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# PRESS RELEASE

## European Medicines Agency Grants Accelerated Assessment, Validates Marketing Authorisation Application for 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*
- *Marketing Authorisation Application (MAA) is supported by data from global registrational clinical development programme across all major HCV genotypes and in patients with specific treatment challenges*

**NORTH CHICAGO, Ill.,** Jan. 24, 2017 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that its marketing authorisation application (MAA) has been validated and is now under accelerated assessment by the European Medicines Agency (EMA) for the company's 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) patients without cirrhosis, who make up the majority of HCV patients, and an additional treatment option to patients with compensated cirrhosis (Child-Pugh A). G/P is also intended to address the 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.

"We are pleased at the potential of our investigational, pan-genotypic regimen and that it has been granted accelerated assessment by the EMA. We will work closely with the EMA as we continue our commitment to potentially provide a cure for as many people living with HCV as possible," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "We believe G/P has the potential to further impact the HCV treatment landscape, shortening the treatment duration to just eight weeks for the majority of people living with HCV without cirrhosis."

The Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), will review the G/P regimen under accelerated assessment, designated to new medicines of major public health interest and therapeutic innovation, and designed to bring new treatments to patients more quickly. Validation of the MAA confirms that the submission is complete and starts the EMA's centralised review process. If approved, AbbVie's G/P regimen could be available for marketing in the European Union (EU) in the second half of 2017.

The MAA is supported by data from eight registrational studies in AbbVie's G/P clinical development programme, which evaluated more than 2,300 patients in 27 countries across all major HCV genotypes and special populations. Patient populations studied included GT1-6, those new and experienced to 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 programme 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 December 19, 2016, AbbVie announced its New Drug Application submission for G/P to the U.S. Food and Drug Administration (FDA) for the treatment of GT1-6 chronic HCV. AbbVie remains on track to submit a New Drug Application for G/P in Japan in Q1 2017.

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.

**About AbbVie's HCV Clinical Development Programme**

AbbVie's Glecaprevir/Pibrentasvir (G/P) clinical development programme 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 (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

**Patients who achieve a sustained virologic response at 12 weeks post treatment ($SVR_{12}$) 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**

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, Pharmacyclics, 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.co.uk.

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