# Enanta Pharmaceuticals' Partner AbbVie Receives European Commission Approval of MAVIRET® (Glecaprevir/Pibrentasvir) for People with Acute Hepatitis C Virus

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- *MAVIRET® (Glecaprevir/Pibrentasvir) is the Only Treatment Approved in the European Union for Both Acute and Chronic Hepatitis C Virus (HCV) Infection*
- *Approval Allows Providers to Treat HCV Patients Immediately at Time of Diagnosis; Early Diagnosis and Treatment Help Reduce Transmission, Long-Term Liver-Related Complications, and Support HCV Elimination Efforts*
- *Glecaprevir, One of the Two Direct-Acting Antivirals in MAVIRET®, was Discovered by Enanta and Developed and Commercialized by AbbVie*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jun. 23, 2026-- 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 European Commission has approved MAVIRET® (glecaprevir/pibrentasvir), an oral pangenotypic direct-acting antiviral (DAA) therapy, for the treatment of acute HCV infection without cirrhosis or with compensated cirrhosis in adults and children aged 3 years and older. MAVIRET is now the only treatment approved in the European Union (EU) for both acute and chronic HCV infection.

"The European Commission's approval of MAVIRET for acute HCV infection is a meaningful step for the more than 12 million individuals in Europe living with HCV, by enabling earlier treatment and supporting timely intervention at a stage when the disease may be asymptomatic and can go undetected," said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. "Given acute HCV is typically diagnosed incidentally, starting treatment before a patient has advanced to chronic HCV can be difficult. Today's approval supports public health efforts by accelerating treatment, reducing transmission and addressing unmet need. We take pride in the role our discovery of glecaprevir has played in bringing forward a therapy that continues to benefit HCV patients worldwide. We are pleased that AbbVie continues to collaborate with global regulatory authorities to support access to MAVIRET for people who have acute HCV infection."

The EU approval for acute HCV infection was supported by data from the Phase 3, multicenter, single-arm prospective study evaluating the safety and efficacy of MAVIRET eight-week treatment in patients with acute HCV infection.[1] The study results showed MAVIRET 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, diarrhea, headache, and asthenia.[1]

HCV is a highly infectious, blood-borne disease that affects the liver and if left untreated can lead to serious complications, including liver cirrhosis and cancer.[2] Acute HCV infection is frequently asymptomatic and many people remain unaware of the infection until it has progressed to a later stage.[2] Clinical guidelines support treating nearly all individuals with acute or chronic HCV.[3] Globally, hepatitis C imposes a substantial health and economic burden[4], underscoring the importance of early diagnosis and timely access to treatment.

**About the Phase 3 M20-350 Study[1]**
The multicenter, single-arm prospective Phase 3 M20-350 clinical trial was designed to evaluate the safety and efficacy of MAVIRET (glecaprevir/pibrentasvir) eight-week treatment in adults and adolescent participants aged 12 years and older 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 MAVIRET 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 ($SVR_{12}$) in the intent-to-treat population (ITT). The study met its primary endpoint, with 96.2% of patients in the ITT population achieving $SVR_{12}$ ($p<0.0001$). The key secondary endpoint was also met with 100% of patients in the modified ITT-Virologic Failure population achieving $SVR_{12}$ ($p<0.0001$). The overall safety profile observed in the M20-350 study was similar to that observed in patients with chronic HCV infection. No serious adverse reactions or adverse reactions leading to treatment discontinuation were observed among patients with acute HCV infection. The most commonly reported adverse reactions were fatigue (3%), asthenia (2%), headache (2%), and diarrhea (2%). No on-treatment virologic failures or post-treatment relapses were observed, and post-treatment reinfection occurred in 0.7% of patients. More information on the study can be found at www.clinicaltrials.gov (NCT04903626).

**About MAVIRET® (glecaprevir/pibrentasvir)**
MAVIRET® (glecaprevir/pibrentasvir) is an oral, pangenotypic, once-daily, ribavirin-free direct-acting antiviral treatment for chronic hepatitis C virus (HCV) infection. MAVIRET combines glecaprevir, an NS3/4A protease inhibitor, and pibrentasvir, an NS5A inhibitor, and is administered once daily with food.

In the European Union, MAVIRET is approved for the treatment of chronic HCV infection in adults and children aged 3 years and older. In adults and adolescents aged 12 years and older, or children weighing at least 45 kg, the recommended dose is three 100 mg/40 mg tablets once daily with food. In children aged 3 years to less than 12 years and weighing 12 kg to less than 45 kg, MAVIRET is available as coated granules in sachets, with dosing based on body weight. MAVIRET is approved for use in patients with chronic HCV infection with compensated liver disease, including those with compensated cirrhosis, and in patients with severe renal impairment, including those on dialysis, according to the approved EU label.

**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 (e.g., rifampicin, carbamazepine, St. John's wort [Hypericum perforatum], 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. HBV/HCV co-infected patients are at risk of HBV reactivation, and should, therefore, be monitored and managed according to current clinical guidelines.

**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 NS3/4A and/or NS5A inhibitors.

**Use in diabetic patients**

Diabetics may experience improved glucose control and potential symptomatic hypoglycaemia 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 (≥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 viral infections and immunological diseases. In virology, Enanta's clinical programs are focused on the development of first-in-disease and best-in-disease treatments for respiratory syncytial virus (RSV). The Company's immunology pipeline aims to develop treatments for inflammatory diseases by targeting key drivers of the type 2 immune response, with KIT, STAT6 and MRGPRX2 inhibition.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing 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, 2025, 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.

**References**


[1] MAVIRET® Summary of Product Characteristics. AbbVie; 2026.

[2] Hepatitis C. World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/hepatitis-c. Last accessed: June 2026.

[3] European Association for the Study of the Liver, et al. EASL recommendations on treatment of hepatitis C: Final update of the series. *J Hepatol.* 2020 Nov;73(5):1170-1218.

[4] Cacoub P. Comment on Nuño Solinís R, et al. "Value of Treating All Stages of Chronic Hepatitis C: A Comprehensive Review of Clinical and Economic Evidence". *Infect Dis Ther*. 2017 Jun;6(2):297-301.


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