



## Enanta Announces U.S. FDA Approval of AbbVie's MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6) in as Little as 8 Weeks

August 3, 2017

- MAVYRET is a new, 8-week, pan-genotypic treatment for hepatitis C patients without cirrhosis and new to treatment
- FDA approval is supported by an overall 98 percent cure rate (rates ranged between 92-100 percent) in patients who received the recommended duration of treatment
- MAVYRET is approved for use across all stages of chronic kidney disease in patients with any of the major HCV genotypes
- MAVYRET may be used in up to 95 percent of HCV patients, depending on stage of liver disease and prior treatment history\*
- Glecaprevir, one of the two new direct-acting antivirals (DAAs) in MAVYRET, is Enanta's second protease inhibitor being developed and commercialized by AbbVie

WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 3, 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 U.S. Food and Drug Administration (FDA) approved AbbVie's MAVYRET™ (glecaprevir/pibrentasvir), a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6). MAVYRET is an 8-week, pan-genotypic treatment for patients without cirrhosis and new to treatment. Up to 95 percent of HCV patients in the U.S. may be eligible for treatment with MAVYRET, including patients with compensated cirrhosis or without cirrhosis, and those with limited treatment options, such as patients with chronic kidney disease (CKD).\*

Following this approval of MAVYRET in the U.S., Enanta expects to receive a \$40 million milestone payment from AbbVie.

"A majority of the estimated 3.4 million Americans chronically infected with HCV have not yet been treated for the disease and do not yet have cirrhosis. The FDA approval of MAVYRET provides them a new, 8-week treatment option regardless of their HCV genotype," stated Jay R. Luly, Ph.D., President and CEO, Enanta. "Our second protease inhibitor, glecaprevir, is part of this new combination treatment that has now been approved in the E.U. and the U.S."

Approximately 3.4 million Americans are chronically infected with HCV.<sup>1</sup> Additionally, HCV is common among people with severe CKD, with more than 500,000<sup>#</sup> people in the U.S. estimated to have both chronic HCV and CKD.<sup>2</sup> MAVYRET was designed to deliver a cure\*\* across all major genotypes and for specific treatment challenges, such as patients with severe CKD, and GT1 patients not cured by a NS5A inhibitor or a NS3/4A protease inhibitor (PI) in a direct-acting antiviral (DAA) treatment, but not both. MAVYRET combines two new DAAs that target and inhibit proteins essential for the replication of the hepatitis C virus.

The approval of MAVYRET is supported by data from nine registrational studies in AbbVie's clinical development program, which evaluated more than 2,300 patients in 27 countries across all major HCV genotypes (GT1-6) and special populations.

AbbVie's pan-genotypic regimen also was recently granted marketing authorization by the European Commission, which means it is now licensed for use in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway.

\*Ipsos Healthcare HCV Monitor, 2017. New York, NY: Ipsos in North America. ©Ipsos 2017, all rights reserved.

\*\*Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR<sub>12</sub>) are considered cured of hepatitis C.

<sup>#</sup>Based on IMS Dx (Oct. 2016) distribution of 15.7% Renal patients in diagnosed population applied to ~3.4M HCV prevalence population of all major HCV genotypes

### About 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 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 priortreatment experience with either a protease inhibitor or an 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 approved for use in patients across all stages of CKD with any of the major HCV genotypes (GT1-6).

Full prescribing information can be found at [www.rxabbvie.com](http://www.rxabbvie.com).

### 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 of hepatitis C virus with MAVYRET. Hepatitis B virus becoming 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 (Evotaz®, Reyataz®)
  - rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)

**What should people tell a doctor before taking MAVYRET?**

- If they have ever had hepatitis B virus infection, liver problems other than hep C infection, 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see full Prescribing Information, including the Patient Information.**

**If people cannot afford their medication, they should contact [www.pparx.org](http://www.pparx.org) for assistance.**

**About Enanta**

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development efforts 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). Enanta has also discovered novel protease inhibitors that have been developed as part of AbbVie's hepatitis C virus (HCV) treatment regimens under a collaboration that now provides Enanta a payment stream, which it is using to fund its research and development programs. Please visit [www.enanta.com](http://www.enanta.com) for more information on Enanta's programs and pipeline.

**FORWARD LOOKING STATEMENTS**

This press release contains forward-looking statements, including statements with respect to the prospects for commercialization of MAVYRET in the United States. 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 MAVYRET) to commercialize MAVYRET successfully in the U.S. 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 MAVYRET, 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.

<sup>1</sup> Messina JP, Humphreys I., Flaxman A., et.al. Global distribution and prevalence of hepatitis C virus genotypes. *Hepatology*. 2015;61(1): 77-87 (and supplementary appendix).

<sup>2</sup>IMS Health. IMS Dx/LRx. December 2016. (©IMS Health Inc., all rights reserved).

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