Methods To study the benefits of Darbepoetin and Pegfilgrastim in patients with de-compensated liver cirrhosis. Prospectively clinical data recorded since October 2014. Patients with active bleed, hepatorenal syndrome, hepatoma, portal vessel thrombosis were excluded. Patients started on Injection Darbepoetin alpha 200 microgram and Injection Pegfilgrastim 6 mg subcutaneously every 15days, total of three visits of patients, then three months follow up planned. Improvement in clinical, laboratory parameters analyzed. Median calculated, Wilcoxon Signed-Rank Test applied to compare both groups.

Results N=22 all male, 3 lost to follow up, aetiology of cirrhosis were Non-alcoholic Fatty Liver Disease 5, Hepatitis B Virus 3, Hepatitis C Virus 2 and Alcohol 12. Median age 59years (range: 40 to 70). Improvement in Haemoglobin from 10.1 gram% (range 5.9–13.4 gm%) to 10.6 gm% (range: 7.5–13.7 gm%) p value 0.00374, Total leukocyte count from 5100/cu mm to 7100/cu mm p value 0.00214, Platelet count 90,000/cu mm to 146,000/cu mm, p value 0.00096, INR 1.7 (range 1.5–4.8) to 1.4 p value 0.00064, Albumin 2.4 gram/dl (range 1.6–2.9) to 2.5 gm/dl (range 1.8–3.5) P value 0.043, Child score from 10 to 8 P value 0.007, ascites score 2 to 1, P value 0.00222. No significant improvement in Serum creatinine, sodium, potassium, calcium, bilirubin, total protein and hepatic encephalopathy. High cost of medicine was the limiting factor.

Conclusions Our study suggests that Darbepoetin Alpha and Pegfilgrastim is significantly effective in improving hematology, International normalized ratio, Albumin, ascites and Child score of liver cirrhosis patients.

IDDF2019-ABS-0210

PRELIMINARY EFFICACY AND SAFETY OF 8-WEEK GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH HCV GENOTYPE 1–6 INFECTION AND COMPENSATED CIRRHOSIS: THE EXPEDITION-8 STUDY

¹Robert S Brown Jr*, ²Christopher Hezode, ³Stanley Wang, ⁴Maria Buti, ⁵Wan-Long Chuang, ⁶Humberto Aguilar, ⁷Gabor Horvath, ⁸Barbara Rosado Carrion, ⁹Federico Rodriguez-Perez, ³Eric Cohen, ³Yiran B Hu, ³Gretja Schnell, ³Chih-Wei Lin, ³Lino Rodrigues, ³Roger Trinh, ³Federico J Mensa. ¹Weill Cornell Medical College, Center for Liver Disease and Transplantation, USA; ²Department of Hepatology, Hôpital Henri Mondor, Université Paris-Est, Paris, France; ³AbbVie Inc., North Chicago, Illinois, USA; ⁴Vall d'Hebron University Hospital and CIBERHED del Instituto Carlos III, Barcelona, Spain; ⁵Kaohsiung Medical University Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan; ⁶Louisiana Research Center, Shreveport, LA, USA; ⁷Hepatology Center of Buda, Budapest, Hungary; ⁸Director of GHGCR Research Institute, Puerto Rico; ⁹GHWC and Gastroenterology Section, San Juan, Puerto Rico

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Background The pangenotypic direct-acting antivirals glecaprevir (identified by AbbVie and Enanta) coformulated with pibrentasvir (G/P) are approved to treat chronic HCV genotype (GT) 1–6

infection. Eight-week G/P achieved high SVR12 rates in Phase 2 and 3 studies, but was not studied in patients with compensated cirrhosis. Based on the high SVR12 rates demonstrated in treatment-naïve patients with HCV GT1–6 infection and compensated cirrhosis treated with 12-week G/P, this study evaluates the efficacy and safety of an 8-week G/P treatment duration in that population.

Methods EXPEDITION-8 is an ongoing phase 3, non-randomized, single arm, open-label, multicenter study conducted in adults with chronic HCV GT1–6 infection with compensated cirrhosis who are HCV treatment-naïve. A recently approved protocol amendment enabled the inclusion of HCV GT3-infected patients, who are not included in this analysis. G/P (300 mg/120 mg) is being dosed orally once-daily with food for 8 weeks. The primary efficacy endpoint is the SVR12 rate. Secondary endpoints are the on-treatment virologic failure and relapse rates. Adverse events and clinical laboratory abnormalities are being monitored in all patients.

