ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/07/2015

Grantor: CDER IND/IDE Number: 76,574 Serial Number:

A Study to Compare Tenofovir DF Versus the Combination of Emtricitabine Plus Tenofovir DF for the Treatment of Chronic Hepatitis B in Patients With Normal Alanine Aminotransferase (ALT)

This study has been completed.

Sponsor:	Gilead Sciences
Collaborators:	
Information provided by (Responsible Party):	Gilead Sciences
ClinicalTrials.gov Identifier:	NCT00507507

Purpose

The main objective of the study was to evaluate the antiviral activity of tenofovir disoproxil fumarate (tenofovir DF) monotherapy versus emtricitabine (FTC) plus tenofovir DF combination therapy for the treatment of chronic hepatitis B (HBV) in participants in the immune tolerant phase of HBV infection.

The efficacy of tenofovir DF monotherapy versus FTC plus tenofovir DF combination therapy was evaluated for suppression of the virus (decrease in HBV DNA), serological response (generation of antibodies to the virus), biochemical response (changes in liver enzymes), and the development of drug-resistant mutations. The safety and tolerability of both tenofovir DF monotherapy and FTC plus tenofovir DF were evaluated by routine monitoring for adverse events and changes in laboratory parameters.

Participants were randomized in a 1:1 ratio to receive tenofovir DF monotherapy or FTC plus tenofovir DF. All subjects were to continue on blinded study medication until the last subject reached Week 192. Participants who permanently discontinued study drug (on or before Week 192) were followed for a 24-week treatment-free follow-up period, or until initiation of alternative HBV therapy, whichever occurred first. Subjects who discontinued study drug on or after Week 48 because of hepatitis B surface antigen (HBsAg) loss or seroconversion to antibody to hepatitis B surface antigen (anti-HBs), however, were to have returned for their regularly scheduled through Week 192 and every 16 weeks thereafter until the last subject reached Week 192.

Condition	Intervention	Phase
Chronic Hepatitis B	Drug: Tenofovir DF Drug: FTC	Phase 2

Condition	Intervention	Phase
	Drug: Placebo	

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety/Efficacy Study
Official Title: A Randomized, Double-Blind Study Evaluating Tenofovir Disoproxil Fumarate (DF) Monotherapy Versus the Combination of Emtricitabine and Tenofovir DF for the Treatment of Chronic Hepatitis B

Further study details as provided by Gilead Sciences:

Primary Outcome Measure:

- Percentage of Participants With HBV DNA < 400 Copies/mL at Week 192 [Time Frame: Week 192] [Designated as safety issue: No]
  The percentage of participants with HBV DNA < 400 copies/mL at Week 192 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.

Secondary Outcome Measures:

- Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144 [Time Frame: Weeks 48, 96, and 144] [Designated as safety issue: No]
  The percentage of participants with HBV DNA < 400 copies/mL at Weeks 48, 96, and 144 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
- Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  The percentage of participants with HBV DNA < 169 copies/mL at Weeks 48, 96, 144, and 192 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
- Change From Baseline in HBV DNA at Week 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  The change from baseline in HBV DNA at Week 48 was analyzed.
- Change From Baseline in HBV DNA at Week 96 [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  The change from baseline in HBV DNA at Week 96 was analyzed.
- Change From Baseline in HBV DNA at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  The change from baseline in HBV DNA at Week 144 was analyzed.
- Change From Baseline in HBV DNA at Week 192 [Time Frame: Baseline to Week 192] [Designated as safety issue: No]
  The change from baseline in HBV DNA at Week 192 was analyzed.
- Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  Range of normal ALT was 6 to 34 U/L for females, 6 to 43 U/L for males. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
- Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  The number of participants with HBeAg loss at Weeks 48, 96, 144, and 192 was analyzed. Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. No statistical analysis is presented for Week 48 because no participants met the criteria at that time point.
- Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  The number of participants with seroconversion to anti-HBe at Weeks 48, 96, 144, and 192 was analyzed. Seroconversion to anti-HBe was defined as change of detectable antibody to HBeAg from negative to positive. No statistical analysis is presented for Week 48 because no participants met the criteria at that time point.

