

## **AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1-6) in as Short as 8 Weeks**

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- MAVYRET is a new 8-week, pan-genotypic treatment for hepatitis C patients without cirrhosis and who are 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 a pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease
- MAVYRET may be used in up to 95 percent of HCV patients, depending on stage of liver disease and prior treatment history\*

NORTH CHICAGO, Ill., Aug. 3, 2017 /PRNewswire/ -- AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) approved 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 who are 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).\*

"With MAVYRET, physicians and patients now have a treatment option that is highly effective and has the potential to cure the majority of HCV patients in as short as 8 weeks, regardless of genotype," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "The approval of MAVYRET demonstrates AbbVie's commitment to advancing science to help address unmet needs by delivering a new cure for patients who historically had limited treatment options, including those with genotype 3 HCV, individuals with CKD and certain DAA failure patients."

Approximately 3.4 million Americans are chronically infected with HCV.<sup>1</sup> Additionally, HCV is common among people with severe CKD, with an estimated more than 500,000 people having both chronic HCV and CKD.<sup>2</sup> MAVYRET was designed to deliver a cure\*\* across all major genotypes and 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) 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 clinical trial program for MAVYRET resulted in high cure rates across a range of patient populations, from those who have never been treated and who do not have cirrhosis, all the way to patients with compensated cirrhosis," said Fred Poordad, M.D., vice president, academic and clinical affairs, Texas Liver Institute and professor of

medicine, University of Texas Health, San Antonio. "This approval helps achieve physicians' goals of delivering effective options for a broad range of patients."

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.

Approval of MAVYRET follows an FDA-granted Breakthrough Therapy Designation for the treatment of GT1 HCV patients who were not cured with prior DAA therapy, as well as Priority Review. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of therapies for serious or life-threatening conditions, which may offer substantial improvement over available therapies.

AbbVie's pan-genotypic regimen was also recently granted marketing authorization by the European Commission. AbbVie's treatment 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.*

*#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 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.