

## PRESS RELEASE

### Health Canada Approves MAVIRET® 8-Week Treatment Duration for Treatment-Naïve Patients with Genotype 3 Compensated Cirrhosis

- *MAVIRET® (glecaprevir/pibrentasvir) is the only 8-week oral treatment approved for all Hepatitis C virus (HCV) Genotypes.<sup>1</sup>*
- *MAVIRET is indicated for the treatment of chronic HCV infection in adults and adolescent patients 12 to 18 years of age.<sup>1</sup>*
- *MAVIRET is available and reimbursed across Canada. \*\**

MONTREAL (Quebec), November 10, 2020 – AbbVie (NYSE: ABBV), a global, research and development-based biopharmaceutical company announced today that Health Canada has approved a label change for MAVIRET® (glecaprevir/pibrentasvir tablets) to include Treatment-Naïve Genotype 3 patients with compensated cirrhosis.<sup>1</sup> With this change, the recommended treatment duration for ALL individuals\* with chronic hepatitis C virus (HCV) infection who are treatment naïve, genotypes 1-6 with/or without compensated cirrhosis is 8 weeks.

“I witness the destructive effects hepatitis C has on patients, our community and healthcare system. At the Ottawa Hospital, we see thousands of people on a yearly basis with a variety of liver diseases. Having access to effective HCV treatment options that cover all hepatitis C genotypes is a game changer,” said Dr. Curtis Cooper, Director, The Ottawa Hospital and Regional Hepatitis Program. “We now have an opportunity to eliminate this deadly virus with testing, treatment and care in shorter periods of time also available for patients with Genotype 3”

“In 2016, Canada committed on the world stage to eliminate viral hepatitis by 2030. In order to accomplish this important goal, we need population-specific strategies that include equitable access to scaled-up testing and treatment,” said, Gerard Yetman, Chair, Action Hepatitis Canada (AHC). “If we want to eliminate hepatitis C in Canada, we need public access to effective treatment options that cover all genotypes.”

Health Canada first approved MAVIRET in August 2017. MAVIRET is a once-daily ribavirin-free treatment for adults and adolescent patients 12 to 18 years of age with chronic hepatitis C virus infection across all major HCV genotypes (GT1-6).<sup>2</sup> It is an 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment.\*

MAVIRET’s efficacy and safety were evaluated in nine phase II-III clinical trials, in over 2300 patients with genotype 1, 2, 3, 4, 5 or 6 HCV infection and with compensated liver disease (with or without cirrhosis).<sup>1</sup>

“AbbVie is committed to eliminating hepatitis C by 2030 and sees this objective as a national public health priority. Through meaningful partnerships, we are working to find sustainable solutions that allow more patients to be screened, linked to care, and treated sooner,” said Denis Hello, Vice-President and General Manager AbbVie Canada.

## About Hepatitis C

An estimated 250,000 people in Canada are living with chronic hepatitis C but as many as 44% are not aware that they have it.<sup>3</sup> Left undiagnosed and untreated, chronic hepatitis C can lead to cirrhosis, liver cancer or liver failure. Currently, hepatitis C is the leading indication for liver transplant in Canada.<sup>4</sup> AbbVie supports a range of efforts to help elevate and prioritize HCV elimination because we know achieving the shared goal of elimination by 2030 will take more than medicine. It will take transparent and collaborative partnerships with all stakeholders – industry, healthcare providers, healthcare systems, patient groups and their support networks. Joint efforts and maximizing the time we have left will enable us to reach this goal.

## About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at [www.abbvie.ca](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow [@abbviecanada](https://twitter.com/abbviecanada) on Twitter or find us on [Facebook](#), [LinkedIn](#) and [Instagram](#).

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\* The safety and efficacy of MAVIRET in patients less than 12 years of age have not been established. MAVIRET exposures in HCV-infected patients 12 to 18 years were comparable to those in HCV-infected adults; however, the safety and efficacy of MAVIRET in patients 12 to 18 years infected with HCV genotype 5 or 6 and/or with compensated cirrhosis and/or previously treated with a regimen containing NS5B inhibitor have not been studied.

\*\* Please refer to your province's or Territory's specific reimbursement criteria.

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<sup>1</sup> [AbbVie Corporation MAVIRET \(glecaprevir/pibrentasvir tablets\) Product Monograph. Date of Preparation: August 16, 2017. Date of Revision: October 30, 2020.](#)

<sup>2</sup> CADTH Canadian Drug Expert Committee Recommendation – Final. [www.cadth.ca/sites/default/files/cdr/complete/SR0523\\_Maviret\\_complete-Jan-25-18.pdf](http://www.cadth.ca/sites/default/files/cdr/complete/SR0523_Maviret_complete-Jan-25-18.pdf). Accessed September 2020.

<sup>3</sup> Canadian Network on Hepatitis C (CanHepC). Blueprint to inform hepatitis C elimination efforts in Canada. [https://www.canhepc.ca/sites/default/files/media/documents/blueprint\\_hcv\\_2019\\_05.pdf](https://www.canhepc.ca/sites/default/files/media/documents/blueprint_hcv_2019_05.pdf) Accessed September 2020.<sup>4</sup>The

<sup>4</sup> Canadian Liver Foundation. [www.liver.ca/how-you-help/advocate/](http://www.liver.ca/how-you-help/advocate/). Accessed September 2020.