- Number of Participants With Hepatitis B Surface Antigen (HBsAg) Loss at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  The number of participants with HBsAg loss at Weeks 48, 96, 144, and 192 was analyzed. Loss of HBsAg was defined as change of detectable HBsAg from positive to negative.
- Number of Participants With Seroconversion to Antibody to HBsAg (Anti-HBs) at Weeks 48, 96, 144, and 192 [Time Frame: Weeks 48, 96, 144, and 192] [Designated as safety issue: No]
  The number of participants with seroconversion to anti-HBs at Weeks 48, 96, 144, and 192 was analyzed. Seroconversion to anti-HBs was defined as change of detectable antibody to HBsAg from negative to positive.
- Occurrence of HBV Resistance Mutations [Time Frame: Baseline to Week 192] [Designated as safety issue: No]
  The development of HBV resistance mutations (occurrence of conserved site changes and/or polymorphic site changes) was analyzed for the overall study period (through Week 192).

Enrollment: 126
Study Start Date: September 2007
Primary Completion Date: February 2012
Study Completion Date: August 2012

Arms	Assigned Interventions
Experimental: Tenofovir DF Participants were randomized to receive tenofovir DF plus placebo to match FTC once daily.	Drug: Tenofovir DF Tenofovir disoproxil fumarate (tenofovir DF) 300 mg tablet taken orally once daily Other Names: Viread® Drug: Placebo Placebo to match FTC taken once daily
Experimental: FTC+Tenofovir DF Participants were randomized to receive FTC plus tenofovir DF once daily.	Drug: Tenofovir DF Tenofovir disoproxil fumarate (tenofovir DF) 300 mg tablet taken orally once daily Other Names: Viread® Drug: FTC Emtricitabine (FTC) 200 mg capsule taken orally once daily Other Names: Emtriva®

Eligibility

Ages Eligible for Study: 18 Years to 69 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Chronic HBV infection, defined as positive serum HBsAg for at least 6 months or HBsAg positive > 3 months and positive for immunoglobulin G antibody against hepatitis B core antigen
- 18 through 69 years of age, inclusive
- Hepatitis B e antigen (HBeAg) positive
- HBV DNA ≥ 10^8 copies/mL
- ALT ≤ the upper limit of the normal range (ULN)
- Willing and able to provide written informed consent
- Negative serum beta-human chorionic gonadotropin (for females of childbearing potential only)
- Calculated creatinine clearance ≥ 70 mL/min
- Hemoglobin ≥ 10 g/dL
- Neutrophils ≥ 1,500/mm^3
- No prior oral HBV therapy (eg, nucleotide and/or nucleoside therapy or other investigational agents for HBV infection)

Exclusion Criteria:

- Pregnant women, women who were breast feeding, or who believed they may have wished to become pregnant during the course of the study
- Males and females of reproductive potential unwilling to use an effective method of contraception during the study
- Decompensated liver disease defined as direct (conjugated) bilirubin > 1.2 x ULN, prothrombin time > 1.2 x ULN, platelets < 150,000/mm^3, serum albumin < 3.5 g/dL, or prior history of clinical hepatic decompensation (eg, ascites, jaundice, encephalopathy, or variceal hemorrhage)
- Received interferon (pegylated or not) therapy within 6 months of the screening visit
- Alpha-fetoprotein > 50 ng/mL
- Evidence of hepatocellular carcinoma
- Coinfection with hepatitis C virus (by serology), HIV, or hepatitis D virus
- Significant renal, cardiovascular, pulmonary, or neurological disease
- Received solid organ or bone marrow transplantation
- Was currently receiving therapy with immunomodulators (eg, corticosteroids, etc.), investigational agents, nephrotoxic agents, or agents susceptible of modifying renal excretion
- Had proximal tubulopathy
- Known hypersensitivity to the study drugs, the metabolites, or formulation excipients

Contacts and Locations

Locations

United States, California
- Los Angeles, California, United States, 90048
- San Diego, California, United States, 92115
- San Francisco, California, United States, 11355

