Enanta's HCV Collaboration Partner AbbVie Receives Marketing Authorization from European Commission to Shorten MAVIRET® (glecaprevir/pibrentasvir) Duration to Eight Weeks for Treatment-Naïve Genotype 3 HCV Patients with Compensated Cirrhosis

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- *MAVIRET now available in the EU as an 8-week treatment option for treatment-naïve, chronic hepatitis C virus (HCV) patients without cirrhosis or with compensated cirrhosis, regardless of genotype**
- *European Commission's decision makes MAVIRET the only 8-week treatment regimen indicated for all common HCV genotypes (GT1—6) in treatment-naïve, chronic HCV patients both without cirrhosis or with compensated cirrhosis, without the need for HCV genotype testing*
- *Glecaprevir, one of the two direct-acting antivirals (DAAs) in MAVIRET, was discovered by Enanta and developed and commercialized by AbbVie*

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced that the European Commission has granted marketing authorization to its HCV collaboration partner AbbVie for MAVIRET® (glecaprevir/pibrentasvir) to shorten the once-daily treatment duration from 12 to 8 weeks in treatment-naïve, compensated cirrhotic, chronic HCV patients with genotype (GT) 3 infection. MAVIRET was already indicated as an 8-week, pan-genotypic (GT1-6), once-daily regimen for treatment-naïve HCV patients without cirrhosis, and as an 8-week, once-daily regimen for treatment-naïve GT 1, 2, 4, 5 and 6 HCV patients with compensated cirrhosis.[1*]

"We are pleased with the European Commission's authorization which makes MAVIRET the only eight-week treatment regimen indicated for all common HCV genotypes in treatment-naïve, chronic HCV patients both without cirrhosis or with compensated cirrhosis, without the need for HCV genotype testing," said Jay Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. "Our hope is that a shorter-duration therapeutic option and simplified pre-treatment requirements will eliminate the need for extra tests in many cases and allow for faster time-to-treatment for newly diagnosed patients."

The EC approval is supported by data from the Phase 3b EXPEDITION-8 study, which evaluated the safety and efficacy of MAVIRET in treatment-naïve chronic HCV patients with compensated cirrhosis across all major genotypes (GT1-6). The results have been reported for GT 1, 2, 3, 4, 5, and 6 (n=343) patients[2] and showed that with 8 weeks of MAVIRET, 97.7 percent (n=335/343) of GT1- 6 patients achieved a sustained virologic response 12 weeks after treatment (SVR_{12}) (ITT). For patients with GT3, the SVR_{12} rate was 95.2% (n= 60/63) (ITT).**

To date, one virologic failure has been reported and no patients have discontinued treatment due to adverse events. In the study, most patients that did not achieve SVR_{12}** were lost to follow-up versus experiencing treatment failure, and no new safety signals were identified.[2]

In the WHO European Region, 14 million people are estimated to be chronically infected with the HCV and many of them are unaware that they are infected.[3] Each year 112,500 people die from HCV-related liver disease.[3]

About the EXPEDITION-8 Study[2]

EXPEDITION-8 was a single-arm, open-label, Phase 3b study in treatment-naïve, GT1-6 chronic HCV patients with compensated cirrhosis (n=343) who received MAVIRET treatment for 8 weeks.

The primary efficacy endpoints were SVR_{12}** in patients with GT1, 2, 4, 5, and 6 in a per-protocol (PP) and intent-to-treat (ITT) population versus historical SVR_{12}** rates based on the efficacy of MAVIRET for 12 weeks in treatment-naïve patients with compensated cirrhosis. The key secondary efficacy endpoints were the percentages of GT1-6 patients achieving SVR_{12}** in a PP and ITT population.

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

About MAVIRET® (glecaprevir/pibrentasvir) [1]

MAVIRET is approved in the European Union for the treatment of chronic hepatitis C virus (HCV) infection in adults, and in adolescents aged 12 to <18 years, 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.

