Enanta Pharmaceuticals' Partner AbbVie Receives U.S. FDA Approval of an Expanded Indication for MAVYRET® (glecaprevir/pibrentasvir) as the First and Only Treatment for People with Acute Hepatitis C Virus

June 11, 2025

- *MAVYRET® (glecaprevir/pibrentasvir) is Now the Only Direct Acting Antiviral Therapy Approved to Treat Patients with Acute Hepatitis C Virus (HCV) in Eight Weeks with a 96% Cure Rate[1*†]*
- *FDA Approval Now Allows Providers to Treat HCV Patients Immediately at Time of Diagnosis*
- *If Left Untreated, Patients with Acute HCV Could Progress to Chronic Disease, Including Cirrhosis or Liver Cancer[2]*
- *Glecaprevir, One of the Two Direct-Acting Antivirals in MAVYRET®, was Discovered by Enanta and Developed and Commercialized by AbbVie*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jun. 11, 2025-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections and immunological diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved a label expansion for MAVYRET® (glecaprevir/pibrentasvir), an oral pangenotypic direct acting antiviral (DAA) therapy. It is now approved as the only eight-week treatment for adults and pediatric patients three years and older with acute or chronic HCV infection without cirrhosis or with compensated cirrhosis.*

"The FDA's expanded indication of MAVYRET for acute HCV infection marks a significant milestone for patients with HCV. We are proud that our discovery of glecaprevir contributed to a therapy that continues to make a meaningful difference for patients worldwide," said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "More than one million patients with chronic HCV have been treated with MAVYRET and today's approval could allow even more patients to benefit from access to a cure. Our hope is that by being able to treat acute HCV infection, we will significantly simplify and accelerate the treatment of this condition and, in doing so, help to eliminate the physical, emotional, and economic burden of HCV. With this approval, the global public health community now has another tool to help prevent disease transmission and ultimately help drive progress toward the global public health goal of HCV elimination by 2030."

The label expansion was supported by data from the Phase 3, multicenter, single-arm prospective study evaluating the safety and efficacy of MAVYRET eight-week treatment in adults with acute HCV infection.[1] The study results showed MAVYRET to be a highly efficacious treatment for people with acute HCV.[1] The majority of the adverse events reported were mild or moderate in severity.[1] The most common adverse events were fatigue, asthenia, headache, and diarrhea.[1]

The FDA granted Breakthrough Therapy Designation (BTD) for MAVYRET for the treatment of acute HCV. The BTD program is designed to expedite the development and review of medicines that are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.[3]

HCV is a highly infectious blood-borne disease affecting the liver.[2] If left untreated, HCV could lead to liver-related complications such as cirrhosis or liver cancer.[2] Acute HCV refers to people recently infected with the virus and can be a short-term illness.[4] However, for many people, acute infection leads to chronic infection.[4] Current global clinical guidance call for the universal treatment of nearly all people with acute or chronic HCV infection.[5] Widespread implementation of these guidelines has the potential to substantially reduce the global spread of the disease.[5]

Led by the World Health Organization, the public health community aims to eliminate HCV as a public health problem by 2030.[6] This involves diagnosing and treating a large portion of those infected, as well as preventing new transmissions through measures like safe injection practices and harm reduction for people who inject drugs. However, approximately 80% of high-income countries, including the U.S., are not on track to achieve this goal until after 2050.[7,8]

About the Phase 3 M20-350 Study[9]

The multicenter, single-arm prospective Phase 3 M20-350 clinical trial was designed to evaluate the safety and efficacy of MAVYRET® (glecaprevir/pibrentasvir) eight-week treatment in adults and pediatric patients with acute HCV infection. The study enrolled 286 treatment-naïve adult patients with acute HCV infection across 70 locations globally. Patients received oral tablets of MAVYRET® once daily for eight weeks and were followed for 12 weeks after the end of treatment. The primary endpoint was the percentage of patients with sustained virological response 12 weeks post-treatment (SVR12) in the Intention-to-Treat (ITT) population. Secondary endpoints included the percentage of patients achieving SVR12 in the Modified ITT-Virologic Failure (mITT-VF) population, and the percentage of patients with on-treatment virologic failure and post-treatment relapse in the ITT population. More information on the study can be found on www.clinicaltrials.gov (NCT04903626).

* For treatment-naïve non-cirrhotic and compensated cirrhotic patients. Liver or kidney transplant recipients are not eligible for an 8-week regimen.
†Cure rate = sustained virologic response (SVR12); HCV RNA less than the lower limit of quantification at 12 weeks after the end of treatment.

About MAVYRET® (glecaprevir/pibrentasvir)

USE

MAVYRET is a prescription medicine used to treat adults and children 3 years of age and older with:

- Acute (recently infected) or 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.
- Hep C genotype 1 infection who have been previously treated with a regimen that contained a hep C NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about MAVYRET?

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

Do not take MAVYRET if you:

- Have moderate or severe liver impairment (Child-Pugh B or C) or any history of prior liver decompensation
- Are taking the medicines atazanavir or rifampin

What should I tell my doctor before taking MAVYRET?

- If you have had hep B infection, have liver problems other than hep C infection, have HIV-1 infection, have had a liver or a kidney transplant, and all other medical conditions.
- If you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed. It is not known if MAVYRET will harm your unborn baby or pass into your breast milk. Talk to your doctor about the best way to feed your baby if you take MAVYRET.
- **About all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. MAVYRET and other medicines may affect each other. This can cause you to have too much or not enough MAVYRET or other medicines in your body. This may affect the way MAVYRET or your other medicines work or may cause side effects.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take MAVYRET with other medicines.

What are the possible side effects of MAVYRET?

- **In people who had or have advanced liver problems before starting treatment with MAVYRET, there is a rare risk of worsening liver problems, liver failure, and death.** Your doctor will check you for signs and symptoms of worsening liver problems during treatment with MAVYRET. Tell your doctor right away if you have any of the following: nausea; tiredness; yellowing of your skin or white part of your eyes; bleeding or bruising more easily than normal; confusion; dark, black, or bloody stool; loss of appetite; diarrhea; dark or brown (tea-colored) urine; swelling or pain on the upper right side of your stomach area (abdomen); sleepiness; vomiting of blood; or lightheadedness.
- The most common side effects of MAVYRET are headache and tiredness.

These are not all the possible side effects of MAVYRET. Call your doctor for medical advice about side effects.

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

MAVYRET oral pellets are dispensed in unit-dose packets. Each packet contains 50 mg glecaprevir/20 mg pibrentasvir.

You 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.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/PatientAccessSupport to learn more.

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 with an emphasis on indications in virology and immunology. Enanta's clinical programs are currently focused on respiratory syncytial virus (RSV) and its earlier-stage immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, including KIT and STAT6 inhibition.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic and acute hepatitis C virus (HCV) infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from HCV products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations. 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 Form 10-K for the fiscal year ended September 30, 2024, and any 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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