United States, Florida
- Miami, Florida, United States, 33136

United States, Michigan
- Detroit, Michigan, United States, 48202

United States, New York

Manhasset, New York, United States, 11030
New York, New York, United States, 10029-6574
New York, New York, United States, 10021
United States, Tennessee
Germantown, Tennessee, United States, 38138
United States, Washington
Seattle, Washington, United States, 98111
Australia, New South Wales
Camperdown, New South Wales, Australia, 2050
Westmead, New South Wales, Australia, 2145
Australia, Victoria
Heidelburg, Victoria, Australia, 3081
Melbourne, Victoria, Australia, 3004
Canada, Alberta
Calgary, Alberta, Canada, T2N4N1
Canada, British Columbia
Vancouver, British Columbia, Canada, V5Z1H2
Canada, Ontario
Toronto, Ontario, Canada, M5G 2C4
France
Lille, France, 59037
Lyon, France, 69288
Strasbourg, France, 67091
Germany
Berlin, Germany, 10969
Berlin, Germany, 13353
Duesseldorf, Germany, 40237
Frankfurt, Germany, 60590
Hamburg, Germany, 20251
Hannover, Germany, 30623
Heidelberg, Germany, 69120
Herne, Germany, 44623
Mainz, Germany, 55131
Hong Kong
Pokfulam, Hong Kong
Shatin, Hong Kong
Tai Po, Hong Kong
New Zealand
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More Information

Responsible Party: Gilead Sciences
Study ID Numbers: GS-US-203-0101
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	Participants were enrolled at 34 sites in the North America, Europe, Asia, Australia, and New Zealand. The first participant was screened on 04 September 2007. The last participant observation for the Week 192 analysis was on 03 February 2012.
Pre-Assignment Details	309 participants were screened and 129 were randomized; 126 randomized participants received at least one dose of study drug, and comprise the Safety Analysis Set and the Full Analysis Set.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir disoproxil fumarate (tenofovir DF; 300 mg tablet) plus placebo to match emtricitabine (FTC; tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Treatment Period

	Tenofovir DF	FTC+Tenofovir DF
Started	64	62

	Tenofovir DF	FTC+Tenofovir DF
Completed 192 Weeks of Treatment	52	52
Completed	12	9
Not Completed	52	53
Lost to Follow-up	0	2
Physician Decision	4	1
Protocol Violation	1	2
Adverse Event	1	1
Withdrawal by Subject	46	47

24-week Treatment-free Follow-up Period

	Tenofovir DF	FTC+Tenofovir DF
Started	26 [1]	29 [1]
Completed	16	12
Not Completed	10	17
Physician Decision	1	0
Adverse Event	0	1
Withdrawal by Subject	9	16

[1] Participants who discontinued treatment early may have entered the treatment-free follow-up period.

Baseline Characteristics

Analysis Population Description

Participants who were randomized and treated were analyzed for baseline characteristics.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Baseline Measures

	Tenofovir DF	FTC+Tenofovir DF	Total
Number of Participants	64	62	126
Age, Continuous [units: years] Mean (Standard Deviation)	33 (9.5)	33 (11.2)	33 (10.3)
Gender, Male/Female [units: participants]			
Female	33	31	64
Male	31	31	62
Ethnicity (NIH/OMB) [units: participants]			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	64	62	126
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized [units: participants]			
Asian	56	56	112
White	4	1	5
Black	2	2	4
Pacific Islander	1	3	4
Other	1	0	1
Region of Enrollment [1] [units: participants]			
Australia	0	2	2
Canada	4	3	7
France	4	3	7
Germany	3	3	6
Hong Kong	28	33	61
New Zealand	2	4	6
Poland	2	0	2

	Tenofovir DF	FTC+Tenofovir DF	Total
Singapore	2	0	2
Taiwan	6	6	12
United Kingdom	0	2	2
United States	14	8	22
Hepatitis B Virus (HBV) DNA [units: log_10 copies/mL] Mean (Standard Deviation)	9.18 (0.402)	9.16 (0.395)	9.17 (0.397)
Alanine Aminotransferase (ALT) [units: U/L] Mean (Standard Deviation)	26.9 (14.05)	26.2 (9.88)	26.6 (12.13)
Hepatitis B e Antigen (HBeAg) [units: participants]			
Negative	1	0	1
Positive	63	62	125
Antibody to HBeAg (Anti-HBe) [units: participants]			
Negative	0	1	1
Positive	1	0	1
Missing/Unevaluable	63	61	124

[1] All randomized participants were analyzed for Region of Enrollment. (Tenofovir DF, n = 65; FTC+tenofovir DF, n = 64.)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With HBV DNA < 400 Copies/mL at Week 192
Measure Description	The percentage of participants with HBV DNA < 400 copies/mL at Week 192 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
Time Frame	Week 192
Safety Issue?	No