MAVIRET is an 8-week, pan-genotypic (GT 1-6) option for patients without cirrhosis or with compensated cirrhosis and who are new to treatment.* MAVIRET is also approved as a treatment for patients with specific treatment challenges, including those with compensated cirrhosis across all major genotypes, and those who previously had limited treatment options, such as patients with severe chronic kidney disease (CKD) or those with genotype 3 chronic HCV infection. MAVIRET is a pan-genotypic treatment approved for use in patients across all stages of CKD.

MAVIRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C) and is not recommended in patients with moderate hepatic impairment (Child-Pugh B).

Glecaprevir (GLE) was discovered by Enanta during its ongoing collaboration with AbbVie for development of HCV protease inhibitors and HCV treatment regimens that include those protease inhibitors.

EU Indication

MAVIRET is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and in adolescents aged 12 to <18 years old.

Important EU Safety Information

Contraindications:

MAVIRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C). Concomitant use with atazanavir containing products, atorvastatin, simvastatin, dabigatran etexilate, ethinyl oestradiol-containing products, strong P-gp and CYP3A inducers, such as rifampicin, carbamazepine, St. John's wort, phenobarbital, phenytoin, and primidone.

Special warnings and precautions for use:

Hepatitis B virus reactivation

Cases of hepatitis B virus (HBV) reactivation, some of them fatal, have been reported during or after treatment with direct-acting antiviral agents. HBV screening should be performed in all patients before initiation of treatment.

Hepatic impairment

MAVIRET is not recommended in patients with moderate hepatic impairment (Child-Pugh B).

Patients who failed a prior regimen containing an NS5A- and/or an NS3/4A-inhibitor

MAVIRET is not recommended for the re-treatment of patients with prior exposure to NS3A/4A and/or NS5A-inhibitors.

Use in diabetic patients

Diabetics may experience improved glucose control and potential symptomatic hypoglycaemia after initiating HCV direct acting antiviral treatment. Glucose levels should be closely monitored, particularly within the first 3 months of treatment.

Adverse Reactions

Most common (≥10%) adverse reactions for MAVIRET were headache and fatigue.

This is not a complete summary of all safety information. See MAVIRET full summary of product characteristics (SmPC) at www.ema.europa.eu. Globally, prescribing information varies; refer to the individual country product label for complete information.

About Enanta

Enanta is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases. Enanta's research and development efforts have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC), hepatitis B virus (HBV), and human metapneumovirus (hMPV).

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta and now marketed by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection, is sold under the tradenames MAVYRET (U.S.) and MAVIRET (ex-U.S.) (glecaprevir/pibrentasvir). Please visit www.enanta.com for more information.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie sales of Enanta's licensed products. 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: Enanta's royalty revenues are dependent upon the continued success of AbbVie's commercialization of its MAVYRET/MAVIRET regimen; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for HCV; reimbursement and pricing actions affecting MAVYRET/MAVIRET or any competitive treatment for HCV; Enanta's need to obtain and maintain patent protection for its product candidates 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-Q for the fiscal quarter ended December 31, 2019 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.

*The recommended duration of MAVIRET is 12 weeks in liver or kidney transplant recipients without cirrhosis or with compensated cirrhosis.

**Sustained virologic response (SVR12), defined as HCV RNA less than lower limit of quantification (LLOQ) at 12 weeks after the end of treatment, was the primary endpoint in all the studies.

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[1] MAVIRET® tablets (glecaprevir/pibrentasvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd.

[2] Brown RS et al. Glecaprevir/pibrentasvir for 8 weeks in treatment-naïve patients with chronic HCV genotypes 1–6 and compensated cirrhosis: The EXPEDITION-8 trial. J Hepatol (2019) the HCV cure rate. (ref 1)

[3] Hepatitis C in the WHO European Region. WHO Fact Sheet July 2019. Available at: http://www.euro.who.int/__data/assets/pdf_file/0009/377253/Fact-Sheet-Hepatitis-C_2019_ENG.PDF?ua=1 Last accessed February 2020

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