Results In total, 280 treatment-naïve patients with compensated cirrhosis have enrolled and are included in the analysis. To date, 116 patients have completed the post-treatment week 12 visit; (figure 1) shows preliminary efficacy results for those with available post-treatment week 4 and/or 12 data. No virologic failures have occurred. Adverse events (AEs) have been mostly mild, with the most common (at least 5%) AEs being pruritus and fatigue (both 9%), headache (7%) and nausea (6%). No AEs have led to discontinuation of G/P; 5 serious AEs have occurred, none of which were deemed related to G/P.

Conclusions In this ongoing study, G/P for 8 weeks in treatment-naïve patients with HCV infection and compensated cirrhosis has been well-tolerated and achieved high rates of SVR, with no virologic failures to date. Updated efficacy and safety data will be presented at the meeting.

IDDF2019-ABS-0211

EFFICACY AND SAFETY OF GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH HCV GENOTYPE 5 OR 6 INFECTION: AN INTEGRATED ANALYSIS OF PHASE 2 AND 3 STUDIES

¹Betty B Yao*, ²Tarik Asselah, ¹Linda Frederick, ¹Gretja Schnell, ³Kris Kowdley, ⁴Paul Y Kwo, ⁵Fred Poordad, ⁶Kinh Nguyen, ⁷Samuel S Lee. ¹AbbVie Inc., North Chicago, Illinois, USA; ²Centre de Recherche sur l'Inflammation, INSERM UMR 1149, Université Paris Diderot, Department of Hepatology, AP-HP Hôpital Beaujon, Clichy, France; ³Swedish Medical Center, Seattle, USA; ⁴Stanford University School of Medicine, Palo Alto, CA, USA; ⁵The Texas Liver Institute, University of Texas Health, San Antonio, TX, USA; ⁶National Hospital for Tropical Diseases, Vietnam; ⁷University of Calgary, Calgary, AB, Canada

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Background The pangenotypic direct-acting antivirals (DAAs) glecaprevir (identified by AbbVie and Enanta) coformulated

Abstract IDDF2019-ABS-0211 Figure 1 Efficacy with G/P in GT5/GT6 patients

with pibrentasvir (G/P) are approved for the treatment of chronic HCV genotype (GT) 1–6 infection. However, the efficacy and safety data of G/P are limited in patients infected with HCV GT5 and GT6.

Methods The data analysis integrated data from 10 Phase 2b, 3a (registrational) and 3b (post-registrational) studies. The patient population comprised adults with chronic HCV GT5 or GT6 infection and compensated liver disease (with or without cirrhosis) who were treatment-naïve or experienced with regimens containing interferon (IFN) or pegylated IFN (pegIFN) ± ribavirin or sofosbuvir + ribavirin ± pegIFN. Patients received 8 or 12 weeks of G/P (300 mg/120 mg) depending on the design of the original study. Efficacy was evaluated as the rate of sustained virologic response (SVR) at post-treatment week (PTW) 12 (SVR12). HCV subtype was identified by phylogenetic analysis.

Results Data from 181 patients were included in this integrated analysis, including 56 (30.9%) with HCV GT5 and 125 (69.1%) with HCV GT6 infection. Overall, 102 (56.4%) patients were treated for 8 weeks and 79 (43.6%) for 12 weeks, irrespective of the presence of cirrhosis. Most patients were male (54.1%), Asian (64.6%), < 65 years of age (72.4%), treatment-naïve (87.8%), with F0–F1 fibrosis (68%), and non-cirrhotic (non-F4, 84.5%). Overall, 1% (1/102) of patients on 8-week treatment and no (0/76) patient on 12-week treatment experienced a relapse. SVR12 rates by cirrhosis status and treatment duration are shown in (Abstract IDDF2019-ABS-0211 figure 1). Treatment-emergent adverse events (AEs) were mostly mild or moderate in severity (175/181, 96.7%). Most common AEs in at least 10% of patients were fatigue (29/181, 16%) and headache (27/181, 14.9%).

Conclusions HCV GT5- and GT6-infected patients without cirrhosis or with compensated cirrhosis treated with G/P for 8 or 12 weeks achieved high rates of SVR12. There were no added efficacy benefits when treatment was extended from 8 to 12 weeks, even in patients with compensated cirrhosis. The G/P regimen was well-tolerated.

