Methods Virally suppressed patients (HBV DNA <20 IU/mL at screening) on TDF were randomized (1:1) to switch to TAF or continue TDF for 48 weeks in a double-blind fashion. Viral suppression and changes in bone (BMD by DXA) and renal (creatinine clearance [eGFR_{CG}]) parameters were assessed over 48 weeks.

Results Among the 400 Asian patients enrolled, 288 (72%) had at least 1 TDF RF. At Week 48, similar proportions with ≥ 1 RF had HBV-DNA <20IU/mL (TAF 97%; TDF 97%) and normal ALT by 2018 AASLD criteria (TAF 76%; TDF 73%). TAF subjects with ≥ 1 RF had increases in eGFR_{CG} compared to decreases on TDF [median (Q1, Q3) change; TAF: +2.6 (-2.01, 7.34); TDF: -2.7 (-7.56, +15.79); $p < 0.0001$]. Among patients with ≥ 1 RF, improvements were seen in BMD for TAF vs. continued declines in TDF patients at both spine ($p < 0.0001$) and hip ($p < 0.0001$).

Conclusions Virally suppressed Asian patients with CHB and risk factors for TDF who switched to TAF showed improved bone and renal safety while efficacy was well-maintained.

IDDF2020-ABS-0059

SAFETY AND EFFICACY OF SOFOSBUVIR/VELPATASVIR (SOF/VEL) IN PEDIATRIC PATIENTS 6 TO < 18 YEARS OLD WITH CHRONIC HEPATITIS C (CHC) INFECTION

¹Maureen Jonas*, ²Rene Romero, ³Etienne Sokal, ⁴Philip Rosenthal, ⁵Gabriella Verucchi, ⁶Chuan-Hao Lin, ⁷Jessica Wen, ⁸Michael Narkewicz, ⁹Sanjay Bansal, ¹⁰Jiang Shao, ¹⁰Sean Hsueh, ¹⁰Anuj Gaggar, ¹⁰Kathryn Kersey, ¹⁰Carol Yee Kwan Chan, ¹¹Regino Gonzalez-Peralta, ¹²Daniel Leung, ¹³William Balistreri, ¹⁴Karen Murray, ¹⁵Kathleen Schwarz. ¹Boston Children's Hospital, Boston, MA, USA; ²Emory University School of Medicine and Children's Healthcare of Atlanta, Atlanta, USA; ³Cliniques Universitaires Saint-Luc, UC Louvain, Brussels, Belgium; ⁴University of California San Francisco, San Francisco, USA; ⁵University of Bologna, Bologna, Italy; ⁶Children's Hospital Los Angeles, Los Angeles, USA; ⁷University of Pennsylvania and The Children's Hospital of Philadelphia, Pennsylvania, USA; ⁸University of Colorado School of Medicine and Children's Hospital of Colorado, Aurora, USA; ⁹Kings College Hospital, UK; ¹⁰Gilead Sciences, Inc, Foster City, USA; ¹¹Pediatric Gastroenterology, Hepatology and Liver Transplant, AdventHealth for Children, Orlando, USA; ¹²Baylor College of Medicine and Texas Children's Hospital, Houston, USA; ¹³Cincinnati Children's Hospital Medical Center, Cincinnati, USA; ¹⁴University of Washington School of Medicine and Seattle Children's Hospital, Seattle, USA; ¹⁵Johns Hopkins University School of Medicine, Baltimore, USA

10.1136/gutjnl-2020-IDDF.142

Background DAA regimens have been approved for CHC treatment in 12 to <18 years, but for younger children, the standard of care is still pegylated-interferon plus ribavirin for ≤ 48 weeks. We evaluated the safety and efficacy of the pangenotypic regimen of SOF/VEL in children 6 to <18 years.

Methods Patients 6 to <18 years with CHC of any genotype (GT) were enrolled in this open-label, ongoing study. Patients 6 to <12 years received SOF/VEL 200 mg/50 mg and 12 to <18 years SOF/VEL 400 mg/100 mg QD for 12 weeks. Key efficacy endpoint was SVR12. Safety was assessed by adverse events (AEs) and clinical/laboratory data. Intensive pharmacokinetic sampling on Day 7 in a subgroup of patients of each age group was done to confirm the appropriateness of the chosen dose.