Analysis Population Description

Full Analysis Set: participants who were randomized and received at least one dose of study drug

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Percentage of Participants With HBV DNA < 400 Copies/mL at Week 192 [units: percentage of participants]	54.7	75.8

Statistical Analysis 1 for Percentage of Participants With HBV DNA < 400 Copies/mL at Week 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	The null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 400 copies/mL at Week 192 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference. The sample size provided at least 85% power to detect a difference of 30% between the groups, assuming response rates of 30% and 60% in the Tenofovir DF and FTC+Tenofovir DF groups, respectively.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.016
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144

Measure Description	The percentage of participants with HBV DNA < 400 copies/mL at Weeks 48, 96, and 144 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
Time Frame	Weeks 48, 96, and 144
Safety Issue?	No

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144 [units: percentage of participants]		
Week 48	40.6	59.7
Week 96	53.1	75.8
Week 144	62.5	80.6

Statistical Analysis 1 for Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 48: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 400 copies/mL at Week 48 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.050
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 96: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 400 copies/mL at Week 96 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.009
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3 for Percentage of Participants With HBV DNA < 400 Copies/mL at Weeks 48, 96, and 144

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 144: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 400 copies/mL at Week 144 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.030
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192
Measure Description	The percentage of participants with HBV DNA < 169 copies/mL at Weeks 48, 96, 144, and 192 was analyzed. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
Time Frame	Weeks 48, 96, 144, and 192
Safety Issue?	No

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192 [units: percentage of participants]		
Week 48	29.7	33.9
Week 96	45.3	64.5
Week 144	50.0	72.6
Week 192	45.3	69.4

Statistical Analysis 1 for Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 48: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 169 copies/mL at Week 48 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.703
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 96: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 169 copies/mL at Week 96 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.034
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3 for Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 144: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 169 copies/mL at Week 144 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.011
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.

	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 4 for Percentage of Participants With HBV DNA < 169 Copies/mL at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 192: the null hypothesis was that there was no difference in the proportion of subjects with HBV DNA < 169 copies/mL at Week 192 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.007
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in HBV DNA at Week 48
Measure Description	The change from baseline in HBV DNA at Week 48 was analyzed.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with evaluable change data at Week 48 were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	58
Change From Baseline in HBV DNA at Week 48 [units: log_10 copies/mL] Mean (Standard Deviation)	-6.22 (0.608)	-6.49 (0.577)

Statistical Analysis 1 for Change From Baseline in HBV DNA at Week 48

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	The null hypothesis was that there was no difference of change in HBV DNA from baseline between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.010
	Comments	A Wilcoxon rank-sum (2-sided) test was used, with no adjustments for covariates.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in HBV DNA at Week 96
Measure Description	The change from baseline in HBV DNA at Week 96 was analyzed.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with evaluable change data at Week 96 were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	59	56
Change From Baseline in HBV DNA at Week 96 [units: log_10 copies/mL] Mean (Standard Deviation)	-6.46 (0.763)	-6.55 (1.176)

Statistical Analysis 1 for Change From Baseline in HBV DNA at Week 96

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	The null hypothesis was that there was no difference of change in HBV DNA from baseline between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.019
	Comments	A Wilcoxon rank-sum (2-sided) test was used, with no adjustments for covariates.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in HBV DNA at Week 144
Measure Description	The change from baseline in HBV DNA at Week 144 was analyzed.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with evaluable change data at Week 96 were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	55	56
Change From Baseline in HBV DNA at Week 144 [units: log_10 copies/mL] Mean (Standard Deviation)	-6.66 (0.655)	-6.62 (1.318)

Statistical Analysis 1 for Change From Baseline in HBV DNA at Week 144

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	The null hypothesis was that there was no difference of change in HBV DNA from baseline between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.186
	Comments	A Wilcoxon rank-sum (2-sided) test was used, with no adjustments for covariates.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in HBV DNA at Week 192

Measure Description	The change from baseline in HBV DNA at Week 192 was analyzed.
Time Frame	Baseline to Week 192
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with evaluable change data at Week 96 were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	53	54
Change From Baseline in HBV DNA at Week 192 [units: log_10 copies/mL] Mean (Standard Deviation)	-6.32 (1.463)	-6.70 (0.913)

