Abstract IDDF2021-ABS-0071 Figure 2

performance status 1(HR:1.362,95%CI:1.127-1.647, $p<0.001$) and status 2(HR:1.553,95%CI: 1.237-1.948, $p<0.001$) were associated with increased mortality. High TBS had decreased overall survival in comparison with medium TBS and low TBS ($p<0.001$, IDDF2021-ABS-0071 Figure 2. The survival distribution of different TBS in HCC patients undergoing TACE). Patients with high TBS had poor overall survival in Barcelona Clinic Liver Cancer (BCLC) stage B/C and different ALBI grades.

Conclusions TBS is a feasible new prognostic surrogate marker of tumor burden in HCC and can well discriminate survival in patients undergoing TACE across different baseline characteristics.

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EFFICACY AND SAFETY OF TENOFOVIR ALAFENAMIDE (TAF) VS TENOFOVIR DISOPROXIL FUMARATE (TDF) IN EAST ASIAN CHRONIC HEPATITIS B PATIENTS FOLLOWING 5-YEARS OF TREATMENT

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Background Pivotal studies GS-US-320-0108 (HBeAg-negative) and GS-US-320-0110 (HBeAg-positive), demonstrated non-inferior antiviral efficacy of TAF vs. TDF with superior renal/bone safety through 5-years, after up to 3 years of double-blind (DB) treatment, open-label (OL) TAF was available through year 8. We analyzed TAF efficacy and safety among patients of Asian Ethnicity in Studies 108/110.

Methods Efficacy was assessed by individual study and included virologic, biochemical, and serologic assessments. Safety data were pooled including estimated GFR (by Cockcroft-Gault method; eGFR_{CG}) and hip and spine bone mineral density (BMD) changes.

Results Among 1298 patients randomized and treated, 591 (45.5%) were Asian (TAF n=410, while n=84 and n=106 received TDF-OL-TAF-3 years and TDF-OL-TAF-2 years, respectively. Virologic control was achieved and maintained in patients receiving TAF (95%) and for TDF-OL-TAF-3 years (100%) and TDF-OL-TAF-2 years (98%). ALT normalization rates were comparable among groups (TAF: 79%, TDF-OL-TAF-3 years: 80%; TDF-OL-TAF-2-years: 79%). HBeAg loss/seroconversion was similar (TAF: 38.6%/27.4%, TDF-OL-TAF-3 years: 46.9%/37.5%; TDF-OL-TAF-2-years: 47.1%/29.4%). Rates of HBsAg loss/seroconversion were similar in all groups ($\leq 1\%$). Rates of Grade $\frac{3}{4}$ adverse events (AEs) and AEs leading to discontinuation were low (1.5%) among all 3 groups. After experiencing declines in eGFR_{CG} and in hip/spine BMD over 2 or 3 years of TDF treatment, renal and bone outcomes were improved following the switch to OL TAF.

Conclusions After 5 years of treatment, virologic suppression remained high, and TAF was safe and well-tolerated with improved renal and bone safety among patients of Asian Ethnicity switching from TDF.

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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 MODERATE OR SEVERE RENAL IMPAIRMENT, OR WITH END-STAGE RENAL DISEASE (ESRD)

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Background We have previously shown in renally impaired (RI) CHB patients, including those with ESRD on HD, that switching to TAF from TDF and/or other OAVs maintains high rates of viral suppression with stable bone and renal safety parameters at Week 48. Here we present the final Week 96 results.

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.

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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

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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.

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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

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