Renal and Bone Parameters	TDF DB (N=211)	TDF → TAF (N=180)	P -Value
eGFR _{CG} , median (Q1, Q3) change (mL/min)	-0.9 (-6.6, +6.0)	+4.2 (-3.3, +9.0)	<0.001
Hip BMD, mean (SD) % change	n=186 -0.02 (2.89)	n=155 +0.98 (2.36)	<0.001
>3% decline in hip BMD, n/N (%)	20/186 (11)	5/155 (3)	0.011
Spine BMD, mean (SD) % change	n=189 +0.26 (3.29)	n=155 +2.04 (3.20)	<0.001
>3% decline in spine BMD, n/N (%)	25/189 (13)	6/155 (4)	0.002

eGFR_{CG} is creatinine clearance by Cockcroft-Gault method, BMD is bone mineral density by dual energy x-ray absorptiometry (DXA), Q is quartile

Abstract IDDF2019-ABS-0168 Figure 1

Abstract IDDF2019-ABS-0168 Table 1 Efficacy and safety renal and bone results from week 96 to week 144

Renal and Bone Parameters	TDF DB (N=211)	TDF→TAF (N=180)	P - Value
eGFR _{CG} , median (Q1, Q3) change (mL/min)	-0.9 (-6.6, +6.0)	+4.2 (-3.3, +9.0)	<0.001
Hip BMD, mean (SD)% change	n=186 -0.02 (2.89)	n=155 +0.98 (2.36)	<0.001
>3% decline in hip BMD, n/N (%)	20/186 (11)	5/155 (3)	0.011
Spine BMD, mean (SD)% change	n=189 +0.26 (3.29)	n=155 +2.04 (3.20)	<0.001
>3% decline in hip BMD, n/N (%)	25/189 (13)	6/155 (4)	0.002

eGFR_{CG} is creatinine clearance by Cockcroft-Gault method, BMD is bone mineral density by dual energy x-ray absorptiometry (DXA), Q is quartile

renal (CrCl by Cockcroft-Gault [eGFR_{CG}], serum creatinine) parameters, viral suppression, and biochemical responses were assessed in all patients from Week 96 to Week 144.

Results Patient characteristics were similar for those who continued TDF and those switched to TAF. In the TDF→TAF group, improvements in eGFR_{CG} were observed, while those remaining on DB TDF showed a continued decrease in eGFR_{CG} at Week 144 (table 1). Similarly, significant improvements in hip and spine BMD were seen over 1 year in TDF→TAF patients while those remaining on TDF either had continued BMD declines or smaller increases (figure 1). High rates of virologic suppression (HBV DNA <29 IU/mL) were maintained in both groups (TDF→TAF 84% and DB TDF 88%; M=F), while a greater rate of ALT normalization (by 2018 AASLD criteria) was seen in TDF→TAF patients at 1 year following switch (45% vs 29%; M=F).

Conclusions Virologic control was maintained and ALT normalization was increased following switch from TDF to TAF. However, compared to those remaining on TDF for an additional year, patients switched to TAF had improved bone and renal safety.

IDDF2019-ABS-0169

A PHASE 3 STUDY COMPARING SWITCHING FROM TENOFOVIR DISOPROXIL FUMARATE (TDF) TO TENOFOVIR ALAFENAMIDE (TAF) WITH CONTINUED TDF TREATMENT IN VIROLOGICALLY-SUPPRESSED PATIENTS WITH CHRONIC HEPATITIS B (CHB): WEEK 48 EFFICACY AND SAFETY RESULTS

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Background TAF has shown efficacy non-inferior to TDF with improved renal and bone safety in viremic CHB patients at Weeks 48 and 96. We evaluated efficacy and safety in stable, virally-suppressed patients who were switched from TDF to TAF vs. continued TDF for an additional year.

Methods CHB patients on TDF for ³48 weeks with HBV DNA <LLOQ for ³12 weeks and <20 IU/mL at screening were randomized (1:1) to TAF 25 mg QD or TDF 300 mg QD, each with matching placebo, and treated for 48 weeks. All patients then received open-label TAF for an additional 48 weeks. The primary efficacy analysis was the proportion of patients with HBV DNA ³20 IU/mL at Week 48. Key