Statistical Analysis 1 for Change From Baseline in HBV DNA at Week 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	The null hypothesis was that there was no difference of change in HBV DNA from baseline between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.070
	Comments	A Wilcoxon rank-sum (2-sided) test was used, with no adjustments for covariates.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192
Measure Description	Range of normal ALT was 6 to 34 U/L for females, 6 to 43 U/L for males. Participants with missing data were considered to have failed to achieve the criteria for evaluation.
Time Frame	Weeks 48, 96, 144, and 192
Safety Issue?	No

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192 [units: participants]		
Week 48	52	54
Week 96	52	50
Week 144	51	46
Week 192	41	44

Statistical Analysis 1 for Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF

	Comments	Analysis at Week 48: the null hypothesis was that there was no difference in the proportion of subjects with normal ALT at Week 48 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.467
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used, with no adjustments for covariates.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 96: the null hypothesis was that there was no difference in the proportion of subjects with normal ALT at Week 96 between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	1.000
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used, with no adjustments for covariates.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3 for Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 144: the null hypothesis was that there was no difference in the proportion of subjects with normal ALT at Week 144 between the Tenofovir DF and FTC +Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.529
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used, with no adjustments for covariates.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 4 for Number of Participants With Normal Alanine Aminotransferase (ALT) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 192: the null hypothesis was that there was no difference in the proportion of subjects with normal ALT at Week 192 between the Tenofovir DF and FTC +Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.451
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used, with no adjustments for covariates.
	Method	Fisher Exact
	Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192
Measure Description	The number of participants with HBeAg loss at Weeks 48, 96, 144, and 192 was analyzed. Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. No statistical analysis is presented for Week 48 because no participants met the criteria at that time point.
Time Frame	Weeks 48, 96, 144, and 192
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set who were HBeAg positive at baseline were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	63	62
Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192 [units: participants]		
Week 48	0	0
Week 96	2	0
Week 144	4	0
Week 192	4	1

Statistical Analysis 1 for Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 96: the null hypothesis was that there was no difference in the proportion of subjects with HBeAg loss between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.496
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 144: the null hypothesis was that there was no difference in the proportion of subjects with HBeAg loss between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.119
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3 for Number of Participants With Hepatitis B e Antigen (HBeAg) Loss at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 192: the null hypothesis was that there was no difference in the proportion of subjects with HBeAg loss between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.365
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192
Measure Description	The number of participants with seroconversion to anti-HBe at Weeks 48, 96, 144, and 192 was analyzed. Seroconversion to anti-HBe was defined as change of detectable antibody to HBeAg from negative to positive. No statistical analysis is presented for Week 48 because no participants met the criteria at that time point.
Time Frame	Weeks 48, 96, 144, and 192

Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set who were HBeAg positive at baseline were analyzed.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	63	62
Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192 [units: participants]		
Week 48	0	0
Week 96	2	0
Week 144	4	0
Week 192	3	0

Statistical Analysis 1 for Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 96: the null hypothesis was that there was no difference in the proportion of subjects with seroconversion to anti-HBe between the Tenofovir DF and FTC+Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.496
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2 for Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 144: the null hypothesis was that there was no difference in the proportion of subjects with seroconversion to anti-HBe between the Tenofovir DF and FTC +Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.119
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3 for Number of Participants With Seroconversion to Antibody Against HBeAg (Anti-HBe) at Weeks 48, 96, 144, and 192

Statistical Analysis Overview	Comparison Groups	Tenofovir DF, FTC+Tenofovir DF
	Comments	Analysis at Week 192: the null hypothesis was that there was no difference in the proportion of subjects with seroconversion to anti-HBe between the Tenofovir DF and FTC +Tenofovir DF groups; the alternative hypothesis was that there was a difference.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.244
	Comments	A Fisher exact test with a 0.05 two-sided significance level was used.
	Method	Fisher Exact
	Comments	[Not specified]

11. Secondary Outcome Measure:

Measure Title	Number of Participants With Hepatitis B Surface Antigen (HBsAg) Loss at Weeks 48, 96, 144, and 192
Measure Description	The number of participants with HBsAg loss at Weeks 48, 96, 144, and 192 was analyzed. Loss of HBsAg was defined as change of detectable HBsAg from positive to negative.
Time Frame	Weeks 48, 96, 144, and 192
Safety Issue?	No

