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PRESS RELEASE

AbbVie Receives CHMP Positive Opinion for MAVIRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6)

- *If approved, MAVIRET™ will provide a shorter, 8-week, pan-genotypic (GT1-6), once-daily option for the majority of people living with the hepatitis C virus (HCV)[1]**
- *MAVIRET would also be an additional HCV treatment option for patients with specific treatment challenges, such as those with compensated cirrhosis, chronic kidney disease and genotype 3*
- *Final European Commission decision expected Q3 2017*

NORTH CHICAGO, Ill., June 23, 2017 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion recommending marketing authorisation of MAVIRET™ (glecaprevir/pibrentasvir), an investigational, pan-genotypic treatment for adults with chronic hepatitis C virus (HCV) infection. If approved, MAVIRET will be a once-daily, ribavirin-free, 8-week option for patients without cirrhosis and who are new to treatment across all genotypes (GT1-6), who comprise the majority of people living with HCV.[1] The European Commission will now review the CHMP opinion and a final decision is expected in Q3 2017.

“MAVIRET represents a new generation of HCV therapy and has the potential to be a shorter, 8-week option for patients living with this serious, chronic illness,” said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. “Today’s CHMP positive opinion takes us closer to delivering on AbbVie's mission to address continued unmet needs by bringing a new pan-genotypic option to people living with HCV in Europe.”

The CHMP positive opinion is supported by 97.5 percent (n=807/828) SVR_{12} rates with 8 weeks of MAVIRET across GT1-6 chronic HCV infected patients without cirrhosis and who are new to treatment, with varied patient and viral characteristics.[2] In an integrated analysis (n=2,265), less than 0.4 percent of patients discontinued treatment.[3] The reported adverse reactions (incidence greater than or equal to 10 percent) were headache and fatigue.[3] The type and severity of adverse reactions in patients with cirrhosis were overall comparable to those seen in patients without cirrhosis.[3]

“While the HCV treatment landscape has transformed significantly over recent years, the disease continues to be a global public health problem and treatment challenges remain,” said Stefan Zeuzem, M.D., chief of the department of medicine at the J.W. Goethe University Hospital in Frankfurt, Germany. “In clinical studies, MAVIRET demonstrated high SVR rates across all genotypes of HCV patients (GT1-6). If approved, MARIVET would remove many of the complexities of pre-treatment patient evaluation and has the potential to help facilitate the care and management of HCV.”

MAVIRET is also intended to be an additional option for patients with specific treatment challenges. This includes chronic HCV patients with compensated cirrhosis (Child-Pugh A), and those who currently have limited treatment options, such as patients with severe chronic kidney disease, including those on dialysis, and patients infected with genotype 3.

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The marketing authorisation application (MAA) for MAVIRET is under an accelerated assessment by the EMA, which is granted to new medicines of major public health interest. The MAA evaluation is conducted under the centralised licensing procedure, and if approved, will result in a marketing authorisation valid in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway. AbbVie's investigational, pan-genotypic regimen has also been granted accelerated review designations by other regulatory authorities including the U.S. Food and Drug Administration and Japanese Ministry of Health, Labour and Welfare. MAVIRET is an investigational regimen and its safety and efficacy have not been established.

About MAVIRET™ (glecaprevir/pibrentasvir)
AbbVie's MAVIRET™ (glecaprevir/pibrentasvir) clinical development programme was designed to investigate a pan-genotypic, once-daily, ribavirin-free treatment with the potential to provide a faster path to virologic cure** for all major HCV genotypes (GT1-6) and with the goal of addressing specific treatment challenges, including compensated cirrhosis (Child-Pugh A), chronic kidney disease and genotype 3. MAVIRET is being evaluated as a potential 8-week, pan-genotypic treatment for the majority of people living with HCV,[1] those without cirrhosis and who are new to treatment,* and regardless of viral and patient characteristics.

MAVIRET is a fixed-dose combination of two distinct antiviral agents: glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

Glecaprevir was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

**Patients who are treatment-naive or had prior treatment experience with IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).*
***Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR_{12}) are considered cured of hepatitis C.*

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.co.uk.

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[1] Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017
[2] Puoti et al. High SVR rates with 8 and 12 weeks of pan-genotypic G/P: integrated efficacy analysis of genotype 1–6 patients without cirrhosis. Presented at: 52nd Annual Meeting of the European Association for the Study of the Liver; April 19-23, 2017; Amsterdam, the Netherlands. Poster SAT-233.
[3] Dufour et al Safety of Glecaprevir/Pibrentasvir in Adults With Chronic Genotype 1–6 FRI-238 Hepatitis C Virus Infection: An Integrated Analysis