Methods In this study, virally suppressed CHB patients (HBV DNA <LLOQ x 6 months, <20 IU/mL at screening) with moderate or severe RI or with ESRD on HD at screening while receiving TDF and/or other OAVs for ≥48 weeks were enrolled and switched to TAF for 96 weeks. Safety assessments including adverse events (AEs), changes in bone BMD and renal (eGFR_{CG}, serum phosphorus serum creatinine - except in ESRD patients) parameters, viral suppression, serological and biochemical responses were serially assessed.

Results Of 93 patients (mod-severe RI 78; ESRD on HD 15), most (74%) were male and Asian (77%), 51% ≥65 y, 83% HBeAg-negative, 34% cirrhosis, and median ALT 17 U/L. Up to 24% had osteoporosis at hip and/or spine, with most having comorbidities. Twelve (13%; 11 mod-severe RI and 1 ESRD) patients discontinued the study early (5-withdrew consent, 3-deaths [none treatment-related], 2-AE, 2-investigator decision). Viral suppression (HBV DNA<20IU/mL) was maintained in all patients remaining on treatment (i.e. missing equals excluded); a high proportion had target not detected. Overall, TAF was well tolerated with no Grade 3, 4 or serious AEs related to study treatment. Relative to baseline levels, switching to TAF resulted in small median% increases in hip/spine BMD in those with moderate to severe RI, and small median decreases in ESRD patients. 2 patients with mod-severe RI had a bone fracture (ankle, rib). Median eGFR_{CG} increased while urinary markers of proximal tubular function progressively decreased in mod-severe RI patients.

Conclusions Renally-impaired CHB patients, including ESRD patients on HD, who were switched to TAF from TDF and/or other OAVs maintained high rates of viral suppression, and bone and renal parameters remained stable or slightly improved after 2 years of treatment.

IDDF2021-ABS-0079

SWITCHING FROM TENOFOVIR DISOPROXIL FUMARATE (TDF) AND/OR OTHER ORAL ANTIVIRALS (OAVS) TO TENOFOVIR ALAFENAMIDE (TAF) IN VIRALLY SUPPRESSED CHRONIC HEPATITIS B (CHB) PATIENTS WITH HEPATIC IMPAIRMENT: FINAL 2-YEAR EFFICACY AND SAFETY RESULTS FROM A PHASE 2

¹Young-Suk Lim*, ²Chun-Yen Lin, ³Jeong Heo, ⁴Ho Bae, ⁵Wan-Long Chuang, ⁶Tak Yin Owen Tsang, ⁷Claire Fournier, ⁸Aric Josun Hui, ⁹Huy Trinh, ¹⁰Carol Yee Kwan Chan, ¹⁰Susanna K Tan, ¹⁰Yang Zhao, ¹⁰John F Flaherty, ¹⁰Vithika Suri, ¹⁰Anuj Gaggar, ¹⁰Dianna M Brainard, ¹¹Stephen Ryder, ¹²Harry LA Janssen. ¹Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea, South; ²Chang Gung University College of Medicine, Taoyuan City, Taiwan; ³Pusan National University School of Medicine, Pusan National University Hospital, Busan, Korea, South; ⁴Asian Pacific Liver Center, St. Vincent Medical Center, Los Angeles, California, USA; ⁵Kaohsiung Medical University Chung-Ho Memorial Hospital, Kaohsiung City, Taiwan; ⁶Princess Margaret Hospital, Hong Kong; ⁷Université de Montréal, Québec, Canada; ⁸Alice Ho Miu Ling Nethersole Hospital, Hong Kong; ⁹San Jose Gastroenterology, San Jose, California, USA; ¹⁰Gilead Sciences, Inc., Foster City, California, USA; ¹¹NIHR: Nottingham Biomedical Research Centre, Nottingham University Hospitals NHS Trust, Nottingham, UK; ¹²Toronto Centre for Liver Disease, Toronto General Hospital, University Health Network, Toronto, Ontario, Canada

10.1136/gutjnl-2021-IDDF.81

Background We have previously shown that in hepatically impaired CHB patients, switching to TAF from TDF and/or other OAVs maintains high rates of viral suppression with

stable bone and renal safety parameters through 48 weeks. Here we present our final 2-year (Week 96) results.

