



Enanta Announces that AbbVie's MAVYRET™ (glecaprevir/pibrentasvir) Shows High Virologic Cure* Rates in Treatment-Naïve Hepatitis C Patients with Compensated Cirrhosis

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- *EXPEDITION-8 is the first Phase 3b study evaluating 8 weeks of MAVYRET™ in treatment-naïve chronic hepatitis C virus (HCV)-infected patients with compensated cirrhosis across all major genotypes (GT1-6)*¹
- *In cohort one, 100 percent of genotype 1, 2, 4, 5 and 6 treatment-naïve chronic HCV patients with compensated cirrhosis achieved SVR₁₂ with 8 weeks of MAVYRET per protocol analysis*¹
- *Cohort two of the study is ongoing, evaluating treatment-naïve genotype 3 (GT3) patients with compensated cirrhosis*
- *MAVYRET is currently approved as an 8-week, pan-genotypic treatment for treatment-naïve patients without cirrhosis*
- *Glecaprevir, one of the two direct-acting antivirals (DAAs) in MAVYRET, is Enanta's second protease inhibitor being 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 the presentation of new data for AbbVie's pan-genotypic chronic hepatitis C virus (HCV) treatment, MAVYRET™ (glecaprevir/pibrentasvir), in treatment-naïve patients with compensated cirrhosis. Results from AbbVie's Phase 3b EXPEDITION-8 study showed that with 8 weeks of MAVYRET, 100 percent (n=273/273) of genotype 1, 2, 4, 5 and 6 patients achieved a sustained virologic response 12 weeks after treatment (SVR₁₂) per protocol analysis.¹

These data are being presented today 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.

This analysis is part of the ongoing Phase 3b EXPEDITION-8 study being conducted by AbbVie, evaluating the safety and efficacy of MAVYRET in treatment-naïve chronic HCV patients with compensated cirrhosis across all major genotypes (GT1-6). The study includes two cohorts; cohort one with genotype 1, 2, 4, 5, 6 chronic HCV-infected patients, and cohort two with genotype 3 (GT3) chronic HCV-infected patients.¹

To date, no virologic failures have been reported in cohort one of the study and no patients have discontinued treatment due to adverse events.¹ Adverse events (≥5%) reported of the study populations 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.

Data from the ongoing EXPEDITION-8 Phase 3b study will be presented as a late-breaking, oral presentation during the Late-breaking Abstract Oral Session II on November 13 at 8:30 a.m. PST.

MAVYRET is approved in the U.S. as a 12-week pan-genotypic treatment for treatment-naïve patients with compensated cirrhosis.²

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

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. The study investigated two cohorts of patients:

- **Cohort one:** treatment-naïve genotype 1, 2, 4, 5, 6 patients with compensated cirrhosis (n=280)
- **Cohort two:** treatment-naïve GT3 patients with compensated cirrhosis (n=60)

The primary endpoint is the percentage of patients achieving SVR₁₂ in a per-protocol analysis and the secondary endpoints are on-treatment virologic failure and relapse rates. For cohort one, 280 patients were enrolled and seven patients 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).

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

About AbbVie's MAVYRET™ (glecaprevir/pibrentasvir)

MAVYRET™ is approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic hepatitis C virus (HCV) infection in adults across all major genotypes (GT1-6). MAVYRET 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, taken with food.

MAVYRET is an 8-week, pan-genotypic option for patients without cirrhosis and who are new to treatment, who comprise the majority of people living with HCV. MAVYRET is also approved as a treatment for patients with specific treatment challenges, including those (GT1) not cured by prior treatment experience to either a protease inhibitor or NS5A inhibitor (but not both), and in patients with limited treatment options, such as those with severe chronic kidney disease (CKD) or those with genotype 3 chronic HCV. MAVYRET is a pan-genotypic treatment approved for use in patients across all stages of CKD.

Glecaprevir (GLE) was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

Full prescribing information can be found [here](#).

Use and Important Safety Information

USE

MAVYRET™ (glecaprevir and pibrentasvir) tablets are a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C virus (hep C) genotypes 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis.

IMPORTANT SAFETY INFORMATION

What is the most important information to know about MAVYRET?

Hepatitis B virus reactivation: Before starting treatment with MAVYRET, a doctor will do blood tests to check for hepatitis B virus infection. If people have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment for hepatitis C virus with MAVYRET. Hepatitis B virus that becomes active again (called reactivation) may cause serious liver problems including liver failure and death. A doctor will monitor people if they are at risk for hepatitis B virus reactivation during treatment and after they stop taking MAVYRET.

MAVYRET must not be taken if people:

- Have certain liver problems
- Are taking the medicines:
 - atazanavir
 - rifampin

What should people tell a doctor before taking MAVYRET?

- If they have had hepatitis B virus infection, have liver problems other than hep C infection, have HIV-1 infection, have had a liver or a kidney transplant, or any other medical conditions.
- If they are pregnant or plan to become pregnant, or if they are breastfeeding or plan to breastfeed. It is not known if MAVYRET will harm a person's unborn baby or pass into breast milk. A doctor should be consulted about the best way to feed a baby if taking MAVYRET.

About all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. MAVYRET and other medicines may affect each other. This can cause people to have too much or not enough MAVYRET or other medicines in their body. This may affect the way MAVYRET or other medicines work, or may cause side effects.

- **A new medicine must not be started without telling a doctor.** A doctor will provide instruction on whether it is safe to take MAVYRET with other medicines.

What are the common side effects of MAVYRET?

- The most common side effects of MAVYRET are headache and tiredness.

These are not all of the possible side effects of MAVYRET. A doctor should be notified if there is any side effect that is bothersome or that does not go away.

This is the most important information to know about MAVYRET. For more information, people should talk to a doctor or healthcare provider.

People are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full [Prescribing Information](#), including the [Patient Information](#).

About Enanta Pharmaceuticals, Inc.

Enanta Pharmaceuticals 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. Glecaprevir, a protease inhibitor discovered by Enanta, has been developed by AbbVie, and is now approved and sold in numerous countries as part of AbbVie's 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).

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

Forward Looking Statements

This press release contains forward-looking statements. 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-Q for the quarter ended June 30, 2018 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 MAVYRET™ tablets (glecaprevir/pibrentasvir) Prescribing Information. Chicago, U.S. AbbVie Inc.



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