

PRESS RELEASE

Eight Weeks of Treatment with AbbVie's Investigational, Pan-Genotypic Regimen of Glecaprevir/Pibrentasvir (G/P) Achieved High SVR Rates Across All Major Genotypes of Chronic Hepatitis C

- 97.5 percent of chronic HCV infected patients without cirrhosis and new to treatment across all major genotypes (GT1-6) achieved SVR₁₂ with 8 weeks of G/P^{1,2,3}
- *Across the 8-week arms of three registrational studies, no patients discontinued treatment due to adverse events^{1,2,3}*
- *G/P is an investigational, pan-genotypic, once-daily, ribavirin-free regimen for the treatment of chronic HCV*

NORTH CHICAGO, Ill., Nov. 11, 2016 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced high SVR₁₂ rates with 8 weeks of treatment with its investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) across all major chronic hepatitis C virus (HCV) genotypes. In more than 700 genotype 1-6 (GT1-6) chronic HCV infected patients without cirrhosis and who are new to treatment, 97.5 percent (n=693/711) achieved sustained virologic response at 12 weeks post treatment (SVR₁₂), regardless of baseline viral load^{1,2,3}. The rate of virologic failure was 1 percent (n=9/711).^{1,2,3}

These data are the first 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.

"The results we announced today bring us closer to providing a potential pan-genotypic, once-daily treatment option with 8 weeks of therapy for people living without cirrhosis and who are new to treatment," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "With our registrational programme nearing completion, we're on track to submit our next generation, pan-genotypic regimen to regulatory authorities by the end of this year in the U.S. and early 2017 in the European Union and Japan."

These new top-line data comprise results from the 8-week arms of three registrational clinical trials evaluating the efficacy and safety of G/P – the ENDURANCE-1, ENDURANCE-3 and SURVEYOR-2 (Part 4) studies. Across the 8-week arms of all three studies, there were no discontinuations due to adverse events (AEs)^{1,2,3}. The most common AEs, occurring at a rate greater than 10 percent across these arms were headache and fatigue; and there were no AEs in any study arm at a rate greater than 20 percent^{1,2,3}. No clinically relevant laboratory abnormalities, including ALT changes, were observed^{1,2,3}.

"Most patients living with HCV today have never been treated and have earlier stages of liver disease, which have not yet progressed to cirrhosis," said Stefan Zeuzem, M.D., study author and Chief of the Department of Medicine at the J.W. Goethe University Hospital in Frankfurt, Germany. "Therefore, these initial data highlighting the SVR rates achieved in these HCV patients to date, with 8 weeks of treatment with the G/P regimen, are particularly promising."

Overview of preliminary results across the three studies:

Study Name	Patient Population	Treatment Duration	Treatment Regimen	SVR ₁₂ Rate
ENDURANCE-1	GT1 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN +/- RBV or SOF/RBV +/- pegIFN) , and patients co-infected with HIV-1	8 week	G/P	99% (n=348/351)
ENDURANCE-3	GT3 without cirrhosis, new to treatment	8 week	G/P	95% (n=149/157)
SURVEYOR-2 (Part 4)	GT2, 4, 5, 6 without cirrhosis, new to treatment or not cured with previous IFN-based treatments (pegIFN, SOF/RBV or pegIFN/SOF)	8 week	G/P	97% (n=196/203)

G/P is an investigational, pan-genotypic regimen currently being evaluated in a registrational clinical development programme, and its safety and efficacy have not been established. Additional data from the ENDURANCE-1 and SURVEYOR-2 (Part 4) studies will be presented at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston. Additional information on the clinical trials for G/P is available at www.clinicaltrials.gov.

**Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR₁₂) are considered cured of hepatitis C.*

About the ENDURANCE and SURVEYOR Studies

ENDURANCE-1, ENDURANCE-3 and SURVEYOR-2 (Part 4) are open-label, multicentre registrational studies evaluating the safety and efficacy of G/P across all major chronic HCV genotypes (GT1-6). The primary efficacy endpoint for all studies is SVR₁₂.

ENDURANCE-1 is a randomised study designed to evaluate the safety and efficacy of 8 and 12 week treatment durations of G/P in patients with GT1 chronic HCV infection without cirrhosis and new to treatment or not cured with previous IFN-based treatments (pegIFN +/- RBV or SOF/RBV +/- pegIFN), including patients co-infected with HIV-1.

ENDURANCE-3 is a partially randomised study designed to evaluate the safety and efficacy of 8 and 12 week treatment durations of G/P in patients with GT3 chronic HCV infection without cirrhosis and new to treatment. The study has an additional active comparator arm of 12 weeks of sofosbuvir + daclatasvir (SOF+DCV). Additional data from study arms will be presented at an upcoming scientific congress.

SURVEYOR-2 (Part 4) is a single-arm study evaluating an 8 week treatment duration of G/P in patients with GT2, 4-6 chronic HCV infection without cirrhosis and new to treatment or not cured with previous IFN-based treatments (pegIFN, SOF/RBV or pegIFN/SOF).

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 that is being evaluated as a potential cure in 8 weeks for HCV patients without cirrhosis and who are new to treatment, who make up the majority of HCV patients.

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.

GLE was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

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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References

¹ Zeuzem, S et al., ENDURANCE-1: A Phase 3 Evaluation of the Efficacy and Safety of 8- versus 12-week Treatment with ABT-493/ABT-530 in HCV Genotype 1 Infected Patients with or without HIV-1 Co-infection and without Cirrhosis

² Mensa, F et al., ENDURANCE-3: HCV genotype 3 infected, treatment-naive subjects without cirrhosis treated with GLE/PIB for 8 or 12 weeks or SOF+DCV for 12 weeks

³ Hassanein, Tarek I. et al., SURVEYOR-II, Part 4: Glecaprevir/Pibrentasvir Demonstrates High SVR Rates in Patients with HCV Genotype 2, 4, 5, or 6 Infection without Cirrhosis Following an 8-Week Treatment Duration