were associated with a reduced risk of HCC (Figure 1), with adjusted hazard ratios (aHR) (95% confidence interval [CI]) of 0.55 (0.42,0.71), 0.52 (0.41,0.64), 0.47 (0.38,0.58) and 0.46 (0.37,0.56), respectively (all $p < 0.001$). In contrast, ALT 1 to 2 times the ULN and ALT greater than 2 times the ULN at 12 months were associated with a higher risk of HCC as compared to ALTn at 12 months, with aHR (95% CI) of 2.07 (1.67,2.56) and 3.21 (2.32,4.44), respectively, after adjustment for baseline ALT and important covariates.

Conclusions Early on-treatment ALTn reduces the risk of HCC in CHB patients having entecavir/TDF treatment. On-treatment ALT above 1 and 2 times the ULN at 12 months were associated with higher risk of HCC.

IDDF2018-ABS-0067

EFFICACY AND SAFETY OF GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH HCV GENOTYPE 5 OR 6 INFECTION: THE ENDURANCE-5, 6 STUDY

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10.1136/gutjnl-2018-IDDFbestabstracts.17

Background The pangenotypic direct-acting antivirals (DAAs) glecaprevir (developed by AbbVie and Enanta)/pibrentasvir (G/P) are approved to treat chronic HCV genotype (GT)1–6 infection. In Phase 2 and 3 studies, G/P achieved high SVR12 rates with no virologic failures in 80 patients with GT5 or 6 infection. To increase the body of data for these genotypes, ENDURANCE-5,6 evaluates patients from countries where GT5 and GT6 are endemic, such as South Africa (GT5), Myanmar and Vietnam (GT6). This study evaluates the efficacy and safety of G/P in patients with chronic HCV GT5 or GT6 infection.

Methods ENDURANCE-5,6 is an ongoing phase 3b, non-randomised, open-label, multicenter study conducted in adults with chronic HCV GT 5 or 6 infections with or without compensated cirrhosis who are HCV treatment-naïve or experienced with interferon (IFN) or pegIFN with or without ribavirin (RBV) or sofosbuvir and RBV with or without pegIFN. G/P (300 mg/120 mg) was orally dosed once-daily for 8 or 12 weeks in patients without or with compensated cirrhosis, respectively. The primary efficacy endpoint was SVR12. Secondary endpoints were on-treatment virologic failure or relapse. Adverse events and clinical laboratory abnormalities were monitored in all patients.

Results Seventy patients have enrolled to date, 61 and 9 in the 8- and 12 week treatment arms, respectively; 66 have completed treatment. Baseline demographics are shown in table 1. The SVR4 among patients with available data is 61/62 (98%). One HCV GT6c-l-infected patient with

compensated cirrhosis experienced virologic breakthrough at treatment week 12, and one HCV GT5a-infected patient without compensated cirrhosis who achieved SVR4 relapsed at post-treatment week 12. To date, three patients (4%) have experienced treatment-emergent serious adverse events, none of which were related to G/P or led to discontinuation; no Grade 3 alanine aminotransferase elevations have occurred.

Abstract IDDF2018-ABS-0067 Table 1 Baseline Demographics and Disease Characteristics

Characteristics	8 week G/P No Cirrhosis n= 61	12 week G/P Cirrhosis n= 9
Female, n (%)	36 (59)	4 (44)
Asian, n (%)	38 (62)	5 (56)
Age, median years (range)	57 (24–79)	65 (32–75)
Genotype 5, n (%)	20 (33)	3 (33)
Genotype 6, n (%)	41 (67)	6 (67)
GT6a/6b	19 (31)	1 (11)
GT6c-l	22 (36)	5 (56)
HCV treatment-naïve, n (%)	55 (90)	8 (89)
Baseline HCV RNA, median log ₁₀ IU/	6.85 (4.6–7.5)	6.29 (4.9–7.2)
ML (range)		

Conclusions In this ongoing dedicated study, HCV genotype 5- and 6-infected patients without and with compensated cirrhosis treated with G/P for 8 and 12 weeks, respectively, achieved high rates of SVR4. Complete SVR4 and available SVR12 data will be presented.

IDDF2018-ABS-0082

QUANTIFICATION OF CIRCULATING MIR-125B-5P PREDICTS SURVIVAL IN CHRONIC HEPATITIS B PATIENTS WITH ACUTE-ON-CHRONIC LIVER FAILURE

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10.1136/gutjnl-2018-IDDFbestabstracts.18

Background This study aimed to analyse serum levels of miR-125b-5p in CHB patients with varying degrees of liver damage and evaluate its value in predicting the short-term outcome of acute-on-chronic liver failure (ACLF).

Methods CHB patients with normal hepatic function (n=100), moderate-to-severe liver damage (n=90) and ACLF (n=86) were included. Serum levels of miR-125b-5p and miR-122 were measured by quantitative real-time PCR.

Results Serum miR-125b-5p levels were increased along with disease progression, and lower in survival than in death among HBV-ACLF patients. Among HBV-ACLF patients, serum miR125b-5p were positively correlated with total bilirubin (TBil) ($r=0.214$, $p<0.05$) and MELD score ($r=0.382$, $p<0.01$), and negatively correlated with prothrombin activity (PTA) ($r=-0.215$, $p<0.05$). Interesting, serum miR-122 showed a completely opposite performance as compared to that of serum miR-125b-5p. Cox Regression Analysis showed that serum miR-125b-5p, miR122 and PTA were all independent survival predictors of HBV-ACLF; and low miR125b-5p and high miR122 may predict