Results 102 patients 12 to <18 years and 73 patients 6 to <12 years were enrolled. GT distribution was 75% GT1, 5% GT2, 13% GT3, 3% GT4, 3% GT6; 51% female, 80% white, 85% treatment naïve, and 91% vertically infected. Intensive pharmacokinetics confirmed that the doses selected were appropriate. SVR12 rate was 95% (97/102) and 92% (67/73) among patients 12 to <18 years and 6 to 12 years

respectively; 1 patient in each age group had virologic failure, the remaining patients did not achieve SVR for non-virologic reasons. Most AEs were mild or moderate. 5 subjects had serious AE none of which was attributed to treatment, 2 patients discontinued treatment due to AEs and considered treatment unrelated. The most common AEs (>15%) were headache, fatigue, and nausea in adolescents and vomiting, cough and headache in 6 to <12 years.

Conclusions In patients 6 to <18 years with GT1, 2, 3, 4 or 6 CHC infection, treatment with SOF/VEL for 12 weeks resulted in $\geq 92\%$ SVR12 rate. SOF/VEL was well tolerated, supporting its potential as a treatment option for children 6 to 17 years of age. The study is ongoing in children aged 3 to <6 years old.

IDDF2020-ABS-0060

IMPACT OF PRIOR TENOFOVIR DISOPROXIL FUMARATE (TDF) TREATMENT DURATION ON TENOFOVIR ALAFENAMIDE (TAF) SAFETY PROFILE IN VIRALLY SUPPRESSED CHRONIC HBV PATIENTS SWITCHED FROM TDF TO TAF

¹Henry Lik Yuen Chan*, ²Pietro Lampertico, ³Sang Hoon Ahn, ⁴Scott Fung, ⁵Ho Bae, ⁶Alnoor Ramji, ⁷Jung Sung Lee, ⁸Stephen Shafran, ⁹Stuart Gordon, ¹⁰Charles Phan, ¹¹Susanna Tan, ¹¹John Flaherty, ¹¹Anuj Gaggar, ¹¹George Wu, ¹¹Vithika Suri, ¹²Daryl Lau, ¹³Kwan Soo Byun, ¹⁴Kosh Agarwal, ¹⁵Young-Suk Lim, ¹⁶Maria Buti. ¹Institute of Digestive Disease, Department of Medicine and Therapeutics, and State Key Laboratory of Digestive Disease, The Chinese University of Hong Kong, Hong Kong; ²Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Università degli Studi di Milano, Italy; ³Yonsei University College of Medicine, Korea, South; ⁴Toronto Centre for Liver Disease, Toronto General Hospital, University Health Network, Canada; ⁵Asian Pacific Liver Center, St. Vincent Medical Center, USA; ⁶The University of British Columbia, Canada; ⁷Inje University College of Medicine, Korea, South; ⁸University of Alberta, Edmonton, Canada; ⁹Henry Ford Health System, USA; ¹⁰Greater Houston Gastroenterology, Sugar Land, USA; ¹¹Gilead Sciences, Inc., USA; ¹²Beth Israel Deaconess Medical Center, Harvard Medical School, USA; ¹³Korea University Guro Hospital, Korea, South; ¹⁴Institute of Liver Studies, King's College Hospital, UK; ¹⁵Asan Medical Center, University of Ulsan College of Medicine, Korea, South; ¹⁶Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas, Hospital Universitari Valle Hebrón, Spain

10.1136/gutjnl-2020-IDDF.143

Background TAF demonstrated noninferior efficacy to TDF with a superior bone and renal safety profile, in viremic chronic HBV (CHB) patients through week 96, and in virally suppressed patients switched from TDF to TAF at 48 weeks. The duration of prior TDF therapy may influence the degree and rate of recovery of bone and renal function following switch to TAF. Here, we evaluate the impact of prior TDF treatment duration on the safety profile of TAF in virally suppressed patients.

Methods In a double-blind, randomized, multicenter, active-controlled, Phase 3 study, 488 CHB patients who were virologically suppressed on TDF for 1 year, and on TDF monotherapy for 6 months were randomized 1:1 to switch to TAF or continue TDF for 48 weeks. In patients originally randomized to receive TAF, renal, bone, and lipid parameters were categorically evaluated by the duration of prior TDF treatment:

Results Of the 243 patients switched to TAF from TDF, 105 (43%) and 138 (57%) had received TDF for 50 years, 74% male, 80% Asian, median eGFR_{CG} 91 mL/min, 4% and 12% had osteoporosis at hip and spine, respectively. Similar changes in renal, bone, and lipid parameters following 48 weeks of TAF treatment were observed by TDF treatment duration. A