longer survival of HBV-ACLF. Additionally, ROC analysis showed that miR125b-5p(AUC=0.814) had higher performance for survival prediction of HBV-ACLF as compared to miR-122 (AUC=0.804), PTA(AUC=0.762) MELD score(AUC=0.799) and TBil(AUC=0.670) alone; and predictive effectiveness of miR125b-5p was greatly increased by the combination of miR122(AUC=0.898).

Conclusions The increasing of serum miR-125b-5p is associated severity of liver damage, and high serum miR-125b-5p may serve as a novel predictor of poor outcome of HBV-ACLF.

IDDF2018-ABS-0106 **TENOFOVIR ALAFENAMIDE (TAF) COMPARED WITH TENOFOVIR DISOPROXIL FUMARATE (TDF) IN PATIENTS WITH CHRONIC HBV: WEEK 96 EFFICACY AND SAFETY RESULTS IN CHINESE PATIENTS ENROLLED IN 2 GLOBAL PHASE 3 STUDIES**

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Background TAF, a novel prodrug of tenofovir, has demonstrated efficacy noninferior to that of TDF at Week 48 in patients with chronic HBV (CHB) with significantly reduced bone and renal effects. Here we evaluated the efficacy and safety of TAF vs TDF in the subset of patients of Chinese ethnicity enrolled in two overseas studies.

Methods In 2 Phase 3 studies, HBeAg-negative (Study 108) and HBeAg-positive (Study 110) CHB patients were randomised 2:1 to TAF 25 mg QD or TDF 300 mg QD and treated for 96 weeks. In this analysis, the efficacy (HBV DNA).

Results Of 1298 patients randomised and treated, 471 (36%) were of Chinese ethnicity; 156 (TAF 97; TDF 59) and 315 (TAF 207; TDF 108) patients were HBeAg-negative and HBeAg-positive, respectively. For the TAF and TDF groups within each study, baseline characteristics of the study populations were generally similar. Key efficacy results at Weeks 48 and 96 are presented in the Table (table 1). In both HBeAg-negative and HBeAg-positive patients of Chinese ethnicity, the antiviral efficacy of TAF was similar to that of TDF and results were comparable to those in the overall overseas population. Numerically higher percentages of patients treated with TAF achieved normalisation of serum ALT values and anti-HBe seroconversion at Weeks 48 and 96. The safety of TAF and TDF, including changes in renal and bone parameters, were similar to results previously reported in the overall overseas population.

Conclusions In CHB patients of Chinese ethnicity, TAF 25 mg showed similar antiviral efficacy to TDF 300 mg, with less change in bone and renal parameters. Results in this subgroup were comparable to those in the overall population.

Abstract IDDF2018-ABS-0106 Table 1 Efficacy Results at Week 48 and 96

n/N (%)	HBeAg-negative Patients (Study 108)		HBeAg-positive Patients (Study 110)	
	TAF (n= 97)	TDF (n= 59)	TAF (n= 207)	TDF (n= 108)
Week 48				
HBV DNA<29 IU/mL	90 (93%)	55 (93%)	143 (69%)	76 (70%)
ALT normalisation (AASLD criteria) ^a	46/94 (49%)	18/59 (31%)	100/207 (48%)	39/108 (36%)
HBeAg loss	NA ^b	NA	28/204 (14%)	11/103 (11%)
HBeAg seroconversion	NA	NA	23/204 (11%)	8/103 (8%)
Week 96				
HBV DNA<29 IU/mL	88 (91%)	57 (97%)	161 (78%)	86 (80%)
ALT normalisation (AASLD criteria) ^a	46/94 (49%)	24/59 (41%)	119/207 (57%)	46/108 (43%)
HBeAg loss	NA ^b	NA	55/204 (27%)	17/103 (17%)
HBeAg seroconversion	NA	NA	47/204 (23%)	13/103 (13%)

All results are reported as missing=failure; ^aUpper limit of normal (ULN) 30 U/L males, 19 U/L females; ^bNA, not applicable.

IDDF2018-ABS-0113 **THE SAFETY AND TOLERABILITY OF SOF/VEL/VOX FOR 8 OR 12 WEEKS IN >1,000 PATIENTS TREATED IN THE POLARIS-1, POLARIS-2, POLARIS-3, AND POLARIS-4 STUDIES: AN INTEGRATED ANALYSIS**

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Background The once-daily fixed-dose combination tablet of sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) was evaluated for the treatment of genotype 1–6 HCV infection in four phase 3 studies in patients with and without compensated cirrhosis. This analysis describes the safety of SOF/VEL/VOX across 4 Phase 3 studies.

Methods Treatment-emergent adverse events (AEs) and laboratory abnormalities were assessed in patients who received SOF/VEL/VOX or placebo for 12 weeks (POLARIS-1), SOF/VEL/VOX or SOF/VEL for 12 weeks (POLARIS-4), or SOF/

VEL/VOX for 8 weeks or SOF/VEL for 12 weeks (POLARIS-2 and POLARIS-3). SAEs and deaths were followed until post-treatment Week 24. Data were pooled by treatment regimen.

Results 1056 patients were treated with SOF/VEL/VOX for 8 (n=611) or 12 (n=445) weeks, 700 received SOF/VEL for 12 weeks. 38% had compensated cirrhosis, 28% had a BMI $\geq$ 30 kg/m², 36% were female, and 12% were $\geq$ 65 years old. AEs are presented in the table. Two deaths were reported, one illicit drug overdose and one attributed to hypertension (on post-treatment Day 76), neither were related to treatment. SAEs and discontinuations were more frequent in the placebo group and occurred with similar frequency in the other groups; none were related to study treatment. Headache, fatigue, nausea, and diarrhoea were the most common AEs. Mild diarrhoea and nausea occurred more frequently in the SOF/VEL/VOX groups. Overall, 5.1%–6.6% of patients who received SOF/VEL/VOX or SOF/VEL had Grade 3 or 4 laboratory abnormalities. Among patients receiving VOX, one patient each had a Grade 3 elevation in ALT and bilirubin (table 1).

Conclusions SOF/VEL/VOX for 8 or 12 weeks in the POLARIS studies was well tolerated with a low frequency of Grade 3 or 4 AEs, SAEs, and AEs leading to discontinuation. The frequency of AEs in the SOF/VEL/VOX groups was similar to SOF/VEL and placebo groups, with higher rates of mild diarrhoea and nausea compared to SOF/VEL.

REFERENCES

1. Time to get control. A review of the care received by patients who had a severe gastrointestinal haemorrhage. *NCEPOD* 2015.
2. Shaheen AAM, Kaplan GG, Myers RP. Weekend versus weekday admissions and mortality from gastrointestinal haemorrhage caused by peptic ulcer disease. *Clinical Gastroenterology and Hepatology* 2009;**7**:303–310.

Abstract IDDF2018-ABS-0113 Table 1

Subjects	SOF/VEL/VOX 8 Weeks (n=611)	SOF/VEL/VOX 12 Weeks (n=445)	SOF/VEL 12 Weeks (n=700)	Placebo 12 Weeks (n=152)
AE	444 (73)	346 (78)	495 (71)	107 (70)
Grade 3 or 4 AE	14 (2)	7 (2)	12 (2)	4 (2)
SAE	17 (3)	9 (2)	14 (2)	7 (5)
Treatment-related SAE	0	0	0	0
AE Leading to Discontinuation	0	1 (<1)	4 (<1)	3 (2)
Death	1 (<1)	1 (<1)	0	0