PRESS RELEASE

AbbVie Announces New Formulary Listings for its Hepatitis C Treatment MAVIRET™

- *Alberta, Saskatchewan and the Non-Insured Health Benefits (NIHB) Program list MAVIRET on their formularies*
- *MAVIRET is the first and only 8-week, pan-genotypic treatment for chronic hepatitis C patients without cirrhosis and who are new to treatment*[*1]
- *MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease*

MONTREAL, QC, April 4, 2019 – AbbVie (NYSE: ABBV), a global, research and development-based biopharmaceutical company, announced that MAVIRET™ (glecaprevir/pibrentasvir tablets) is now reimbursed in Alberta, Saskatchewan and the Non-Insured Health Benefits (NIHB) Program. MAVIRET is a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6).[2] It is the only 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment.[*]

“Hepatitis C is a public health issue that affects approximately 300,000 Canadians. Over time, chronic hepatitis C can lead to cirrhosis, liver cancer and death,” explains Dr. Samuel S. Lee, MD, Professor of Medicine and hepatologist at the University of Calgary. “In order to reach the elimination target set by the World Health Organization, we not only need concerted efforts by governments, health care professionals and patient associations, but as well access to curative treatments like MAVIRET.”

In Alberta, MAVIRET is listed effective April 1, 2019, under Special Authorization on the AB Health Drug Benefit List for treatment-naïve or treatment-experienced adult patients with chronic hepatitis C infection who meet all of the following criteria[3]:

1. Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available); AND
2. Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6; AND
3. Laboratory confirmed quantitative HCV RNA value within the last 6 months; AND
4. Fibrosis stage of F0 or greater (Metavir scale or equivalent).

“Saskatchewan remains in the midst of a unique hepatitis C (HCV) epidemic, with many more young persons and women infected compared to the rest of Canada. Increased screening and testing is needed as many persons remain undiagnosed, and enhanced supports are required to link those diagnosed to treatment and care," said Dr. Alexander Wong, MD, FRCPC, assistant professor of Infectious Diseases, University of Saskatchewan. “Having a new treatment option like MAVIRET, which can cure nearly all uncomplicated HCV-infected persons in only eight weeks, is a welcome and exciting addition to the drug formulary in Saskatchewan."

In Saskatchewan, MAVIRET is listed effective April 1, 2019, on the Saskatchewan formulary as an Exception Drug Status (EDS) product, for treatment naïve and treatment experienced adult patients with chronic hepatitis C infection (regardless of fibrosis stage) according to the following criteria[4]:

1. Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6; AND
2. Laboratory confirmed quantitative HCV RNA value within the last six months; AND
3. Treatment is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other prescriber experienced in the treatment of hepatitis C as determined by the Drug Plan.

For the Non-Insured Health Benefits program (NIHB), MAVIRET is listed effective April 1, 2019, under Limited Use on the NIHB Drug Benefit List for treatment-naïve or treatment-experienced adult patients with chronic hepatitis C infection who meet all of the following criteria:

1. Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available); AND
2. Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6; AND
3. Laboratory confirmed quantitative HCV RNA value within the last 6 months; AND
4. Fibrosis stage of F0 or greater (Metavir scale or equivalent).

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).

About MAVIRET™

MAVIRET™ is indicated in Canada for the treatment of chronic hepatitis C virus (HCV) infection in adults across all major genotypes (GT1-6).[5] MAVIRET is a 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.[5]

MAVIRET is an 8-week, pan-genotypic virologic cure[**] for use in patients without cirrhosis and who are new to treatment,[*1] such patients comprising the majority of people living with HCV. 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), post-liver and -renal transplant recipients *** and those patients with genotype 3 infection.[5] It is the only pan-genotypic treatment approved for use in patients across all stages of CKD.[5]

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.*

****MAVIRET is recommended for 12 weeks in liver or kidney transplant recipients who are HCV GT-1 to 6 treatment-naïve (TN) or GT-1, -2, -4, -5, -6 PRS- treatment experienced. A 16-week treatment duration should be considered in transplant patients who are GT-1 NS5A inhibitorexperienced (NS3/4A inhibitor-naïve) or GT-3 PRS- treatment experienced.*

About AbbVie

AbbVie is a global, research and development-based 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.

###

Media:
Muriel Haraoui
AbbVie Canada
(514) 717-3764
muriel.haraoui@abbvie.com

[1] Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017.
[2] CADTH Canadian Drug Expert Committee Recommendation – Final: https://www.cadth.ca/sites/default/files/cdr/complete/SR0523_Maviret_complete-Jan-25-18.pdf. Accessed April 2019.
[3] Alberta Health. https://idbl.ab.bluecross.ca/idbl/lookupCoverageCriteria.do?productID=0000084466&priceListID=0013. Accessed April 2019.
[4] Government of Saskatchewan. Saskatchewan Drug Plan. http://formulary.drugplan.ehealthsask.ca/PDFs/APPENDIXA.pdf. Accessed April 2019.
[5] MAVIRET (glecaprevir/pibrentasvir tablets) Product Monograph. Date of Preparation: August 16, 2017. Date of Revision: November 28, 2018. http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/MAVIRET_PM_EN.pdf. Accessed April 2019.