

## PRESS RELEASE

### AbbVie reaches an agreement with the pan-Canadian Pharmaceutical Alliance (pCPA) for its hepatitis C treatment MAVIRET™

- Ontario will be the first province to reimburse MAVIRET as of February 28, 2019
- MAVIRET is the first and only 8-week, pan-genotypic treatment for chronic hepatitis C patients without cirrhosis and who are new to treatment<sup>\*1</sup>
- MAVIRET previously received positive reimbursement recommendations from the CADTH Canadian Drug Expert Committee (CDEC)<sup>2</sup> in January 2018 and the Institut national d'excellence en santé et services sociaux (INESSS) in February 2018
- MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease

MONTREAL, QC, February 21, 2019 – AbbVie (NYSE: ABBV), a global, research and development-based biopharmaceutical company, announced an agreement was reached with the pan-Canadian Pharmaceutical Alliance (pCPA) regarding 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)<sup>2</sup>. MAVIRET is the only 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment,<sup>\*</sup> who make up a large portion of HCV patients in Canada.

Following the positive conclusion with the pCPA, Ontario will be the first province to reimburse MAVIRET on its public formulary as of February 28, 2019. As listed on the Ontario Drug Benefit (ODB)<sup>3</sup> Formulary as a Limited Use product, MAVIRET will be covered for *treatment-naïve and treatment-experienced adult patients with chronic hepatitis C infection (regardless of fibrosis stage)*<sup>3</sup>:

- Laboratory confirmed hepatitis C genotype 1,2,3,4,5,6
- HCV RNA value within the last six months

\*\*\*Prescription by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C).

“After more than 20 years of treating hepatitis C, I am hopeful that soon we will successfully eliminate this virus. But in order to reach this goal in Canada and across the world, we need to work together to test, diagnose and bring these high curative treatments to every individual, regardless of their genotype, fibrosis stage and background,” explains Dr. Magdy Elkhatab, Gastroenterologist/Hepatologist, Director of the Toronto Liver Centre. “As a hepatologist, MAVIRET offers me the opportunity to put my patients on an effective, short duration therapy that has a proven track record.”

Approximately 300,000 Canadians are infected with hepatitis C.<sup>4</sup> Over time chronic hepatitis C can lead to chronic liver diseases, with a risk of developing cirrhosis of up to 30 per cent within 20 years<sup>5</sup> of infection. Additionally, HCV is common among people with severe chronic kidney disease (CKD), and some of these patients previously did not have a direct-acting antiviral (DAA)-based treatment option.<sup>6</sup>

“The Canadian Liver Foundation is committed to seeing Canada meet the target set by the World Health Organization’s Global Strategy on Viral Hepatitis. And that target is to eliminate hepatitis C by 2030. It is within our reach, but all our elimination efforts require support, plans and concrete actions at the local level to combat the increasing burden of HCV infection and the associated stigma,” says Dr. Morris Sherman, Chairman of the Canadian Liver Foundation and Toronto-based hepatologist. “To be successful, we need a comprehensive screening strategy based on risk factors, plus a one-time test for all Canadians born 1945 – 1975<sup>7</sup>, as well as adapted linkage to care to allow access to all available treatment options for all Canadians.”

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).

“AbbVie is committed to the World Health Organization’s targets and looks forward to working with governments, health care professionals and patient associations in their concerted efforts to achieve HCV elimination in Canada,” explains Stéphane Lassignardie, General Manager, AbbVie Canada. “MAVIRET brings value in order to achieve elimination and all Canadians should have access to innovative and curative therapies.”

#### **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).<sup>8</sup> 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.<sup>8</sup>

MAVIRET is an 8-week, pan-genotypic virologic cure<sup>\*\*</sup> for use in patients without cirrhosis and who are new to treatment,<sup>\*1</sup> 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) and those with genotype 3 infection.<sup>8</sup> It is the only pan-genotypic treatment approved for use in patients across all stages of CKD.<sup>8</sup>

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<sub>12</sub>) are considered cured of hepatitis C.*

#### **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

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<sup>1</sup> Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017.

<sup>2</sup> CADTH Canadian Drug Expert Committee Recommendation – Final:  
[https://www.cadth.ca/sites/default/files/cdr/complete/SR0523\\_Maviret\\_complete-Jan-25-18.pdf](https://www.cadth.ca/sites/default/files/cdr/complete/SR0523_Maviret_complete-Jan-25-18.pdf). Accessed February 2019.

<sup>3</sup> Ontario Drug Benefit Formulary/Comparative Drug Index Edition 43. Summary of Changes – February 2019. Effective February 28, 2019. [http://www.health.gov.on.ca/en/pro/programs/drugs/formulary43/summary\\_edition43\\_20190220.pdf](http://www.health.gov.on.ca/en/pro/programs/drugs/formulary43/summary_edition43_20190220.pdf). Accessed February 2019.

<sup>4</sup> The Canadian Liver Foundation. <https://www.liver.ca/how-you-help/advocate/>. Accessed February 2019.

<sup>5</sup> Hepatitis C Fact Sheet. World Health Organization. World Health Organization, July 2017. Web.  
<http://www.who.int/mediacentre/factsheets/fs164/en/>. Accessed February 2019.

<sup>6</sup> Fabrizi F, Poordad FF, Martin P. Hepatitis C infection in the patient with end stage renal disease. *Hepatology*. 2002;36(1):3-10.

<sup>7</sup> The Canadian Liver Foundation, press release: <https://www.newswire.ca/news-releases/not-getting-the-message-too-many-canadians-born-between-1945-1975-unaware-of-their-increased-risk-of-undiagnosed-hepatitis-c-587783871.html>. Accessed February 2019.

<sup>8</sup> MAVIRET (glecaprevir/pibrentasvir tablets) Product Monograph. Date of Preparation: August 16, 2017.  
[http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/MAVIRET\\_PM\\_EN.pdf](http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/MAVIRET_PM_EN.pdf). Accessed February 2019.