



PRESS RELEASE

AbbVie receives a positive recommendation from the CADTH Canadian Drug Expert Committee for MAVIRET™ – an oral therapy for the treatment of patients with hepatitis C

- *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 previously received a Notice of Compliance from Health Canada on August 16, 2017*
- *MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of chronic kidney disease*

MONTREAL, QC, February 6, 2018 – AbbVie (NYSE: ABBV), a global, research and development-based biopharmaceutical company, announced that the CADTH Canadian Drug Expert Committee (CDEC) issued a positive recommendation 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)². 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.

The recommendation states that glecaprevir/pibrentasvir be reimbursed for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis, including patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors, if specific conditions are met.³

“Continued efforts are fundamental to the ultimate goal of eliminating hepatitis C, which is a serious and complex disease in Canada. It is vital that as many patients as possible are able to achieve a virologic cure, as quickly as possible, and we hope that patients throughout Canada will be able to benefit from this latest treatment, which has the potential to cure most HCV patients in eight weeks,” states Dr. Samuel Lee, Hepatologist and Professor, Cumming School of Medicine, University of Calgary.

Approximately 300,000 Canadians are infected with hepatitis C.⁴ 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.⁵ GT1 is the most common genotype in Canada and GT3 is the most difficult to treat.^{4,6} Over time chronic hepatitis C can lead to chronic liver diseases, with a risk of developing cirrhosis of up to 30 percent within 20 years⁷ 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.⁸

“Our goal is to see Canada meet its commitment to the World Health Organization’s Global Strategy on Viral Hepatitis by eliminating hepatitis C by 2030. This is within our reach, but we need a coordinated

national response with a comprehensive action plan to prevent, screen, diagnose and treat Canadians living with hepatitis C,” says Dr. Morris Sherman, Chairman of the Canadian Liver Foundation and Toronto-based hepatologist. “The Canadian Liver Foundation recommends screening for hepatitis C based on risk factors, plus a one-time test for all Canadians born 1945 – 1975⁹. Furthermore, treatment eligibility restrictions that currently exist need to be removed, so that physicians and their patients have affordable and equitable access to all available treatment options, regardless of background, disease severity or the province in which they live.”

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 deeply committed to curing Canadians of hepatitis C. We strongly believe in providing patient and doctor choice when selecting the appropriate medication,” explains Stéphane Lassignardie, General Manager, AbbVie Canada. “The CADTH positive recommendation reinforces our belief that there is a need for innovative therapies like MAVIRET in order to reach the goal set out by the World Health Organization to eliminate HCV by 2030 in Canada and across the world.”

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,^{*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) 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-naïve 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 (SVR₁₂) 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

www.abbvie.ca and www.abbvie.com. Follow [@abbvieCanada](https://twitter.com/abbvieCanada) and [@abbvie](https://twitter.com/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 CADTH Canadian Drug Expert Committee Recommendation – Final:

https://www.cadth.ca/sites/default/files/cdr/complete/SR0523_Maviret_complete-Jan-25-18.pdf. Accessed February 2018.

⁴ Messina, JP et al. "Global distribution and prevalence of hepatitis C virus genotypes." *Hepatology*, 2015; 61: 77–87. Supporting information <http://onlinelibrary.wiley.com/doi/10.1002/hep.27259/full>. Accessed January 2018.

⁵ Hepatitis C: Get the Facts. Government of Canada. <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/poster-hepatitis-c-get-facts.html>. Accessed February 2018.

⁶ 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.

⁷ Hepatitis C Fact Sheet. World Health Organization. World Health Organization, July 2017. Web.

<http://www.who.int/mediacentre/factsheets/fs164/en/>. Accessed February 2018.

⁸ Fabrizi F, Poordad FF, Martin P. Hepatitis C infection in the patient with end stage renal disease. *Hepatology*. 2002;36(1):3-10.

⁹ 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 2018.