



Enanta's HCV Collaboration Partner AbbVie receives Approval by the European Commission for MAVIRET™ (glecaprevir/pibrentasvir) to Shorten Treatment Duration to Eight Weeks for Treatment-Naïve HCV Patients with Compensated Cirrhosis

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- MAVIRET™ is now available as a shorter, 8-week, once-daily option for treatment-naïve, compensated cirrhotic, chronic hepatitis C (HCV) patients with genotype (GT)1, 2, 4, 5 or 6
- Marketing authorization is supported by 97.9 percent cure* rate across this group of patients with no reported virologic failures
- Analysis evaluating MAVIRET as an 8-week, once-daily treatment option for treatment-naïve, compensated cirrhotic, GT3 HCV patients is ongoing
- Glecaprevir, is one of the two direct-acting antivirals (DAAs) in MAVIRET and is Enanta's second protease inhibitor developed and commercialized by AbbVie

WATERTOWN, Mass.--(BUSINESS WIRE)-- 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 Commission has granted marketing authorization to AbbVie for MAVIRET™ (glecaprevir/pibrentasvir) to shorten once-daily treatment duration from 12 to 8 weeks in treatment-naïve, compensated cirrhotic, chronic hepatitis C (HCV) patients with genotype (GT)1, 2, 4, 5, or 6 infection. An analysis from the same clinical trial evaluating MAVIRET as an 8-week, once-daily treatment option for treatment-naïve, compensated cirrhotic, GT3 HCV patients is ongoing. MAVIRET is already approved as an 8-week, pan-genotypic (GT1-6) treatment for treatment-naïve patients without cirrhosis. ^{2**}

The marketing authorization is supported by data from the ongoing Phase 3b EXPEDITION-8 study, which showed that with 8 weeks of MAVIRET, 97.9 percent (n=274/280) of GT1, 2, 4, 5 and 6 patients achieved a sustained virologic response 12 weeks after treatment (SVR₁₂) (ITT).¹ To date, no virologic failures have been reported in these patients and no patients have discontinued treatment due to adverse events.¹ Adverse events (frequency ≥5%) reported in the study include pruritus (9.6%), fatigue (8.6%), headache (8.2%) and nausea (6.4%).¹ Six serious adverse events (2%) have occurred during the study, none of which were deemed to be related to glecaprevir/pibrentasvir.¹ No new safety signals were identified in this study.¹ These data were presented as a late-breaking, oral presentation at The Liver Meeting® 2018 organized by the American Association for the Study of Liver Diseases (AASLD) in San Francisco, California.

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

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

AbbVie's ongoing Phase 3b EXPEDITION-8 study is evaluating the safety and efficacy of MAVIRET in treatment-naïve chronic HCV patients with compensated cirrhosis across all major genotypes (GT1-6).¹ The results have been reported for GT1, 2, 4, 5, and 6 (n=280) patients. Enrollment and treatment of the GT3 patient population was completed later, therefore the analysis of this population is ongoing.

About the EXPEDITION-8 Study¹

EXPEDITION-8 is an ongoing non-randomized, single arm, open-label, multicenter Phase 3b study evaluating the safety and efficacy of glecaprevir/pibrentasvir in treatment-naïve GT1-6 chronic HCV patients with compensated cirrhosis. Analysis of the GT3 patient population is ongoing.

The primary efficacy endpoints are the SVR₁₂ rates in GT1, 2, 4, 5, and 6 patients in a per-protocol (PP) and intent-to-treat (ITT) population versus respective historical SVR₁₂ rates based on the efficacy of MAVIRET for 12 weeks in treatment-naïve patients with compensated cirrhosis. The SVR₁₂ rates were 97.9 percent (n=274/280) and 100 percent (n=273/273) in the ITT and PP populations, respectively. From the 280 patients with GT1, 2, 4, 5 or 6 enrolled, seven were excluded from the SVR₁₂ per-protocol analysis (n=273); five patients were lost to follow up, and two patients received less than 8 weeks of treatment (one of these two patients achieved SVR₁₂). The key secondary efficacy endpoints are the percentage of GT1, 2, 3, 4, 5, and 6 patients achieving SVR₁₂ in a PP and ITT populations.

About AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) in the European Union

MAVIRET® is approved in the European Union for the treatment of chronic hepatitis C virus (HCV) infection in adults and adolescents 12 to <18 years old 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 option (GT1-6) for patients without cirrhosis who are new to treatment*, and for GT1, 2, 4, 5 and 6 patients with compensated cirrhosis who are new to treatment. The recommended duration of therapy for treatment naïve GT3 HCV patients with compensated cirrhosis is 12 weeks. 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).²

EU Indication

MAVIRET is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and adolescents 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 diabetics patients

Diabetics may experience improved glucose control and potential symptomatic hypoglycemia 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 ($\geq 10\%$) 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 Pharmaceuticals, Inc.

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 are currently focused on the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta's research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen 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

This press release contains forward-looking statements, including statements with respect to the commercial prospects for AbbVie's MAVIRET regimen in the European Union. 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 dependence of Enanta's revenues in the short-term upon the success of AbbVie's continuing commercialization efforts for its 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-Q for the fiscal quarter ended March 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.

¹ Brown RS, Hezode C, Wang S, et al. Preliminary Efficacy and Safety of 8-Week Glecaprevir/Pibrentasvir in Patients with HCV Genotype 1–6 Infection and Compensated Cirrhosis: The EXPEDITION-8 Study. Presented at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, U.S., November 13, 2018

² MAVIRET™ tablets (glecaprevir/pibrentasvir) Summary of product characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG



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