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PRESS RELEASE

AbbVie's Investigational, Pan-Genotypic Regimen of Glecaprevir/Pibrentasvir (G/P) Shows High SVR Rates in Chronic Hepatitis C Patients with Severe Chronic Kidney Disease

- *98 percent of patients across all major HCV genotypes (GT1-6) with severe chronic kidney disease (CKD), including patients on dialysis, achieved SVR_{12} with 12 weeks of G/P in the primary intent-to-treat analysis, regardless of previous treatment status or presence of compensated cirrhosis*[1]
- *100 percent of patients achieved SVR_{12} in a modified intent-to-treat analysis*[1]
- *G/P is an investigational, pan-genotypic, once-daily, ribavirin-free, fixed-dose combination for the treatment of chronic HCV*
- *Development of new regimens to treat HCV patients with CKD remains a critical unmet medical need across genotype*[2]

NORTH CHICAGO, Ill., November 15, 2016 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced 98 percent (n=102/104) of chronic hepatitis C virus (HCV) infected patients with severe chronic kidney disease (CKD) achieved sustained virologic response following 12 weeks of treatment (SVR_{12}) with its investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) (G/P) in the primary intent-to-treat (ITT) analysis[1]. In a modified intent-to-treat (mITT) analysis, SVR_{12} was achieved in 100 percent (n=102/102) of severe CKD patients; mITT excludes patients who did not achieve SVR for reasons other than virologic failure[1]. These new data from the Phase 3 EXPEDITION-4 study, evaluating patients with chronic HCV infection across all major genotypes (GT1-6) and severe CKD, will be presented as a late-breaker today at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

The EXPEDITION-4 results 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.

"HCV patients with severe chronic kidney disease present a complex challenge for physicians to treat, particularly as kidney disease progresses, and if the patient has genotype 2 or 3 or has compensated cirrhosis," said Ed Gane, M.D., professor of medicine at the University of Auckland in Auckland, New Zealand. "The results seen in EXPEDITION-4 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."

HCV is common among people with severe CKD, reaching prevalence of up to 80 percent in some regions of the world.[3] In the U.S., it is estimated that over 500,000 people have both chronic HCV and CKD.[4] Some chronic HCV infected patients with severe CKD, particularly those with GT2 and GT3 HCV infection, currently don't have access to direct-acting antivirals (DAAs). The development of new, safe and effective regimens to treat HCV in these patients remains a critical unmet medical need.[2]

"With our investigational, pan-genotypic regimen, our goal is to provide a safe and effective cure to patients across genotypes, including patients with severe chronic kidney disease, regardless of previous treatment status or presence of compensated cirrhosis," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "Our clinical development programme reflects our ongoing commitment to addressing treatment areas of continued unmet need."

The EXPEDITION-4 study enrolled 104 patients with severe chronic kidney disease, including 85 patients (82 percent) who were receiving dialysis at enrollment and 20 patients (19 percent) who had compensated cirrhosis[1]. The study also included those who were not cured with previous sofosbuvir (SOF) with ribavirin (RBV) or interferon (IFN) with RBV; with or without SOF (44 patients, 42 percent)[1].

The majority of treatment related adverse events (AEs) were mild or moderate. The most commonly reported AEs included pruritus, fatigue and nausea. Of the 24 percent of patients who experienced serious AEs, none were considered related to G/P. Four AEs (4 percent) led to the discontinuation of G/P and one patient died after achieving SVR_4 due to a serious AE (intracerebral hemorrhage) considered not-related to G/P.

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

About the EXPEDITION-4 Study

EXPEDITION-4 is a single-arm, open-label, Phase 3 study evaluating the safety and efficacy of 12 weeks of G/P in patients with GT1-6 chronic HCV infection and chronic kidney disease, including those on dialysis. The primary efficacy endpoint is SVR_{12}.

Patients had severe or end stage kidney disease (stage 4 and 5 CKD), with an eGFR < 30 mL/min/1.73 m2 required at screening. Prior treatment in the study is defined as treatment with interferon (IFN)/pegIFN ± RBV, or sofosbuvir (SOF) + RBV ± pegIFN therapy.

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 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. 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 an investigational, once-daily regimen that combines two distinct antiviral agents in a fixed-dose combination of glecaprevir (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor. G/P is 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.

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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[1] Gane, E et al., EXPEDITION-4: Efficacy and safety of glecaprevir/pibrentasvir (ABT-493/ABT-530) in patients with renal impairment and chronic hepatitis C virus genotype 1-6 infection

[2] American Association for the Study of Liver Diseases. Recommendations for Testing, Managing, and Treating Hepatitis C, February 24, 2016, http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have. Accessed March 15, 2016.

[3] Fabrizi F, Poordad FF, Martin P. Hepatitis C infection in the patient with end stage renal disease. Hepatology. 2002;36(1):3-10.

[4] IMS Health, July 2016. Parsippany, NJ; Medivo, July 2016. New York, NY (Estimate based on IMS Health Dx Medical Claims 12/2013-4/2016; IMS Health Life Link Patient Level Data 12/2013-4/2016; Medivo Lab Data 12/2013-4/2016)