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PRESS RELEASE

MAVIRET® (glecaprevir/pibrentasvir) Approved by Health Canada for Pediatric Patients with Chronic Hepatitis C

- *MAVIRET can now be used as an 8-week, once-daily paediatric granule formulation option in treatment-naïve, without cirrhosis or with compensated cirrhosis, chronic Hepatitis C (HCV) paediatric patients aged 3 to <12 years with genotype (GT)1-6, weighing at least 12kg to less than 45kg*
- *Health Canada's decision makes MAVIRET the first pan-genotypic treatment option for treatment-naïve, compensated cirrhotic, chronic HCV patients as young as 3 years of age and weighing 12kg or more*
- *This approval is supported by 98.4 per cent cure* rate across this group of patients who received the approved paediatric granule formulation*

Montreal, QC, June 22, 2022 – AbbVie (NYSE: ABBV) announced today that Health Canada has approved a change in the marketing authorization for MAVIRET® (glecaprevir/pibrentasvir) to include its use for the treatment in paediatric patients 3 to 12 years old, weighing at least 12kg to less than 45kg.[1] MAVIRET is now approved as an 8-week, pan-genotypic (GT1-6) treatment for treatment-naïve, chronic HCV patients, without cirrhosis or with compensated cirrhosis in adults and children aged 3 years and older.[1**]

“There is an estimated 250,000 people living in Canada with chronic hepatitis C including young children who I have witnessed first-hand at SickKids in need of treatment options,” said Dr. Simon Ling, MBChB, MRCP(UK), Division of Gastroenterology, Hepatology and Nutrition, SickKids Toronto. “The approval of MAVIRET® as a paediatric indication is a necessary step that will add a beneficial therapeutic option to treat HCV infection in children.”

The label extension is supported by data from the phase 2/3, non-randomized, open-label, multicenter DORA Part 2 study evaluating the safety and efficacy of weight-based dosing of glecaprevir/pibrentasvir (G/P) granules for 8, 12 or 16 weeks in 80 children aged 3 years to less than 12 years with chronic HCV infection.[1] Patients received a paediatric formulation of glecaprevir (GLE)/pibrentasvir (PIB), comprised of film-coated granules of GLE and PIB, in a sachet mixed together in a small amount of soft food for once-daily oral administration. The mixture of food and granules should be swallowed immediately; the granules should not be crushed or chewed.[1]

“With Canada’s commitment to eliminating viral hepatitis as a public health threat by 2030, the approval of MAVIRET ® for paediatric patients is a positive advancement in reaching our goals,” said Jennifer van Gennip, Executive Director, Action Hepatitis Canada. “Now with access to treatment of viral hepatitis amongst children, one more barrier to elimination is removed.”

In DORA Part 2, the overall SVR12 rate for the subjects who received the final recommended dose was 98.4% (61/62)[1]. No subject taking the final recommended dose experienced virologic failure[1]. The adverse reactions observed in patients 3 less than 12 years of age were consistent with those observed in clinical trials of MAVIRET in adults with the exception of vomiting (occurring at approximately 8%),

rash, and abdominal pain upper (each occurring at approximately 4%) which were observed more frequently than in adults.[1]

“MAVIRET has had a significant impact on the lives of people affected by chronic HCV, and we are pleased that pediatric patients are now also able to benefit from this treatment option,” said Tracey Ramsay, Vice-president and General Manager, AbbVie Canada. "We are committed to helping achieve the World Health Organization’s 2030 goal of HCV elimination and we believe Health Canada’s expanded approval for MAVIRET will help Canadians to get one step closer.”

About the DORA part 2 Study[2]

The efficacy, safety and pharmacokinetics of G/P in children 3 years to less than 18 years old was demonstrated in an open-label study which was comprised of two parts, DORA Part 1[3] and Part 2[2].

DORA Part 2 evaluated the safety and efficacy of weight-based dosing of G/P granules for 8, 12 or 16 weeks in 80 children aged 3 years to less than 12 years. 18 subjects received the initial lower dose, and 62 subjects received the final recommended dose. The median age was 7 years (range: 3 to 11); 73% had HCV genotype 1, 3% had genotype 2, 23% had HCV genotype 3, 3% had HCV genotype 4; 55% were female; 4% were Black; 97.5% were HCV TN; 2.5% were treatment-experienced to interferon; 1% had HIV-coinfection; none had cirrhosis; the mean weight was 25 kg (range: 13 to 44). In DORA Part 2, the overall SVR12 rate for the subjects who received the final recommended dose was 98.4% (61/62). No subject taking the final recommended dose experienced virologic failure. One 9-year-old child with HCV GT3b infection, who had received the initial lower dose, experienced virologic failure. The child had K30R and V31M at baseline and treatment-emergent Y93H at relapse in NS5A; baseline or treatment-emergent substitutions were not detected in NS3. The pattern of adverse reactions observed was comparable with that observed in clinical studies of G/P film-coated tablets in adolescents and adults.

About MAVIRET™ (glecaprevir/pibrentasvir)[1,2]

MAVIRET® is approved by Health Canada for the treatment of chronic hepatitis C virus (HCV) infection in adults and children 3 years and older across all major genotypes (GT1-6). MAVIRET is a pan-genotypic, once-daily, ribavirin-free treatment that combines glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor, dosed once-daily as three oral tablets. The new paediatric formulation consists of MAVIRET coated granules in sachet. Each sachet contains 50mg of glecaprevir and 20mg of pibrentasvir. The recommended dosage in number of sachets is based on body weight for children[1].

MAVIRET is an 8-week, pan-genotypic option for patients without cirrhosis and who are new to treatment[**]. 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[1] disease (CKD). MAVIRET is a pan-genotypic treatment approved for use in patients across all stages of CKD.

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.

MAVIRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C) and is not recommended in patients with moderate hepatic impairment (Child-Pugh B).[1]

For important safety information, please consult the MAVIRET Product Monograph at www.abbvie.ca.

About Hepatitis C

An estimated 250,000 people in Canada are living with chronic hepatitis C but as many as 40% are not aware that they have it.[4] 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.[5] 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. Follow AbbVie Canada on Twitter, on Instagram or find us on LinkedIn.

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**Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR12) are considered cured of hepatitis C.*
***The recommended duration of MAVIRET is 12 weeks in liver or kidney transplant recipients with or without cirrhosis.*

[1]AbbVie Canada. Maviret Product Monograph. Retrieved https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/MAVIRET_PM_EN.pdf. April 2022.
[2]Jonas MM et al. Pharmacokinetics, safety, and efficacy of glecaprevir/pibrentasvir in children with chronic hepatitis C virus: part 2 of the DORA study. J Hepatol (2021)
[3]Jonas, MM et al. Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Adolescents With Chronic Hepatitis C Virus: Part 1 of the DORA Study. J Hepatol (2020)
[4]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 Accessed April 2022.
[5]Canadian Liver Foundation. How you advocate. https://www.liver.ca/how-you-help/advocate/ Accessed April 2022.