Enanta Announces Japanese Ministry of Health, Labour and Welfare Grants Priority Review for AbbVie's Investigational HCV Regimen of Glecaprevir/Pibrentasvir (G/P) for the Treatment of All Major Genotypes of Chronic Hepatitis C

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- *Priority review in Japan follows EMA accelerated assessment and U.S. FDA priority review designations*
- *If approved, G/P may provide a shorter, eight-week, once-daily, ribavirin-free cure* for the majority of the patients living with hepatitis C in Japan1*
- *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 G/P*

WATERTOWN, Mass.--(BUSINESS WIRE)--Mar. 14, 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 priority review has been granted by the Japanese Ministry of Health, Labour and Welfare (MHLW) to AbbVie for its investigational, pan-genotypic, ribavirin-free combination of glecaprevir/pibrentasvir (G/P) for the treatment of all major genotypes (GT1-6) of chronic hepatitis C virus (HCV) infection. The NDA for the G/P regimen in Japan was submitted in February 2017.

"Receiving priority review in the U.S., the E.U. and now Japan validates that there is continued unmet need for patients with HCV around the world," commented Jay R. Luly, Ph.D., President and Chief Executive Officer, Enanta. "If G/P is approved, we look forward to this important treatment option being available to the estimated 1 million people in Japan living with HCV."

The Japanese MHLW designates priority review to certain medicines based on the clinical usefulness of the treatment and severity of the disease. Japan has one of the highest rates of hepatitis C infection in the industrialized world, with approximately 1 million people living with the disease, 99 percent of whom are infected with genotype 1 (GT1) or genotype 2 (GT2).[1,2] If approved, G/P may provide a shorter, eight-week treatment duration for GT1 and GT2 patients without cirrhosis, who make up the majority of HCV patients, and an additional treatment option for patients with any of genotypes 3-6. G/P is also intended to address the needs of patients with specific treatment challenges, including those with severe chronic kidney disease (CKD) and those not cured with previous DAA treatment.

The New Drug Application (NDA) in Japan is supported by data from the Phase 3 CERTAIN studies in Japanese patients and supplemented with registrational studies in AbbVie's G/P global 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 to treatment and the treatment-experienced, those with compensated cirrhosis and without cirrhosis, and patients with specific treatment challenges, including those with severe CKD, and those not cured with a prior DAA-containing regimen. The global 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.

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

About AbbVie's G/P Clinical Development Program

AbbVie's glecaprevir/pibrentasvir (G/P) global 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 and who are new to treatment with direct-acting antivirals (DAA), who make up the majority of HCV patients. AbbVie is also studying G/P in patients with specific treatment challenges, such as patients with genotype 3 HCV, 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.

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

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 (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational HCV regimen of glecaprevir/pibrentasvir (G/P) now in registration in the U.S., the E.U. and Japan. Royalties and any further milestone payments from this collaboration will provide 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 DISCLAIMER

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's G/P regimen for 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.

[1] Gower, E. Global epidemiology and genotype distribution of the hepatitis C virus infection. Journal of Hepatology 2014; 61: S45-S57. Table 2

[2] 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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