirrhosis and without cirrhosis, and those with specific treatment challenges, including those with severe CKD, and those not cured with a prior DAA-containing regimen. The program was 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.

On December 19, 2016, AbbVie announced its New Drug Application submission for G/P to the U.S. Food and Drug Administration (FDA) for the treatment of GT1-6 chronic HCV infection. AbbVie has also announced that they remain on track to submit a New Drug Application for G/P in Japan in 1Q 2017.

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.

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

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.

G/P is an investigational, pan-genotypic regimen being evaluated as a potential cure in 8 weeks for HCV patients without cirrhosis and 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. G/P is a fixed-dose combination of glecaprevir (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

*Patients who achieve a sustained virologic response at 12 weeks post-treatment (SVR_{12}) are considered cured of hepatitis C.

***Patients who are treatment-naive or not cured with previous IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).*

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 (G/P) with pibrentasvir (ABT-530), 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, 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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