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.

Abstract IDDF2019-ABS-0138 Comparison of GS-331007 and LDV exposures in children versus adult Ph2–3 population

<table>
<thead>
<tr>
<th>PK parameters</th>
<th>Mean (%CV)</th>
<th>Test/Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUCtau (hr*ng/mL)</td>
<td>11340 (28.7)</td>
<td>11340 (28.7)</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>1000 (23.3)</td>
<td>1000 (23.3)</td>
</tr>
</tbody>
</table>

*PK parameters presented to 3 significant figures

IDDF2019-ABS-0136 SOFOSBUVIR/VELPATASVIR FOR 12 WEEKS IS SAFE AND EFFECTIVE IN PATIENTS UNDERGOING DIALYSIS

1Sergio Borgia*, 2Janet Dearden, 3Yoav Lurie, 4Stephen Shafarz, 5Ashley Brown, 6Robert Hyland, 7Sophia Lu, 8Svetlana Markova, 9Hadas Dvory-Sobol, 10Anu Osinusi, 11Christina Sze Man Yip, 12Eric Yoshida, 13Jose Luis Calleja, 14Edward Gane, 15GS-US-334-4062 Investigator. 1William Osher Health System, OH, Canada; 2Saint Bartholomew’s Hospital, UK; 3Shaare Zedek Medical Center, Israel; 4Department of Medicine, University of Alberta, AB, Canada; 5Imperial College Healthcare NHS Trust, UK; 6Gilead Sciences, Inc., Foster City, USA; 7Gordon and Leslie Diamond Health Care Centre, BC, Canada; 8Hospital Universitario Puerta De Hierro, Spain; 9Auckland City Hospital, New Zealand.

IDDF2019-ABS-0138 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 of 12 ppm over fasting 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 H2 concentration within 2 hours of glucose ingestion 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 two consecutive readings was considered as OCTT.

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.