assessed the virological and serological responses of Peg-IFN α-2b alone or in combination with tenofovir disoproxil fumarate (TDF) therapies for HBV postpartum women with low HBsAg level. **Methods:** Postpartum patients received TDF during pregnancy or treatment-naïve with HBsAg ≤ 3000 IU/mL were included in this study (No.ChiCTR 2200058096). All of them received at least 48 weeks of Peg-IFN α-2b therapy after delivery. The primary endpoint was HBsAg clearance rate at the end of the treatment (EOT). Clinical and laboratory data and adverse events (AEs) were collected. **Results:** A total of 42 HBV postpartum women were included and half of them had already received TDF during pregnancy. The mean age was 32.4 (± 3.4) years and 38 (90.5%) patients were HBeAg-negative. The mean initial treatment time of Peg-IFN α-2b was 9.4 (± 4.3) months after delivery. Till now, 34 (81.0%) patients completed treatment, and the data of these patients were analyzed. At EOT, 41.2% (14/34) patients achieved HBsAg clearance and 35.3% (12/34) achieved HBsAg seroconversion. The median treatment time for HBsAg clearance was 24.5 (14.5-39.5) weeks and the median HBsAb level in patients with HBsAg seroconversion was 339.3 (107.2-633.2) IU/L. The median baseline HBsAg level in patients with HBsAg clearance was significantly lower than those without HBsAg clearance (271.6 IU/mL vs. 956.9 IU/mL, $p = 0.002$), and the decline degrees of HBsAg at 12th and 24th week from baseline were significantly higher than those without HBsAg clearance (99.8% vs. 43.0%, $p = 0.000$; 100% vs. 70.1%, $p = 0.000$), while the baseline ALT and HBV DNA levels were not significantly different. 90.0% (9/10) patients with HBV DNA-positive at baseline converted to HBV DNA-negative at EOT. Three patients discontinued Peg-IFN α-2b therapy due to AEs, which included abnormal thyroid function (2/3) and thrombocytopenia (1/3). **Conclusion:** Peg-IFN α-2b monotherapy or combined with TDF treatment in HBV postpartum women with low HBsAg levels can obtain relatively high HBsAg clearance rate. The baseline HBsAg level and on-treatment HBsAg declines at 12/24 weeks might be valuable predictors of HBsAg clearance at EOT.

TABLE Baseline and on-treatment characteristics of the 34 postpartum women who completed the therapy

Characteristics	HBsAg Clearance Group (N=14)	HBsAg Persistence Group (N=20)	*P* value
Age, year, mean (± sd)	33.0 (± 3.6)	32.1 (± 3.2)	0.585
Initial time of Peg-IFN α-2b after delivery, months, median (IQR)	11.0 (6.8-11.3)	9.0 (6.3-11)	0.560
Peg-IFN α-2b plus TDF	10 (71.4%)	10 (50.0%)	0.218
Baseline			
HBV DNA-positive	4 (28.6%)	6 (30.0%)	0.698
HBV DNA Level, log_{10}IU/mL, mean (± sd)	3.4 (± 0.9)	3.4 (± 0.4)	0.862
ALT Level, IU/L, median (IQR)	20.6 (14.4-32.2)	16.7 (13.5-20.5)	0.090
HBsAg level, IU/mL, median (IQR)	271.6 (76.9-665.0)	956.9 (538.2-1673.8)	0.002*
HBsAg decline from baseline, %, median (IQR)			
At 12th week of treatment	99.8% (98.9%-100%)	43.0% (-7.5%†-73.0%)	0.000*
At 24th week of treatment	100% (99.9%-100%)	70.1% (31.1%-95.7%)	0.000*

†The negative sign means the HBsAg level was elevated from baseline.
*$P \leq 0.05$ was considered statistical significance.