Methods In this Phase 2 study (NCT03180619), virally suppressed CHB patients (HBV DNA <LLOQ x 6 months and <20 IU/mL at screening) with Child-Turcotte-Pugh (CTP) scores ≥7 and ≤12 at screening (or previously documented to be ≥7) while receiving TDF and/or other OAVs for ≥48 weeks were enrolled and switched to TAF 25 mg QD for 96 weeks. Safety assessments including changes in bone (hip and spine BMD) and renal (CrCL by Cockcroft-Gault [eGFR_{CG}], serum creatinine) parameters, viral suppression, and serological and biochemical responses were serially assessed.

Results Of 31 patients enrolled, mean age was 55 y (29% ≥60 y), 68% male, 81% Asian, and 90% HBeAg-negative; median (Q1, Q3) CTP and MELD scores were 6 (5, 8) and 10 (7.5, 14.2), respectively, median eGFR_{CG} 98.5 mL/min; 19% had osteoporosis on spine DXA. Twenty-five (81%) patients completed 96 weeks of TAF treatment (6 discontinued early: 2-withdrew consent, 1-adverse event [AE; Grade 2 creatinine increase], 1-investigator decision, and 2-death [respiratory failure and aspiration pneumonia - both not treatment-related]). Week 96 efficacy/safety results are summarized in the Table. 96% of patients on TAF treatment had HBV DNA <20 IU/mL with a high proportion having normal ALT levels. Bone and renal parameters remained stable. TAF was well tolerated with no patients having a Grade 3 or 4 AE or a serious AE related to treatment.

Conclusions At 2 years, CHB patients with hepatic impairment who were switched to TAF maintained high rates of viral suppression and normal ALT values while bone and renal parameters remained stable.

IDDF2021-ABS-0080

96-WEEK EFFICACY AND SAFETY OF TENOFOVIR DISOPROXIL FUMARATE (TDF) TO TENOFOVIR ALAFENAMIDE (TAF) SWITCH VS. CONTINUED TDF TREATMENT AMONG VIROLOGICALLY-SUPPRESSED HEPATITIS B PATIENTS OF ASIAN ETHNICITY

¹Sang Hoon Ahn*, ²Jia-Hong Kao, ³Pietro Lampertico, ⁴Alnoor Ramji, ⁵Scott Fung, ⁶Wan-Long Chuang, ⁷Yoon Jun Kim, ⁸Chi-Yi Chen, ⁹Edward Tam, ¹⁰Ho Bae, ¹¹Xiaoli Ma, ¹²June Sung Lee, ¹³Carol Yee Kwan Chan, ¹³Leland J Yee, ¹³Shalini Sethi, ¹³John Flaherty, ¹³Yang Zhao, ¹³Anuj Gaggar, ¹⁴Hie Won Hann, ¹⁵Young-Suk Lim, ¹⁶Henry Lik Yuen Chan. ¹Severance Hospital, Yonsei University College of Medicine, Seoul, Korea, South; ²Division of Gastroenterology and Hepatology, Department of Internal Medicine, National Taiwan University Hospital, Taipei, Taiwan; ³Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Division of Gastroenterology and Hepatology, Milan, Italy. CRC 'A. M. and A. Migliavacca' Center for Liver Disease, Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy; ⁴Gastrointestinal Research Institute (GIRI), Vancouver, Canada; ⁵Toronto Centre for Liver Disease, Toronto General Hospital, University Health Network, Toronto, Canada; ⁶Hepatobiliary Division, Department of Internal Medicine, Kaohsiung Medical University Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan; ⁷Seoul National University Hospital, Seoul, Korea, South; ⁸Division of Gastroenterology and Hepatology, Department of Medicine, Ditmanson Medical Foundation Chiayi Christian Hospital, Chiayi, Taiwan; ⁹Liver and Intestinal Research Centre, Vancouver, Canada; ¹⁰Asian Pacific Liver Center, St. Vincent Medical Center, Los Angeles, USA; ¹¹Hahnemann University Hospital, Philadelphia, PA, USA; ¹²Department of Internal Medicine, Inje University Ilsan Paik Hospital, Goyang, Korea, South; ¹³Gilead Sciences, Foster City, CA, USA; ¹⁴Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, USA; ¹⁵Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea, South; ¹⁶The Chinese University of Hong Kong, Hong Kong

10.1136/gutjnl-2021-IDDF.82