IDDF2019-ABS-0212 REAL-WORLD EFFECTIVENESS AND SAFETY OF GLECAPREVIR/PIBRENTASVIR IN ADULTS WITH CHRONIC HEPATITIS C VIRUS INFECTION: A META-ANALYSIS

¹Markus Cornberg*, ²Francesco Negro, ³Pietro Lampertico, ⁴Juan Turnes, ⁵Michael P. Curry, ⁶Ashley Brown, ⁷Heiner Wedemeyer, ⁸Jose A. Carrion, ⁹Nicole Wick, ¹⁰Andreas Pangerl. ¹Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany; ²Divisions of Gastroenterology and Hepatology and of Clinical Pathology, University Hospital, Geneva, Switzerland; ³Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, University of Milan, Milan, Italy; ⁴Department of Gastroenterology and Hepatology, C.H.U. Pontevedra and IIS Galicia Sur, Spain; ⁵Beth Israel Deaconess Medical Center, Boston, MA, USA; ⁶Imperial College Healthcare NHS Trust, London, UK; ⁷University Clinic Essen, Essen, Germany; ⁸Liver Section, Gastroenterology Department, Hospital del Mar, IMIM (Hospital del Mar Medical Research Institute), UAB (Universitat Autònoma de Barcelona), Barcelona, Spain; ⁹Trio Health, La Jolla, USA; ¹⁰AbbVie Inc., North Chicago, IL, USA

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Background Glecaprevir/pibrentasvir (G/P) is approved for adults infected with hepatitis C virus (HCV) genotypes 1–6. In clinical trials, G/P was associated with high rates of sustained virologic response at post-treatment Week 12 (SVR12)

and was well tolerated. Currently, real-world evidence (RWE) regarding G/P use is being collected. A systematic review and meta-analysis of RWE reporting the effectiveness and safety of G/P were undertaken.

Methods Biosis, Derwent Drug File, Embase®, International Pharmaceutical Abstracts, Medline®, and SciSearch databases were searched using pre-defined terms for 'G/P' and 'RWE' to identify real-world prospective/retrospective studies (1 January 2017–15 October 2018) that reported SVR12 and/or safety parameters in HCV-infected adults (N≥20) treated with G/P. Congress presentations up to 12 November 2018 were included. Random effects meta-analysis was used to determine SVR12 and naïve pooling for adverse event (AE) rates. Intention-to-treat (ITT) SVR12 analyses included all patients dosed with G/P; modified ITT (mITT) excluded those who had non-virologic failure.

Results 10,048 adults treated with G/P in 16 studies were included; ITT SVR12 rates were reported in 14 studies and mITT SVR12 rates in 11 studies. SVR12 rates overall and by subgroups based on ITT and mITT populations are shown (table 1). AEs were summarised in 6 studies and reported in 12.7% (724/5685) of patients. Treatment discontinuations due to AEs were summarised in 5 studies and reported in 0.5% (24/4508) of patients. The most frequent AEs were pruritus (4.7%; 126/2698), fatigue (4.4%; 146/3305), and headache (2.7%; 102/3759). SVR12 and safety data will be updated in the final presentation.

Abstract IDDF2019-ABS-0212 Table 1

	ITT- Patients, n (studies, n)	Meta-analysis ITT-SVR12, %; 95% CI	mITT- Patients, n (studies, n)	Meta-analysis mITT-SVR12, % (95% CI)
Overall	8279 (14)	96.6; 95.2–98.0	5995 (11)	98.1; 96.7–99.5
Cirrhosis				
Yes	629 (6)	97.8; 96.2–99.4	688 (7)	97.7; 96.1–99.3
No	3862 (5)	96.9; 94.2–99.6	4685 (6)	97.7; 95.3–100
HCV genotype				
1	1685 (6)	95.5; 92.5–98.4	2468 (4)	97.5; 93.9–100
2	375 (6)	96.4; 93.4–99.3	383 (4)	97.1; 94.5–99.8
3	1084 (6)	95.2; 92.0–98.4	700 (6)	95.8; 92.7–98.9
4	214 (4)	99.0; 97.6–100	165 (2)	98.5; 96.6–100
HCV treatment experience				
Treatment-naïve	NA	NA	3893 (4)	97.3; 94.0–100
Treatment-experienced (PRs or DAA)	181 (5)	97.7; 95.6–99.9	643 (5)	96.5; 93.4–99.7
Treatment duration				
8 weeks	1781 (4)	96.2; 92.7–99.7	3514 (6)	98.1; 95.6–100
12 weeks	603 (4)	95.7; 92.2–99.3	593 (3)	95.7; 91.8–99.6
16 weeks	NA	NA	NA	NA

Conclusions Consistent with results observed in clinical trials, RWE indicates that G/P is a well-tolerated and highly effective pangenotypic treatment option for a broad range of HCV-infected patients (table 1).