Abstracts

SOF metabolite GS-3310007 were approximately 6 fold higher than in the LDV/SOF Phase 3 trials. SOF and LDV concentrations were similar to those with normal, mild or moderate RI. The most common adverse events (AEs) were fatigue (22%), headache (22%), and hyperkalemia (22%). Six serious AEs were reported among 4 patients (22%), including 2 renal events; no SAEs related to study drugs. There were no treatment-related cardiac AEs, including bradycardia, and no meaningful changes in QTc intervals or other parameters.

Conclusions Treatment with LDV/SOF (90/400 mg) for 12 weeks in genotype 1 patients with and without cirrhosis and severe renal impairment resulted in 100% SVR12 rate. The regimen was safe and well-tolerated with no treatment discontinuations and no treatment-related SAEs. (no table selected) (No Image Selected) Co-Author Disclosure Status.

IDDF2018-ABS-0112 SAFETY AND EFFICACY OF SOFOSBUVIR/VELPATASVIR IN A GENOTYPE 1–6 HCV INFECTED POPULATION FROM SINGAPORE, MALAYSIA, THAILAND, AND VIETNAM: RESULTS FROM A PHASE 3, CLINICAL TRIAL

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Background The prevalence of hepatitis C virus (HCV) in Singapore, Malaysia, Thailand, and Vietnam, ranges from 1%–3%. Because of the heterogeneity of genotypes (GTs) in these countries (primarily GT1, 2, 3, and 6), there is a critical need for a pangenotypic, all oral regimen to address the burden of HCV infection. This study evaluated the efficacy and safety of SOF/VEL for 12 weeks in patients with chronic GT1–6 HCV infection.

Methods Treatment experienced and treatment naive patients with chronic GT1–6 HCV infection with no cirrhosis or with compensated cirrhosis were eligible to enrol in a single-arm, open-label trial to receive a fixed dosed combination of SOF/VEL 400/100 mg daily for 12 weeks. Patients were recruited from 13 sites in Singapore, Malaysia, Thailand, and Vietnam. The primary efficacy endpoint was SVR12 using the CAP/CTM HCV 2.0 assay (LLOQ=15 IU/mL), and the primary safety endpoint was adverse events (AEs) leading to SOF/VEL discontinuation.

Results A total of 111 patients were enrolled and treated. Of these, 51% were male, 14% had compensated cirrhosis, 18% were treatment-experienced, 82% had IL28B CC genotype, 20% had GT1a, 23% GT1b, 3% GT2, 23% GT3, and 31% GT6 HCV infection. The overall SVR12 rate was 97% (108/111) GT specific SVR12 rates are presented in the Table

(IDDF2018-ABS-0112 Table 1). All 3 patients who did not achieve SVR experienced a virologic relapse. All 15 cirrhotic patients, including 8 with GT3 HCV infection achieved SVR12. Virology data will be presented. There were no discontinuations due to AEs. There were 50 patients (45%) who experienced any adverse events (AEs), with no AEs occurring in >10% of patients. No serious or severe AEs were assessed by the investigator as related to study drug and there were no deaths.

Abstract IDDF2018-ABS-0112 Table 1 SVR12 for GT1–6 HCV Infected Patients

N(%)	Total n=111	GT1a n=22	GT1b n=25	GT1 (total) n=47	GT2 n=3	GT3 n=25	GT6 n=34	Indeterminate ^a n=2
SVR12	108/111 (97)	22/22 (100)	25/25 (100)	47/47 (100)	3/3 (100)	23/25 (92)	33/34 (97)	2/2 (100)

a. Sequence analysis to determine genotype pending

Conclusions Treatment with the single tablet, pangenotypic regimen of SOF/VEL for 12 weeks was highly effective and well tolerated in a GT 1,2,3, and 6 HCV infected population with and without cirrhosis from Singapore, Malaysia, Thailand, and Vietnam. *Seng Gee Lim is the presenter of the abstract.

IDDF2018-ABS-0114 SOF/VEL/VOX RESULTS IN HIGH SVR12 RATES WHEN ADMINISTERED FOR 12 WEEKS IN DAA-EXPERIENCED PATIENTS OR FOR 8 WEEKS IN DAA-NAIVE PATIENTS: AN INTEGRATED ANALYSIS OF THE POLARIS-1, POLARIS-2, POLARIS-3 AND POLARIS-4 STUDIES

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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 direct-acting antiviral (DAA)-experienced (POLARIS-1 and POLARIS-4) and DAA-naïve