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1414-C | EFFICACY AND SAFETY OF TENOFOVIR ALAFENAMIDE (TAF) AT 2 YEARS IN CHILDREN AND ADOLESCENTS WITH CHRONIC HEPATITIS B (CHB)

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Background: TAF, a novel prodrug of tenofovir, has shown noninferior efficacy with superior bone and renal safety compared to tenofovir disoproxil fumarate in randomized trials in adults with CHB. The US FDA has recently approved TAF for treatment of CHB in patients aged 12 and older and weighing ≥35 kg with compensated liver disease, based on Week (W) 24 findings from a randomized, double-blind, placebo (PBO)-controlled trial (GS-US-320-1092; NCT02932150) in children and adolescents. Here we report W96 (2 y) findings from this study. **Methods:** CHB patients 12 to < 18 y and ≥35 kg body weight (Cohort 1; adolescents) and 6 to < 12 y weighing ≥25 kg (Cohort 2, Group 1; children), with HBV DNA ≥ 2×10^4 IU/mL, ALT ≥1.5 × ULN (30 U/L), and creatinine clearance (eGFR; Schwartz method) ≥80 mL/min/1.73m^2 were randomized (2:1) to TAF 25 mg or matching PBO once daily (QD) for 24 weeks followed by an open-label (OL) extension phase where all patients received TAF 25 mg

Symbols: ♦, Poster of Distinction; ★, Foundation Award Recipient

QD through W240 (ie, TAF vs PBO→TAF). At W96, efficacy was assessed by proportion with HBV DNA < 20 IU/mL, serologic, and biochemical responses. Safety assessments included adverse events (AEs) and serious AEs (SAEs) during OL and changes in bone mineral density (BMD) by DXA, eGFR, and resistance surveillance. **Results:** 88 patients were randomized and treated (adolescents: n = 70 [TAF 47, PBO 23]; children: n = 18 [TAF 12, PBO 6]). Overall, mean (range) age and BMI were 14 (7-17) y, and 20.0 (13.6-29.4) kg/m^2; 58% male, 66% Asian, 99% HBeAg-positive, 68% with HBV DNA ≥ 8 $\log_{10}$ IU/mL; median (Q1, Q3) ALT was 66 (52,103) U/L, and 22% had prior nucleos(t)ide use. Forty-four percent were HBV genotype (GT) D, with 24%, 23%, and 7% being GT C, B, and A, respectively. Results at W96 vs W48 showed increasing proportions with HBV DNA < 20 IU/mL in both groups: TAF (61% vs 37%) and PBO→TAF (48% vs 21%). In the TAF group, there was a trend for higher viral suppression in adolescents vs children at W96: 64% vs 50%. Most AEs were mild-moderate; no patient had a Grade 3 or 4 AE or serious AE related to study treatment, and none discontinued TAF due to an AE. At W96, changes from baseline in BMD and in eGFR for the TAF vs PBO→TAF groups were similar (Table), and no participant had eGFR < 90 mL/min/1.73m^2. Resistance to TAF was not detected through W96. **Conclusion:** Increasing rates of viral suppression were seen in pediatric CHB patients treated with TAF for 2 years, while the safety profile remained favorable.

Table. Efficacy and safety outcomes at Week 96

	TAF (N=59)	PBO→TAF (N=29)
HBV DNA <20 IU/mL, n (%)*	36/59 (61)	14/29 (48)
ALT normalization (AASLD)*,#	30/56 (54)	16/28 (57)
HBeAg loss, n/N*	14/58 (24)	5/29 (17)
HBsAg loss, n/N*	1/59 (2)	0/29
Change from BL in eGFR, mL/min/1.73m^2, median (Q1, Q3)**	-13 (-30, 12)	-11 (-21, 2)
% Change from BL in Spine BMD, mean (SD) **	+6.4 (8.99)	+7.6 (11.10)
% Change from BL in Whole Body BMD (minus head), mean (SD)**	+6.6 (6.80)	+7.1 (7.13)

BL, baseline
*Missing = Failure analysis
#Includes only patients with ALT >ULN at baseline; AASLD ULN: 30 U/L
**Observed data
All TAF vs PBO→TAF comparisons were P>0.05

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1415-C | EFFICACY AND SAFETY OF TENOFOVIR ALAFENAMIDE FOR 48 WEEKS IN HBEAG-POSITIVE CHB PATIENTS: A REAL-WORLD, MULTICENTER COHORT STUDY