Abstract IDDF2019-ABS-0169 Table 1 Key efficacy and safety results

n/N (%)	TAF (N=243)	TDF (N=245)	P value
Efficacy			
HBV DNA ≥ 20 IU/mL ^a	1/243 (0.4)	1/245 (0.4)	0.95 ^b
HBV DNA < 20 IU/mL	234/243 (96.3)	236/245 (96.3)	0.98
No virologic data in Week 48 window	8/243 (3.3)	8/245 (3.3)	-
ALT normal (2018 AASLD criteria) ^{c,d}	192/243 (79)	184/245 (75.1)	0.31
HBeAg seroconversion ^e	2/78 (2.6)	0	0.13
HBeAg seroconversion	0	0	-
Bone safety			
Hip BMD, mean (SD)% change	+0.66 (2.08)	-0.51 (1.91)	<0.001
Spine BMD, mean (SD)% change	+1.74 (3.46)	-0.11 (3.13)	<0.001
CTX, median (Q1, Q3)% change (ng/mL) ^f	-29.4 (-44.2, -14.3)	+7.1 (-14.8, 32)	<0.001
P1NP, median (Q1, Q3)% change (ng/mL) ^g	-19.4 (-32.2, -7.5)	+1.70 (-12.4, 17)	<0.001
Renal safety			
eGFR _{CG} , median (Q1, Q3) change (mL/min)	+0.99 (-4.47, 6.31)	-2.74 (-7.87, 1.98)	<0.001
RBP/Cr, median (Q1, Q3)% change ^h	-17.7 (-41.3, 17.2)	+18.6 (-15.3, 67.3)	<0.001
β 2MG/Cr, median (Q1, Q3)% change ⁱ	-36.0 (-61.9, -1.1)	+10.7 (-33.9, 90.6)	<0.001

^aHBV DNA results by modified US FDA Snapshot algorithm; other efficacy data are missing=failure; ^bStratified Cochran-Mantel-Haenszel test; ^cALT normal is the proportion with ALT $\leq$ ULN at Week 48, regardless of baseline status; ^dULN 35 U/L males, 25 U/L females; ^eHBeAg-positive at baseline; ^fC-type collagen sequence (bone resorption marker); ^gProcollagen type 1 N-terminal propeptide (bone formation marker); ^hRetinol binding protein/creatinine (tubular marker); ⁱBeta-2 microglobulin/creatinine (tubular marker).

prespecified secondary safety endpoints were changes in hip and spine bone mineral density (BMD), estimated creatinine clearance by Cockcroft-Gault (eGFR_{CG}), and markers of bone turnover and renal tubular function. Viral resistance was evaluated by population sequencing those patients who experienced virologic breakthrough or viremia at the time of discontinuation.

Results 488 patients were randomized and treated. At baseline the groups were similar: median age 52 y, 71% male, 82% Asian, 68% HBeAg-negative, median ALT 23 U/L, median eGFR_{CG} 90.5 mL/min; 45% and 50% had low BMD by T scores at hip and spine, respectively. Median (Q1, Q3) duration of prior TDF was 222 (145, 305) weeks. Key efficacy/safety results are summarized (table 1). TAF demonstrated non-inferior efficacy to TDF with a similar rate (0.4%) of having HBV DNA ≥ 20 IU/mL at Week 48. TAF resulted in hip/spine BMD increases with less impact on bone turnover makers; switching from TDF to TAF resulted in eGFR_{CG} increases and decreased tubular function markers. Rates of ³Grade 2 adverse events (AEs) and serious AEs were low and similar between groups. No viral resistance was observed.

Conclusions Virologically-suppressed CHB patients who were switched to TAF demonstrated noninferior efficacy to continued TDF with improved bone and renal safety.

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ENDOSCOPIC HUMAN THROMBIN INJECTION-PROMISING AND SAFE THERAPY FOR THE MANAGEMENT OF BLEEDING GASTRIC VARICES

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Background Human thrombin appears to be a new effective tool in the armamentarium of management of bleeding gastric varices, but here are paucity of data on its use. Thus, we share our experience with human thrombin in the treatment of bleeding gastric varices.

Methods It was a prospective interventional study conducted between September 2015 and Feb 2019. Patients with upper gastrointestinal bleeding from gastric varices were included, while patients with the previous history of cyanoacrylate glue injection or band ligation were excluded. One vial of human thrombin contains 500 IU which was reconstituted with 1 ml of calcium chloride and 4 ml distilled water. Each ml of reconstituted solution contains 100 IU which was injected into bleeding varices with standard sclerotherapy needle. Amount of thrombin injected depends on the size of varix. (figure 1)

Results A total of 30 patients (M:F-23:7) with mean age 33.1 [17–60] years) presenting with gastric variceal bleeding requiring endoscopic injection of human thrombin were studied. The underlying diagnosis was cirrhosis in 12 patients(40%) , extra-hepatic portal vein thrombosis in 9 patients(30%) , noncirrhotic portal fibrosis in 4 patients(13.3%), chronic pancreatitis in 3 patients (10%), Budd Chiari syndrome in 2 patients (6.6%).

Isolated gastric varices were found in 9 patients while 20 patients had gastroesophageal varices (GOV) (GOV1–3, GOV2–17), ectopic jejunal varices were seen in 1 patient. Patients received 1 to 3 sessions (mean = 1.3) of thrombin with a mean total dose of 600 IU (range = 500–1500 IU). Mean follow up was 33 months (range 3–42 months). Hemostasis in the acute setting was successfully managed in all the

FIGURE- ECTOPIC VARICES IN JEJUNUM

Abstract IDDF2019-ABS-0170 Figure 1