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Number of Participants With Hepatitis B Surface Antigen (HBsAg) Loss at Weeks 48, 96, 144, and 192 [units: participants]		
Week 48	0	0
Week 96	0	0
Week 144	0	0
Week 192	0	0

12. Secondary Outcome Measure:

Measure Title	Number of Participants With Seroconversion to Antibody to HBsAg (Anti-HBs) at Weeks 48, 96, 144, and 192
Measure Description	The number of participants with seroconversion to anti-HBs at Weeks 48, 96, 144, and 192 was analyzed. Seroconversion to anti-HBs was defined as change of detectable antibody to HBsAg from negative to positive.
Time Frame	Weeks 48, 96, 144, and 192

Safety Issue?	No

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	64	62
Number of Participants With Seroconversion to Antibody to HBsAg (Anti-HBs) at Weeks 48, 96, 144, and 192 [units: participants]		
Week 48	0	0
Week 96	0	0
Week 144	0	0
Week 192	0	0

13. Secondary Outcome Measure:

Measure Title	Occurrence of HBV Resistance Mutations
Measure Description	The development of HBV resistance mutations (occurrence of conserved site changes and/or polymorphic site changes) was analyzed for the overall study period (through Week 192).
Time Frame	Baseline to Week 192
Safety Issue?	No

Analysis Population Description

Genotyping was attempted for all participants with HBV DNA ≥ 400 copies/mL at Week 48, 96, 144, 192 and/or the early discontinuation visit, and for all participants (with HBV DNA ≥ 400 copies/mL) after Week 192 who were on study for at least 216 weeks when the last participant reached Week 192.

Reporting Groups

	Description
Tenofovir DF	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily.
FTC+Tenofovir DF	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily.

Measured Values

	Tenofovir DF	FTC+Tenofovir DF
Number of Participants Analyzed	40	29
Occurrence of HBV Resistance Mutations [units: participants]		
Conserved (with/without polymorphic) site changes	6	5
Polymorphic site changes only	16	9

Reported Adverse Events

Time Frame	Baseline until the last participant reached Week 192, and 24-week treatment-free follow-up.
Additional Description	Treatment-emergent adverse events were collected until the last participant reached Week 192. Adverse events were also collected for those participants who permanently discontinued study drug on or before Week 192 and were followed for 24 weeks off treatment or until initiation of alternative HBV therapy, whichever occurred first.

Reporting Groups

	Description
Tenofovir DF (Treatment Period)	Participants were randomized to receive tenofovir DF (300 mg tablet) plus placebo to match FTC (tablet) orally once daily. Adverse events (AEs) for this reporting group are reported for the entire treatment period.
FTC+Tenofovir DF (Treatment Period)	Participants were randomized to receive FTC (200 mg tablet) plus tenofovir DF (300 mg tablet) orally once daily. AEs for this reporting group are reported for the entire treatment period.

	Description
Tenofovir DF (24-week Treatment-free Follow-up Period)	This reporting group includes participants randomized to the Tenofovir DF group who permanently discontinued study drug on or before the last subject reached Week 192 and were followed for 24 weeks off treatment or until initiation of alternative HBV therapy, whichever occurred first. AEs reported for this reporting group are those that occurred during the 24-week treatment-free follow-up period only.
FTC+Tenofovir DF (24-week Treatment-free Follow-up Period)	This reporting group includes participants randomized to the FTC+Tenofovir DF group who permanently discontinued study drug on or before the last subject reached Week 192 and were followed for 24 weeks off treatment or until initiation of alternative HBV therapy, whichever occurred first. AEs reported for this reporting group are those that occurred during the 24-week treatment-free follow-up period only.

