PRESS RELEASE

AbbVie's MAVIRET™ Approved by Health Canada for the Treatment of Chronic Hepatitis C in All Major Genotypes

- *MAVIRET is the first and only 8-week, pan-genotypic treatment for hepatitis C patients without cirrhosis and who are new to treatment*[*1]*
- *The approval is supported by a 97 percent (n=639/657) cure*[**]* *rate across GT1-6 patients without cirrhosis and who are new to treatment*[2]*
- *MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease*

MONTREAL, QC, August 17, 2017 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that Health Canada has granted approval for MAVIRET™ (glecaprevir/pibrentasvir tablets), a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6). MAVIRET is the only 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment,[*] who make up a large portion of HCV patients in Canada.

"Despite recent advances in HCV treatment, physicians still face challenges treating patients with less common genotypes and those with other complicating health conditions," said Dr. Morris Sherman, MD, FRCPC, Chairperson, Canadian Liver Foundation. "In order to eliminate hepatitis C in Canada, we need to identify all those living with the virus and have effective treatment options for everyone. This new therapy provides another tool for physicians to expand treatment to a greater number of patients while at the same time shortening the duration which may lead to cost savings for the health care system."

MAVIRET is also approved for use in patients with specific treatment challenges, including those with compensated cirrhosis across all major genotypes, and those who previously had limited treatment options, such as patients with severe chronic kidney disease (CKD), those GT1 patients not previously cured with certain direct-acting antiviral (DAA) treatment, and those with GT3 chronic HCV infection.[2] MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of CKD.[2]

"With the approval of MAVIRET, we are proud to bring the hope of a new cure to people living with hepatitis C in Canada, reflecting AbbVie's dedication to addressing critical unmet needs for patients," said Stéphane Lassignardie, General Manager, AbbVie Canada. "MAVIRET is designed to deliver a virologic cure for most HCV patients including those with specific treatment challenges. AbbVie will continue to work with local health authorities and stakeholders across Canada to get our treatment to as many patients as possible."

The efficacy and safety of MAVIRET was evaluated in nine Phase 2-3 clinical trials, in over 2,300 patients with genotype 1, 2, 3, 4, 5 or 6 HCV infection and with compensated liver disease (with or without cirrhosis).

Approximately 300,000 Canadians are infected with hepatitis C.[3] In 2012 alone, more than 10,000 new cases of hepatitis C were reported, but 40 percent of patients are estimated to be living unaware of their disease.[4] GT1 is the most common genotype in Canada and GT3 is the most difficult to treat.[3,5] Over time chronic hepatitis C can lead to chronic liver diseases, with a risk of developing cirrhosis of up to 30 percent within 20 years[6] of infection. Additionally, HCV is common among people with severe CKD, and some of these patients previously did not have a DAA-based treatment option.[7]

With 8 weeks of treatment, 97 percent (n= 639/657) of GT1-6 patients without cirrhosis and who were new to treatment achieved a virologic cure.[1] These high cure rates were achieved in patients with varied patient and viral characteristics and including those with CKD.[2] Additionally, 97.5 percent (n=274/281) of patients with compensated cirrhosis achieved a virologic cure with the recommended duration of treatment, including patients with CKD.[2] In registrational studies for MAVIRET, less than 0.1 percent of patients permanently discontinued treatment due to adverse reactions.[2] The most commonly reported adverse reactions (incidence greater than or equal to 10 percent) were headache and fatigue.[2]

“In an extensive clinical trial program, patients achieved high cure rates with MAVIRET regardless of genotype, fibrosis score, viral load, and even in patients with resistant virus strains and those with chronic kidney disease,” said Dr. Magdy Elkhashab, Gastroenterologist/Hepatologist, Director of the Toronto Liver Centre. “In clinical practice, MAVIRET has the potential to simplify treatment decisions for physicians, offering, in one therapy, a cure for the majority of HCV patients and cutting out pre-testing before treatment initiation.”

MAVIRET combines two new, potent direct-acting antivirals that target and inhibit proteins essential for the replication of the hepatitis C virus.[2] The presence of most genotypes or baseline mutations that are commonly associated with resistance have been shown to have no relevant impact on efficacy. [2]

Canadians prescribed MAVIRET will have the opportunity to be enrolled in AbbVie Care, AbbVie’s signature patient support program designed to provide a wide range of services including reimbursement assistance, education and ongoing disease management support. AbbVie Care will support people living with HCV throughout their treatment journey to achieve high cure rates in the real world.

Approval of MAVIRET followed Health Canada’s Priority Review process, which is granted to new medicines intended for patients with a life-threatening disease where there is no existing treatment with the same profile or where the new product represents a significant improvement in the benefit/risk profile over existing products.[8] AbbVie's investigational, pan-genotypic regimen was also recently approved by the European Commission and the U.S. Food and Drug Administration.

About MAVIRET™

MAVIRET™ is approved in Canada for the treatment of chronic hepatitis C virus (HCV) infection in adults across all major genotypes (GT1-6).[2] MAVIRET is a new, pan-genotypic, once-daily, ribavirin-free treatment that combines glecaprevir (100 mg), an NS3/4A protease inhibitor, and pibrentasvir (40 mg), an NS5A inhibitor, dosed once-daily as three oral tablets.[2]

MAVIRET is an 8-week, pan-genotypic virologic cure[**] for use in patients without cirrhosis and who are new to treatment,[*] such patients comprising the majority of people living with HCV.[1] MAVIRET is also approved as a treatment for patients with specific treatment challenges, including those with compensated cirrhosis across all major genotypes, and those who previously had limited treatment

options, such as patients with severe chronic kidney disease (CKD) and those with genotype 3 infection.[2] It is the only pan-genotypic treatment approved for use in patients across all stages of CKD.[2]

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.

**Patients without cirrhosis and new to treatment with DAAs [either treatment-naive or not cured with previous 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.ca and www.abbvie.com. Follow @abbvieCanada and @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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[1] Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017.
[2] MAVIRET (glecaprevir/pibrentasvir tablets) Product Monograph. Date of Preparation: August 16, 2017.
[3] Messina, JP et al. "The global distribution of HCV genotypes." Hepatology, 2015; 61: 77–87. Supporting information hep27259-sup-0001-suppinfo.pdf. Accessed August, 2017.
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[5] Wyles, D et al. SURVEYOR-II, Part 3: Efficacy and Safety of ABT-493/ABT-530 in Patients with Hepatitis C Virus Genotype 3 Infection with Prior Treatment Experience and/or Cirrhosis. Presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, US on November 11-15, 2016.
[6] Hepatitis C Fact Sheet. World Health Organization. World Health Organization, July 2017. Web. http://www.who.int/mediacentre/factsheets/fs164/en/. Accessed August, 2017.
[7] Fabrizi F, Poordad FF, Martin P. Hepatitis C infection in the patient with end stage renal disease. Hepatology. 2002;36(1):3-10.
[8] Priority Review of Drug Submissions. Government of Canada. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/priority-review-drug-submissions-therapeutic-products.html. Accessed August, 2017.