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# PRESS RELEASE

## Eight Weeks of Treatment with AbbVie's Investigational, Pan-Genotypic Regimen of Glecaprevir/Pibrentasvir (G/P) Achieved High $SVR_{12}$ Rates in Challenging to Treat Genotype 3 Chronic Hepatitis C

- *95 percent of patients infected with genotype 3 (GT3) chronic hepatitis C virus (HCV), without cirrhosis and who are new to treatment, achieved $SVR_{12}$ with 8 weeks of treatment*[1]
- *Together with previously reported data, these study results support the potential of G/P as an 8-week treatment for the majority of people living with HCV across all genotypes*
- *GT3 is the second most common genotype worldwide and the most challenging to treat; limited treatment options exist for newly diagnosed patients*

**AMSTERDAM, Netherlands**, April 21, 2017– AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced high SVR rates were achieved with 8 weeks of treatment with its investigational, once-daily, ribavirin-free, pan-genotypic regimen of glecaprevir/pibrentasvir (G/P) in patients with challenging to treat genotype 3 (GT3) chronic hepatitis C virus (HCV) infection. In results from the Phase 3 ENDURANCE-3 study, 95 percent (n=149/157) of GT3 chronic HCV infected patients without cirrhosis and who are new to treatment achieved sustained virologic response at 12 weeks post-treatment ($SVR_{12}$) following 8 weeks of treatment with G/P.[1] These new data will be featured as an oral presentation today at The International Liver Congress™ (ILC) 2017 in Amsterdam, The Netherlands.[1,2]

As well as evaluating 8 weeks of treatment with G/P, the ENDURANCE-3 study was designed to evaluate whether 12 weeks of G/P is non-inferior to 12 weeks of sofosbuvir plus daclatasvir (SOF+DCV), a current standard of care for GT3 chronic HCV infected patients.[1] $SVR_{12}$ rates of 95 percent were seen in both 8 weeks (n=149/157) and 12 weeks (n=222/233) of treatment with G/P.[1] Additionally, 12 weeks of treatment with G/P was demonstrated to be non-inferior to 12 weeks of treatment with SOF+DCV (97 percent, n=111/115).[1]

Full results from ENDURANCE-3 are the latest to be released from registrational studies in AbbVie's G/P clinical development programme, 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.

GT3 is the second most common genotype globally, accounting for 18 percent of patients worldwide and 26 percent of patients in Europe.[2] Patients with GT3 HCV have more rapid disease progression, with the highest rates of associated fibrosis, steatosis (fatty liver), and hepatocellular carcinoma (HCC).[3] Treatment guidelines with current standards of care recommend 12 weeks of treatment in GT3 patients without cirrhosis and who are new to treatment.[4]

"GT3 is widely recognised as the most challenging to treat genotype, with limited treatment options for newly diagnosed patients," said Edward Gane, M.D., Professor of Medicine at University of Auckland, New Zealand. "When looked at in parallel with a current standard of care, the ENDURANCE-3 study results explore the potential of G/P as an 8 week treatment in these patients without cirrhosis."

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"These results, along with a number of other ILC presentations from our G/P clinical development programme, investigate the potential of our regimen in patients with specific treatment challenges and explore an 8 week virologic cure for the majority of patients across all major genotypes," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "The evidence gathered from the ENDURANCE-3 study is therefore a key part of our G/P clinical development programme, underscoring our commitment to the HCV community by investigating a pan-genotypic treatment option."

In the ENDURANCE-3 study, no patients who received 8 weeks of G/P discontinued treatment due to adverse events (AEs).[1] AEs were mostly mild (71 percent) in patients receiving both 8 and 12 weeks of G/P. The most common AEs (≥10 percent) in patients receiving 8 weeks and 12 weeks of G/P were headache (20 and 26 percent), fatigue (13 and 19 percent) and nausea (12 and 14 percent), respectively and with patients receiving 12 weeks of SOF+DCV treatment (headache 20 percent, fatigue 14 percent and nausea 13 percent).[1]

Authorisation applications for G/P are currently under review by regulatory authorities around the world. G/P has been granted accelerated assessment by the European Medicines Agency, and priority review designations by the U.S. Food and Drug Administration and Japanese Ministry of Health, Labour and Welfare. G/P is an investigational regimen and its safety and efficacy have not been established.

*The ENDURANCE-3 study will be featured in the official ILC press conference on Friday, April 21 from 11:30-12:30 local time.*

**About the ENDURANCE-3 Study**
ENDURANCE-3 is a Phase 3, open-label, active-controlled study evaluating patients who are new to treatment with HCV GT3 infection without cirrhosis. The study included 505 patients who were randomised to receive either 12 weeks of G/P (Arm A, n= 233) or 12 weeks of SOF + DCV (Arm B, n=115), with subsequently enrolled patients receiving 8 weeks of G/P (Arm C, n=157). The primary endpoint was the percentage of patients achieving $SVR_{12}$. The rate of virologic failure was 1.7 percent (n=4/233) in Arm A, 0.8 percent (n=1/115) in Arm B and 3.8 percent (n=6/157) in Arm C.

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.

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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 (SVR12) are considered cured of hepatitis C.*
***Patients who are treatment-naive or had prior treatment experience with 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 approximately 29,000 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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**Media:**
Sarah Beck
+44 (0)7818 428111
sarah.beck@abbvie.com

[1] Foster, GR et al. ENDURANCE-3: safety and efficacy of glecaprevir/pibrentasvir compared to sofosbuvir plus daclatasvir in treatment-naïve HCV genotype 3-infected patients without cirrhosis. Presented at The International Liver Congress™ (ILC) in Amsterdam, The Netherlands, April 19-23, 2017.
[2] Petruzziello, A. et al. Global epidemiology of hepatitis C virus infection: An up-date of the distribution and circulation of hepatitis C virus genotypes. World J Gastroenterol. 2016; 22(34): 7824-7840
[3] 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.
[4] EASL Recommendations on Treatment of Hepatitis C 2016. J Hepatol (2016), http://dx.doi.org/10.1016/j.jhep.2016.09.001.

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