Enanta Announces that AbbVie Receives CHMP Positive Opinion for MAVIRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6)

June 23, 2017

- *If approved, MAVIRET™ will provide a shorter, 8-week, pan-genotypic (GT1-6), once-daily treatment option for the majority of people living with chronic hepatitis C virus (HCV)*
- *MAVIRET would also be an additional HCV treatment option for patients with specific treatment challenges, such as those with compensated cirrhosis, chronic kidney disease and genotype 3*
- *Final European Commission decision expected Q3 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 (DAAs) in MAVIRET*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jun. 23, 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 the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted AbbVie a positive opinion recommending marketing authorization of MAVIRET™ (glecaprevir/pibrentasvir), an investigational, pan-genotypic treatment for adults with chronic hepatitis C virus (HCV) infection. If approved, MAVIRET will be a once-daily, ribavirin-free, 8-week treatment option for HCV patients across all genotypes (GT1-6) without cirrhosis and new to treatment, who comprise the majority of people living with HCV.[1]The European Commission will now review the CHMP opinion and a final decision is expected in the next quarter. Glecaprevir is Enanta's second protease inhibitor being developed through its collaboration with AbbVie and is one of the two new direct-acting antivirals (DAAs) combined in MAVIRET.

The CHMP positive opinion is supported by 97.5 percent (n=807/828) SVR_{12} rates with 8 weeks of MAVIRET across GT1-6 chronic HCV-infected patients without cirrhosis and new to treatment, with varied patient and viral characteristics.[2] In an integrated analysis (n=2,265), less than 0.4 percent of patients discontinued treatment.[3] The reported adverse reactions (incidence greater than or equal to 10 percent) were headache and fatigue.[3] The type and severity of adverse reactions in patients with cirrhosis were comparable overall to those seen in patients without cirrhosis.[3]

"HCV is a global health problem and MAVIRET has the potential to address the majority of patients with a simple 8-week treatment option," stated Jay R. Luly, Ph.D., President and CEO, Enanta. "We are pleased to have our second protease inhibitor be part of this exciting new HCV regimen."

MAVIRET is also intended to be an additional option for patients with specific treatment challenges. These include chronic HCV patients with compensated cirrhosis (Child-Pugh A), and those who currently have limited treatment options, such as patients with severe chronic kidney disease, including those on dialysis, and patients infected with genotype 3.

The marketing authorization application (MAA) for MAVIRET is under an accelerated assessment, which is granted by the EMA to new medicines of major public health interest. The MAA evaluation is conducted under the European Union's centralized licensing procedure, and if approved will result in a marketing authorization valid in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway. It would then be subject to separate reimbursement approvals in each of the member states. AbbVie's investigational, pan-genotypic combination of glecaprevir/pibrentasvir has also been granted priority review designations by the U.S. Food and Drug Administration and Japanese Ministry of Health, Labour and Welfare. MAVIRET is an investigational regimen and its safety and efficacy have not been established by any regulatory approval.

About MAVIRET™ (glecaprevir/pibrentasvir)

AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) clinical development program was designed to investigate a pan-genotypic, once-daily, ribavirin-free treatment with the potential to provide a faster path to virologic cure** for all major HCV genotypes (GT1-6) and with the goal of addressing specific treatment challenges, including compensated cirrhosis (Child-Pugh A), chronic kidney disease and genotype 3. MAVIRET is being evaluated as a potential 8-week, pan-genotypic treatment for the majority of people living with HCV,[1] namely those without cirrhosis and new to treatment,* and regardless of viral and patient characteristics.

MAVIRET is a fixed-dose combination of two distinct antiviral agents: glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

*Patients who are treatment-naive or had prior treatment experience with IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).

**Patients who achieve 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 the following 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 for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, currently marketed in AbbVie's HCV regimens, and glecaprevir, Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational, pan-genotypic HCV regimen of glecaprevir/pibrentasvir, or MAVIRET™, now under accelerated assessment by the EMA. This combination has also been granted priority review designation by regulatory agencies in the U.S. and Japan. Royalties and any further milestone payments from this collaboration will provide additional funding for Enanta's earlier development programs, including its Phase 1 FXR agonist program for NASH/PBC, and its preclinical programs for HBV and RSV. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements, including statements with respect to the prospects for commercialization regulatory approval for MAVIRET.

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 MAVIRET) to obtain regulatory approvals of the 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 MAVIRET, 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]Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017

[2]Puoti et al. High SVR rates with 8 and 12 weeks of pan-genotypic G/P: integrated efficacy analysis of genotype 1–6 patients without cirrhosis. Presented at: 52nd Annual Meeting of the European Association for the Study of the Liver; April 19-23, 2017; Amsterdam, the Netherlands. Poster SAT-233.

[3]Dufour et al Safety of Glecaprevir/Pibrentasvir in Adults With Chronic Genotype 1–6 FRI-238 Hepatitis C Virus Infection: An Integrated Analysis

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