Serious Adverse Events

	Tenofovir DF (Treatment Period)	FTC+Tenofovir DF (Treatment Period)	Tenofovir DF (24-week Treatment-free Follow-up Period)	FTC+Tenofovir DF (24-week Treatment-free Follow-up Period)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/64 (9.38%)	3/62 (4.84%)	0/26 (0%)	0/29 (0%)
Infections and infestations				
Appendicitis [A] †	1/64 (1.56%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Gastroenteritis [A] †	1/64 (1.56%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Hepatitis B [A] †	1/64 (1.56%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Urinary tract infection [A] †	1/64 (1.56%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)
Investigations				
Blood creatine phosphokinase increased [A] †	1/64 (1.56%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Uterine leiomyoma [A] †	1/64 (1.56%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous [A] †	0/64 (0%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)
Reproductive system and breast disorders				

	Tenofovir DF (Treatment Period)	FTC+Tenofovir DF (Treatment Period)	Tenofovir DF (24-week Treatment-free Follow-up Period)	FTC+Tenofovir DF (24-week Treatment-free Follow-up Period)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Ovarian cyst [A] †	0/64 (0%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (14.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Tenofovir DF (Treatment Period)	FTC+Tenofovir DF (Treatment Period)	Tenofovir DF (24-week Treatment-free Follow-up Period)	FTC+Tenofovir DF (24-week Treatment-free Follow-up Period)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	41/64 (64.06%)	39/62 (62.9%)	2/26 (7.69%)	7/29 (24.14%)
Gastrointestinal disorders				
Abdominal pain upper [A] †	6/64 (9.38%)	5/62 (8.06%)	0/26 (0%)	0/29 (0%)
Constipation [A] †	5/64 (7.81%)	0/62 (0%)	0/26 (0%)	0/29 (0%)
Diarrhoea [A] †	1/64 (1.56%)	4/62 (6.45%)	0/26 (0%)	0/29 (0%)
Nausea [A] †	4/64 (6.25%)	3/62 (4.84%)	0/26 (0%)	0/29 (0%)
Vomiting [A] †	5/64 (7.81%)	2/62 (3.23%)	0/26 (0%)	0/29 (0%)
General disorders				
Asthenia [A] †	4/64 (6.25%)	3/62 (4.84%)	0/26 (0%)	0/29 (0%)
Fatigue [A] †	5/64 (7.81%)	4/62 (6.45%)	0/26 (0%)	2/29 (6.9%)
Influenza like illness [A] †	6/64 (9.38%)	6/62 (9.68%)	0/26 (0%)	0/29 (0%)
Pyrexia [A] †	0/64 (0%)	0/62 (0%)	1/26 (3.85%)	2/29 (6.9%)
Infections and infestations				
Gastroenteritis [A] †	6/64 (9.38%)	4/62 (6.45%)	0/26 (0%)	0/29 (0%)
Influenza [A] †	14/64 (21.88%)	12/62 (19.35%)	2/26 (7.69%)	3/29 (10.34%)

	Tenofovir DF (Treatment Period)	FTC+Tenofovir DF (Treatment Period)	Tenofovir DF (24-week Treatment-free Follow-up Period)	FTC+Tenofovir DF (24-week Treatment-free Follow-up Period)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nasopharyngitis [A] †	5/64 (7.81%)	6/62 (9.68%)	0/26 (0%)	0/29 (0%)
Upper respiratory tract infection [A] †	7/64 (10.94%)	8/62 (12.9%)	0/26 (0%)	0/29 (0%)
Investigations				
Blood creatine phosphokinase increased [A] †	5/64 (7.81%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	7/64 (10.94%)	2/62 (3.23%)	0/26 (0%)	0/29 (0%)
Back pain [A] †	4/64 (6.25%)	5/62 (8.06%)	0/26 (0%)	0/29 (0%)
Myalgia [A] †	4/64 (6.25%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)
Nervous system disorders				
Headache [A] †	8/64 (12.5%)	10/62 (16.13%)	0/26 (0%)	0/29 (0%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	8/64 (12.5%)	7/62 (11.29%)	0/26 (0%)	0/29 (0%)
Oropharyngeal Pain [A] †	4/64 (6.25%)	3/62 (4.84%)	0/26 (0%)	0/29 (0%)
Skin and subcutaneous tissue disorders				
Urticaria [A] †	4/64 (6.25%)	1/62 (1.61%)	0/26 (0%)	0/29 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (14.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:
Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

After conclusion of the study and without prior written approval from Gilead, investigators in this study may communicate, orally present, or publish in scientific journals or other media only after the following conditions have been met:

- The results of the study in their entirety have been publicly disclosed by or with the consent of Gilead in an abstract, manuscript, or presentation form; or
- The study has been completed at all study sites for at least 2 years

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