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Background: There is a limited number of real-world studies investigating the efficacy of tenofovir alafenamide (TAF) in China. Nucleotide analogues (such as tenofovir disoproxil fumarate) have been reported to exhibit additional immunoregulatory effects compared to nucleoside analogues. But there are few clinical studies to explore the immunoregulatory effects of TAF, and a lack of prospective cohort studies evaluating serum cytokine changes during treatment. We conducted a multicenter prospective cohort study to assess the efficacy and safety of TAF, HBsAg and cytokines profile was also conducted during 48-week TAF treatment for chronic hepatitis B virus (HBV) infection. **Methods:** We performed a multicentre, prospective real-world study in China, which enrolled 98 HBeAg positive, treatment-naïve CHB patients with baseline HBV DNA > 2×10^4/mL. The enrolled patients were treated with TAF for 48 weeks. Blood samples were collected at 0, 12, 24 and 48 weeks to detect HBsAg level, cytokines (IFN-λ3, IP-10, IL-12, IL-21, IL-10) in patient serum. **Results:** A total of 98 patients were included. The medium levels of baseline HBV DNA and HBsAg were 7.7 $\log_{10}$ IU/mL and 4.3 $\log_{10}$ IU/mL, respectively. After 48 weeks of TAF treatment, HBsAg declined significantly by a median level of 0.53 log10 IU/mL. Among the patients, 28.6% experienced a decline in HBsAg of more than 1 $\log_{10}$ IU/mL, while no patient achieved HBsAg clearance. Additionally, 12 patients (12.2%) achieved HBeAg clearance, 52 patients (53.1%) achieved the complete virological response (HBV DNA ≤ 20 IU/mL), and ALT normalization (the American Association for the Study of Liver Diseases criteria) in 56.5% of patients after 48 weeks of treatment. Compared with baseline, there were small mean increases in serum creatinine at week 48 (mean change 0.03 mg/dL [0.01-0.05], $p = 0.006$), with almost no change in blood phosphorus and calcium. During the 48-week treatment, IP-10 declined significantly from baseline to 48 weeks (0W, 12W, 24w, 48w median: 671.3 vs 431.3 vs 287.3 vs 269.5 pg/mL, $p < 0.001$). Similarly, IFN-λ3 slightly decreased during 48-week treatment. IL-12, IL-21 and IL-10 remained stable and did not show significant changes. Based on multivariate analysis, it was found that the baseline IP-10 > 1000 pg/mL was an independent predictor of complete virological response at 48 weeks (OR = 5.26, 95% CI:1.27-21.71, $p = 0.022$). Moreover, baseline HBsAg > 4.6 $\log_{10}$ IU/mL , ALT > 299 U/L and IP-10 > 680 pg/mL were independently related with the decline in HBsAg of more than 1 $\log_{10}$ IU/mL after 48 weeks. **Conclusion:** HBsAg declined significantly after 48-week TAF treatment. TAF demonstrated good renal safety during the 48-week treatment period. Moreover, baseline IP-10 level may be related with antiviral efficacy.

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1416-C | EFFICACY AND SAFETY OF TENOFOVIR ALAFENAMIDE IN THE TREATMENT OF DECOMPENSATED CIRRHOTIC PATIENTS WITH CHRONIC HEPATITIS B

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Background: Hepatitis B viral (HBV) infection is a leading cause of liver cirrhosis and hepatocellular carcinoma (HCC) worldwide. Tenofovir alafenamide (TAF) is a new antiviral drug approved for the treatment of chronic HBV (CHB) infection. However, the effect of TAF therapy on viral suppression and hepatic function in CHB patients with decompensated cirrhosis remains unknown. This study aims to evaluate the efficacy and safety of TAF treatment in CHB patients with decompensated cirrhosis. **Methods:** Decompensated CHB patients with ascites were enrolled and provided 25 mg/day of TAF. Treatment outcomes were evaluated after 24 weeks of treatment, including clinical events, virological, serological, and biochemical responses. **Results:** Among the 182 recruited patients, 126 have completed the 24-week study thus far. At week 24, an undetectable HBV-DNA level was achieved in 56.3% (71/126) of patients, and ALT normalization was observed in 76.2% (96/126) of patients. Additionally, 69 (54.8%) patients experienced resolution of ascites. During the study, one patient died, three patients developed HCC, six patients developed gastroesophageal variceal bleeding, and five patients

Symbols: ♦, Poster of Distinction; ★, Foundation Award Recipient