Enanta Announces That AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) Is Now Available in Japan for the Treatment of Chronic Hepatitis C Across All Major Genotypes (GT1-6)

November 30, 2017

WATERTOWN, Mass.,--(BUSINESS WIRE)--Nov. 30, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a chemistry-driven biotechnology company dedicated to creating and developing small molecule drugs for viral infections and liver diseases, today announced that AbbVie's MAVIRET™ (glecaprevir/pibrentasvir), a new once-daily, ribavirin-free treatment approved for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6) in Japan, has been approved for reimbursement by the Ministry of Health, Labour and Welfare and is now commercially available in Japan. MAVIRET is the first and only 8-week treatment in Japan for genotype 1 (GT1) and genotype 2 (GT2) HCV infected patients without cirrhosis and who are new to direct-acting antiviral (DAA) treatment.*

Glecaprevir, one of the two new, direct-acting antivirals (DAAs) in MAVIRET (marketed as MAVYRET™ in the U.S.), is Enanta's second protease inhibitor being developed and commercialized by AbbVie. With the reimbursement approval in Japan, Enanta has now earned a $15 million milestone payment, which it expects to receive this quarter.

"Enanta has now earned all of the clinical and regulatory milestones for two products, paritaprevir and now glecaprevir, within the Enanta/AbbVie HCV collaboration," stated Jay R. Luly, Ph.D., President and CEO. "AbbVie has recently stated that it is confident that the MAVIRET combination therapy will allow AbbVie to significantly grow its position within the HCV market globally, and that it will ultimately deliver a multibillion-dollar peak-year of sales. We are fortunate to have a partner that is bringing such important therapies as MAVIRET to HCV patients in markets around the world."

Japan has one of the highest rates of HCV infection in the industrialized world, with 97 percent of its HCV patients infected with GT1 or GT2 chronic HCV.[2,3] Japan also has the highest prevalence of liver cancer amongst the industrialized countries, with chronic hepatitis C and its complications being the leading causes.[4]

The New Drug Application (NDA) for MAVIRET in Japan was filed in February 2017, designated for priority review by the Ministry of Health, Labour and Welfare in March 2017, and granted marketing authorization in September 2017.

*Patients without previous treatment that included a DAA (direct-acting antiviral) NS3/4A protease inhibitor, NS5A inhibitor and/or NS5B polymerase inhibitor.

About AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) in Japan

MAVIRET™ is approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of chronic hepatitis C virus (HCV) infection in adults across all major genotypes (GT1-6). MAVIRET™ is a pan-genotypic, once-daily, ribavirin-free treatment that combines glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

In Japan, MAVIRET™ is an 8-week treatment option for GT1 and GT2 HCV infected patients without cirrhosis and who are new to DAA (direct-acting antiviral) treatment,* who comprise the majority of people living with HCV in Japan. MAVIRET™ is the only pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease. MAVIRET™ is also a 12-week option for patients infected with GT3-6, patients with specific treatment challenges including patients with compensated cirrhosis, and those with limited treatment options such as those not cured with previous DAA treatment.[1]

About Enanta

Enanta Pharmaceuticals has used its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery of small molecule drugs for the treatment of viral infections and liver diseases. Two protease inhibitors, paritaprevir and glecaprevir, discovered and developed through Enanta's collaboration with AbbVie, have now been approved in jurisdictions around the world as part of AbbVie's direct-acting antiviral (DAA) regimens for the treatment of hepatitis C virus (HCV) infection, including the U.S.-marketed regimens MAVYRET™ (glecaprevir/pibrentasvir) and VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir).

Royalties and milestone payments from the AbbVie collaboration are helping to fund Enanta's research and development efforts, which 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). Please visit www.enanta.com for more information.

Forward Looking Statements

This press release contains forward-looking statements, including statements with respect to the commercial prospects for AbbVie's MAVIRET regimen in Japan and globally. 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: Enanta's revenues in the short-term are dependent upon the success of AbbVie's continuing commercialization efforts for its new MAVYRET/MAVIRET regimen; competitive pricing, market acceptance and reimbursement rates for MAVYRET/MAVIRET compared to competitive HCV products on the market; Enanta's and AbbVie's need to obtain and maintain patent protection for its HCV products 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] MAVIRET™[package insert]. Tokyo, Japan: AbbVie Ltd.

[2] Yu ML, Chuang WL. Treatment of chronic hepatitis C in Asia: when East meets West. J Gastroenterol Hepatal. 2009;24(3):336-45.

[3] Liu GG, DiBonaventura M, Yuan Y, et al, The burden of illness for patients with viral hepatitis C: evidence from a national survey in Japan. Value Health. 2012;15(1 Suppl):565-71.

[4] Yatsuhashi, H. Past, Present, and Future of Viral Hepatitis C in Japan. Euroasian Journal of Hepato-Gastroenterology 6, 49-51 (2016).

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