Enanta Announces that AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) Received Approval in Japan for the Treatment of All Major Genotypes (GT1-6) of Chronic Hepatitis C

September 27, 2017

- *MAVIRET is the first and only 8-week treatment approved in Japan for genotype 1 and 2 hepatitis C virus (HCV) infected patients without cirrhosis and who are new to DAA treatment**
- *Approval is supported by a 99 percent virologic cure*** rate in these patients, who comprise the majority of people living in Japan with HCV[1,2]*
- *Japan has one of the highest rates of HCV infection in the industrialized world [2,3]*
- *Glecaprevir, one of the two new, direct-acting antivirals (DAAs) in MAVIRET, is Enanta's second protease inhibitor being developed and commercialized by AbbVie*

WATERTOWN, Mass.--(BUSINESS WIRE)--Sep. 27, 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 Japanese Ministry of Health, Labour and Welfare (MHLW) approved AbbVie's MAVIRET™ (glecaprevir/pibrentasvir), a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6). MAVIRET is the first and only 8-week treatment option in Japan for GT1 and GT2 HCV infected patients without cirrhosis and who are new to direct-acting antiviral (DAA) treatment,* including those with chronic kidney disease (CKD). These patients represent the majority of people living with HCV in Japan.[2]

In Japan, MAVIRET is also approved as 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]

Enanta expects to receive a $15 million milestone payment from AbbVie in the quarter ending December 31, 2017, upon price reimbursement approval of MAVIRET in Japan.

"With the approval of this new, pan-genotypic treatment, the majority of the 2 million people infected with HCV in Japan will now be able to be treated in as little as eight weeks," stated Jay R. Luly, Ph.D., President and CEO, Enanta.

Japan has one of the highest rates of HCV infection in the industrialized world, with approximately 2 million people living with the disease, 97 percent of whom are 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]

This approval of MAVIRET is supported by data from the Phase 3 CERTAIN studies in Japanese patients and supplemented with registrational studies from AbbVie's global clinical development program for MAVIRET. With just 8 weeks of treatment, a 99 percent (n=226/229) SVR_{12} rate was achieved across GT1 and GT2 chronic HCV infected Japanese patientswithout cirrhosis and who were new to DAA treatment*.[1] This high SVR_{12} rate was achieved in patients with varied patient and viral characteristics, including those with CKD.[1] In patients not cured with previous DAA treatment, a 94 percent (n=31/33) SVR_{12} rate was achieved with 12 weeks of treatment. The most commonly reported adverse reactions were pruritus, headache, malaise and blood bilirubin increase (none of which had an incidence greater than 5 percent).[1]

MAVIRET combines two new, potent# direct-acting antivirals that target and inhibit proteins essential for the replication of the hepatitis C virus. The presence of more difficult-to-treat genotypes or baseline mutations that are commonly associated with resistance have been shown to have minimal impact on the efficacy of MAVIRET.

Approval of MAVIRET follows priority review, a designation by the Japanese MHLW granted to certain medicines based on the clinical usefulness of the treatment and severity of the disease. AbbVie's pan-genotypic treatment was also recently granted marketing authorization by the European Commission and approved by the U.S. Food and Drug Administration as an 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment.

**Patients without previous treatment that included a DAA (direct-acting antiviral) NS3/4A protease inhibitor, NS5A inhibitor and/or NS5B polymerase inhibitor.*
***Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR12) are considered cured of hepatitis C.*
#Based on EC50 values of glecaprevir and pibrentasvir against full-length or chimeric replicons encoding NS3 or NS5A from laboratory strains and chimeric replicons from clinical isolates.[1]

About 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, including those with chronic kidney disease (CKD) and those new to DAA (direct-acting antiviral) treatment,* who comprise the majority of people living with HCV. MAVIRET is also a 12-week option for patients infected with GT3-6 chronic HCV, 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]

Indication in Japan

Improvement of viremia in chronic hepatitis C or compensated hepatic cirrhosis C.

Summary of Safety Information

Contraindications

MAVIRET is contraindicated in patients with a history of known hypersensitivity to the ingredients of MAVIRET, patients with severe hepatic impairment (Child-Pugh C) and patients being treated with atazanavir sulfate, atorvastatin calcium hydrate, or rifampin.

Precautions for Use

Positive result for HCV RNA should be confirmed before administering MAVIRET and decompensated cirrhosis should also be excluded by hepatic reserve or clinical symptoms.

While HCV viral load is decreased, HBV reactivation in patients who are chronically infected with HBV or patients who have a history of HBV infection (HBs-Ag negative and HBc-Ab or HBs-Ab positive) has been reported after initiation of HCV DAA treatment. Patients should be evaluated for the presence of HBV infection prior to the treatment with MAVIRET.

Glecaprevir is an inhibitor of P-gp, BCRP, and OATP1B1/1B3. Pibrentasvir is an inhibitor of P-gp, BCRP and OATP1B1. Glecaprevir is a substrate of P-gp, BCRP, and OATP1B1/1B3. Pibrentasvir is a substrate of P-gp. Co-administration of MAVIRET with these drugs may result in increased plasma concentrations of such drugs or increased or decreased plasma concentrations of MAVIRET, potentially requiring dose adjustment or clinical monitoring.

The safety of MAVIRET in pregnant women has not been established. Administration to women who are pregnant or may be pregnant must be limited to the cases in which the benefits of the treatment are deemed to outweigh the risks.

Administration to lactating women must be avoided, or breastfeeding must be avoided when administration to a lactating woman is unavoidable.

Safety and efficacy has not been established in children.

Adverse Reactions

Common adverse reactions included pruritus in 16 subjects (4.8%), headache in 14 subjects (4.2%), malaise in 10 subjects (3.0%) and blood bilirubin increased in 8 subjects (2.4%).

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 prospects for reimbursement approval and commercialization of MAVIRET in the Japan. 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 commercialize MAVIRET successfully in the Japan and to obtain regulatory approvals of the glecaprevir/pibrentasvir (G/P) combination and commercialize it successfully in other jurisdictions; 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] MAVIRET [package insert]. Tokyo, Japan: AbbVie GK.
[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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Source: Enanta Pharmaceuticals, Inc.

Investors:
Enanta Pharmaceuticals, Inc.
Carol Miceli, 617-607-0710
cmiceli@enanta.com
or
Media:
MacDougall Biomedical Communications
Kari Watson, 781-235-3060
kwatson@macbiocom.com