Abstract IDDF2019-ABS-0135 Table 1 Comparison of GS-331007 and LDV exposures in children versus adult Ph2–3 population

PK parameters ^a	3 to <6 y (Test)	Ph2/3 Adult PopPK (Reference) ^b	GLSM Ratio (90% CI) Test/Reference
SOF + RBV (N=10 ^c ; Test/Reference)			
GS-331007			
AUC _{tau} (hr*ng/mL)	10300 (18.1)	7120 (30.7)	150 (127, 176)
C _{max} (ng/mL)	1320 (20.0)	582 (36.3)	239 (195,292)
LDV/SOF (N=13 ^d ; Test/Reference)			
LDV			
AUC _{tau} (hr*ng/mL)	9300 (34.6)	8530 (60.8)	121 (93.2, 156)
C _{max} (ng/mL)	531 (28.5)	364 (51.4)	158 (126, 197)
GS-331007			
AUC _{tau} (hr*ng/mL)	11700 (28.8)	12500 (29.2)	94.0 (82.5, 107)
C _{max} (ng/mL)	1000 (23.3)	736 (28.2)	138 (121, 157)

^aPK parameters presented to 3 significant figures^bN=1695 (SOF Ph2/3); N=2113 (LDV/SOF Ph2/3)^cN=1 subject received tablet formulation instead of granules^dN=1 subject dosed over several hours; both were excluded from the summary statistics

Conclusions SOF 200 or 150 mg or LDV/SOF 45/200 or 33.75/150 mg, for subjects ≥ 17 kg or < 17 kg, respectively, were well tolerated and provided similar exposures to those observed in adults. These data support the ongoing evaluation of these doses in children 3 to < 6 y.

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SOFOBUVIR/VELPATASVIR FOR 12 WEEKS IS SAFE AND EFFECTIVE IN PATIENTS UNDERGOING DIALYSIS

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Background Approved HCV treatments for patients on dialysis are associated with complexities including drug-drug interactions, baseline resistance testing and use of ribavirin. Despite higher concentrations of the primary circulating sofosbuvir (SOF) metabolite, GS-331007, in severe renal impairment, real-world cases demonstrated substantial use of SOF-based regimens in this population without safety concerns identified. This study evaluated the safety, efficacy, and pharmacokinetics (PK) of SOF/velpatasvir (VEL) for 12 weeks in patients with HCV infection on dialysis.

Methods Treatment-naïve or -experienced patients, of any genotype, with or without compensated cirrhosis undergoing hemodialysis or peritoneal dialysis, were enrolled to receive open-label SOF/VEL (400/100 mg) once daily for 12 weeks. The primary efficacy endpoint was a comparison of the SVR12 to a prespecified historic control rate of 83%. The primary safety endpoint was the proportion of patients who discontinued therapy due to adverse events (AEs). Secondary endpoints included safety, viral resistance and PK.

Results 59 patients were enrolled at 21 sites in Canada, United Kingdom, Spain, Israel, Australia and New Zealand. The median age was 62 years (range 49–86), 59% were male, 53% white, 32% treatment experienced, 29% had cirrhosis. Most patients had HCV genotype 1 (42%), or 3 (27%). Most (92%) were on hemodialysis with a mean dialysis duration of 7.3 years. Treatment was well tolerated; no one discontinued therapy due to AEs. One patient was discontinued therapy on day 74 for non-compliance with 48% study medication adherence by pill count. Overall, 56/59 (95%) of patients achieved SVR12. Two (3%) had virologic relapse (one with non-adherence). One patient did not achieve SVR12 due to death from suicide after SVR4. Exposures were consistent with the Phase 1 renal impairment study. The most frequent AEs were headache, fatigue, nausea, and vomiting. Serious AEs occurred in 19% of patients, none was assessed as related to study drug.

Conclusions Treatment with SOF/VEL for 12 weeks in patients with and without cirrhosis undergoing dialysis resulted in a 95% SVR12 rate. The regimen was safe and well-tolerated with no treatment-related discontinuations or treatment-related SAEs.

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CHANGES IN ORO-CECAL TRANSIT TIME (OCTT) AND PREVALENCE OF LACTOSE INTOLERANCE IN PATIENTS OF MICROSCOPIC COLITIS

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Background Microscopic colitis (MC) remains an elusive cause of chronic diarrhea. Histopathology is a gold standard with variable yield. The OCTT and concomitant lactose intolerance in these cases may aid to understand the complex symptoms. We used Hydrogen(H₂) breath tests (H₂BT) for detecting SIBO (Small Intestinal Bacterial Overgrowth), Lactose intolerance and calculation of oro-cecal transit time (OCTT).

Methods 43 MC patients [mean age - 45.83(±15.92)] and 10 controls were studied. Among these, 37(86%) patients with MC & 9 (90%) controls underwent breath tests. SIBO was diagnosed with glucose H₂BT. For confirmation, we took rise ≥ 12 ppm over fasting value in H₂ concentration within 2 hours of glucose ingestion Lactulose H₂BT was done to calculate OCTT. Time taken for rising in breath hydrogen by ≥ 12 ppm over baseline value in two consecutive readings was considered as OCTT. For lactose breath test, 15 minutes samples were taken up to 4 hours. A ≥ 20 ppm rise over fasting value in H₂concentration in two consecutive readings was considered intolerance

Results Four(9.5%) patients of SIBO in Glucose H₂BT were enrolled in controls. Mean (+ SD) OCTT in cases of MC vs controls was 130.38±47.95 mins and 97.14±48.55 mins (p= 0.109) respectively. Thus OCTT increased in 73% cases of MC vs 43% controls. Also, in the MC group, 9(28.1%) patients were lactose intolerant while vs 3(42.9%) controls (p= 0.654). Thus a significant 28% MC patients were lactose intolerant possibly aggravating symptoms

Conclusions Lactose intolerance has lesser prevalence in cases of microscopic colitis. These patients were also detected to