

## Enanta Announces Data to be Presented on AbbVie's MAVYRET™ (glecaprevir/pibrentasvir) at The Liver Meeting® 2017

October 11, 2017

- 16 HCV abstracts to be presented including 12 data presentations on the safety and efficacy of MAVYRET
- MAVYRET is recommended in new AASLD guidelines as a first line treatment option for 8 weeks in treatment-naïve non-cirrhotic HCV patients across all genotypes (GT1-6)
- 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)--Oct. 11, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a chemistry-driven biotechnology company dedicated to creating and developing small molecule drugs for viral infections and liver diseases, today announced, that AbbVie will present new data evaluating MAVYRET™ (glecaprevir/pibrentasvir), its once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6), at the annual meeting of the American Association for the Study of Liver Diseases (AASLD). Sixteen AbbVie scientific abstracts have been accepted, including two oral presentations studying the use of MAVYRET in patients across genotypes (GT1-6) with compensated cirrhosis and in treatment-naïve patients with genotype 3 (GT3) HCV. These populations have historically had limited treatment options. A third oral presentation evaluates adherence to treatment with MAVYRET in the clinical development program. The Liver Meeting 2017 will take place in Washington, D.C., from October 20 – 24, 2017.

Researchers will also present data obtained from AbbVie's MAVYRET clinical program evaluating patients with cardiovascular, metabolic and renal conditions as well as data on HCV patient preferences.

### Select AbbVie clinical presentations include:

#### MAVYRET Abstracts

- **Adherence to Pangenotypic Glecaprevir/Pibrentasvir Treatment and SVR<sub>12</sub> in HCV-Infected Patients: An Integrated Analysis of the Phase 2/3 Clinical Trial Program** - Abstract 198; Oral Presentation; Monday, October 23, 2017; 4:15 p.m. ET
- **Efficacy and Safety of Glecaprevir/Pibrentasvir for 8 or 12 Weeks in Treatment-Naïve Patients with Chronic HCV Genotype 3: An Integrated Phase 2/3 Analysis** - Abstract 62; Oral Presentation; Sunday, October 22, 2017; 1:15 p.m. ET
- **Efficacy, Safety, and Pharmacokinetics of Glecaprevir/Pibrentasvir in Adults With Chronic Genotype 1-6 Hepatitis C Virus Infection and Compensated Cirrhosis: An Integrated Analysis** - Abstract 74; Oral Presentation; Sunday, October 22, 2017; 3:15 p.m. ET
- **Efficacy and Safety of Glecaprevir/Pibrentasvir in Patients Infected with HCV GT1-3 by Renal Impairment Status: A Pooled Analysis of Two Phase 3 Japanese Trials** - Abstract 1179; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Safety and Efficacy of Glecaprevir/Pibrentasvir in Patients With Chronic Hepatitis C Genotypes 1–6 and Recent Drug Use** - Abstract 1182; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Safety and Efficacy of Glecaprevir/Pibrentasvir in Patients Aged 65 Years or Older With Chronic Hepatitis C: A Pooled Analysis of Phase 2 and 3 Clinical Trials** - Abstract 1188; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Impact of Hepatitis C Treatment With Glecaprevir + Pibrentasvir on Patient's Health-Related Quality of Life: Results From Phase 3 CERTAIN Trials** - Abstract 1187; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Exposure-Safety Response Relationship for Glecaprevir and Pibrentasvir in Hepatitis C Virus-Infected Subjects in Phase 2 and 3 Studies** - Abstract 1189; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Exposure-Response Analyses of Virologic Response to Glecaprevir and Pibrentasvir in HCV Subjects from Phase 2 and 3 Studies** - Abstract 1185; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET
- **Glecaprevir and Pibrentasvir Exposures in Hepatitis C Virus-Infected Subjects in Phase 2 and 3 Studies** - Abstract 1190; Poster Session; Saturday, October 21, 2017; 2:00 – 7:00 p.m. ET

#### HCV Health Outcomes Abstract

- **Assessing Patient Preferences for and Relative Importance of Features of New Direct Acting Antiviral (DAA) Treatments for Chronic Hepatitis C Virus (HCV) Infections** - Abstract 741; Poster Session; Friday, October 20, 2017; 8:00 a.m. – 5:30 p.m. ET

The full AASLD 2017 scientific program can be found at [www.aasld.org](http://www.aasld.org).

### **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 chronic HCV patients not cured by prior treatment with either a protease inhibitor or NS5A inhibitor (but not both), and in patients with limited treatment options, such as those with GT-3 chronic HCV and those with severe chronic kidney disease (CKD). MAVYRET is a pan-genotypic treatment approved for use in patients across all stages of CKD.

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 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](#).

#### **About Enanta**

Enanta Pharmaceuticals has used 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. 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](http://www.enanta.com) for more information.

## **FORWARD LOOKING STATEMENTS**

This press release contains forward-looking statements, including statements with respect to the prospects for treatment with MAVYRET and commercialization of MAVYRET. 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 and to obtain further regulatory approvals of the glecaprevir/pibrentasvir (G/P) combination and commercialize it successfully; 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.

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