



## PRESS RELEASE

### Health Canada Grants Priority Review to AbbVie's Investigational Regimen of Glecaprevir/Pibrentasvir (G/P) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6)

- *If approved, G/P may provide a shorter, eight week, once-daily, ribavirin-free treatment option for the majority of HCV patients without cirrhosis*
- *AbbVie's New Drug Submission is supported by data from its global registrational clinical development program across all major HCV genotypes and in patients with specific treatment challenges*

**Montreal, QC**, February 1, 2017 – AbbVie, a global biopharmaceutical company, today announced it has submitted a New Drug Submission (NDS), and received priority review from Health Canada, for its investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) for the treatment of all major chronic hepatitis C virus (HCV) genotypes.

If approved, G/P may provide a shorter treatment duration for genotypes 1-6 (GT1-6) in patients without cirrhosis, who make up a large portion of HCV patients in Canada, and an additional treatment option to patients with compensated cirrhosis (Child-Pugh A). G/P is also intended to address the unmet medical needs of patients with specific treatment challenges, including those with severe chronic kidney disease (CKD) and those not cured with previous direct acting antiviral (DAA) treatment.

"HCV patients with severe chronic kidney disease present a complex challenge for physicians to treat. This is particularly true in those with genotype 2 and 3 infection, and those with cirrhosis," said Dr. Curtis Cooper, Director of the Regional Hepatitis Program at the Ottawa Hospital. "Recent clinical trial results are a positive development in AbbVie's investigation of the G/P regimen for patients with chronic kidney disease, who currently have limited HCV treatment options."

"At no other time in history has the goal of eliminating hepatitis C in Canada been within reach like it is now, said Stéphane Lassignardie, General Manager, AbbVie Canada. "We are firmly committed to seeing this goal accomplished. As such, we have invested significantly in recent years in clinical trials in Canada for our investigational, pan-genotypic G/P regimen and will continue collaborating with Health Canada to help provide a cure for as many Canadians as possible living with HCV."

AbbVie's NDS is supported by data from eight registrational studies in AbbVie's G/P clinical development program, which evaluated more than 2,300 patients in 27 countries, including 174 patients in Canada, across all major HCV genotypes and special populations. Patient populations studied included GT1-6, those new and experienced to antiviral treatment, those with compensated cirrhosis and without cirrhosis, and patients with specific treatment challenges, including those with severe CKD, and those not cured with a prior DAA-containing regimen. The registrational program for G/P was designed to

investigate a faster path to virologic cure\* for all major HCV genotypes (GT1-6) and with the goal of addressing areas of continued unmet need.

On January 24, AbbVie announced its marketing authorization application (MAA) for G/P has been validated and is now under accelerated assessment by the European Medicines Agency (EMA). On December 19, 2016, AbbVie submitted its New Drug Application (NDA) for G/P to the U.S. Food and Drug Administration (FDA) for the treatment of GT1-6 chronic HCV. And on September 30, 2016, AbbVie announced that G/P was granted Breakthrough Therapy Designation by the FDA for genotype 1 patients not cured with prior direct-acting antivirals.

G/P is an investigational product and its safety and efficacy have not been established. Additional information on the clinical trials for G/P is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About AbbVie's HCV Clinical Development Program**

AbbVie's Glecaprevir/Pibrentasvir (G/P) clinical development program was designed to investigate a faster path to virologic cure\* for all major HCV genotypes (GT1-6) and with the goal of addressing treatment areas of continued unmet need.

G/P is an investigational, pan-genotypic regimen being evaluated as a potential cure in 8 weeks for HCV patients without cirrhosis and who are new to treatment with direct-acting antivirals (DAA)\*\*, who make up the majority of HCV patients. AbbVie is also studying G/P in patients with specific treatment challenges, such as genotype 3 patients who were not cured with previous DAA treatment, and those with CKD, including patients on dialysis.

G/P is a once-daily regimen that combines two distinct antiviral agents. G/P is a fixed-dose combination of glecaprevir (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor, dosed once-daily as three oral tablets. Glecaprevir (GLE) was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals for HCV protease inhibitors and regimens that include protease inhibitors.

*\*Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR<sub>12</sub>) are considered cured of hepatitis C.*

*\*\*Patients who are treatment-naive or not cured with previous IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).*

### **About AbbVie Canada**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharnacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit [www.abbvie.ca](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow @abbviecanada on Twitter or view careers on our Facebook or LinkedIn page.

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