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Study Comparing Tenofovir Disoproxil Fumarate (TDF), Emtricitabine (FTC)/TDF, and Entecavir (ETV) in the Treatment of Chronic HBV in Subjects With Decompensated Liver Disease.

This study has been completed.

Sponsor:	Gilead Sciences
Collaborators:	
Information provided by (Responsible Party):	Gilead Sciences
ClinicalTrials.gov Identifier:	NCT00298363

Purpose

This study was designed to evaluate and compare the safety and tolerability of tenofovir disoproxil fumarate (TDF), emtricitabine (FTC)/TDF, and entecavir (ETV) in the treatment of hepatitis B patients with decompensated liver disease. Safety was assessed by evaluating adverse events (AEs) and laboratory abnormalities. Efficacy was assessed by evaluating reductions in Child-Pugh-Turcotte (CPT) and Model for End Stage Liver Disease (MELD) scores, reductions in hepatitis B virus (HBV) deoxyribonucleic acid (DNA), changes in liver enzymes, development of drug-resistant mutations, and generation of antibody to virus.

A maximum randomized treatment duration of 168 weeks was planned. Since subjects with decompensated liver disease were enrolled into this study, it was necessary to provide early intervention strategies if profound viral suppression was not expeditiously achieved. For this reason, subjects with a decrease in plasma HBV DNA from baseline of < 2 log_10 copies/mL and plasma HBV DNA > 10,000 copies/mL (or plasma HBV DNA > 1,000 copies/mL for subjects who entered the study with HBV DNA < 10,000 copies/mL) at Week 8 had the option to start open-label FTC/TDF and continue in the study. Subjects with a virologic breakthrough or who had plasma HBV DNA levels remaining > 400 copies/mL (confirmed) at or after 24 weeks of treatment could have been unblinded at the investigator's discretion for selection of alternative anti-HBV therapy that may have included open-label FTC/TDF. If study drug was permanently discontinued, immediate initiation of another anti-HBV regimen was strongly recommended.

Condition	Intervention	Phase
Chronic Hepatitis B	Drug: Tenofovir disoproxil fumarate (tenofovir DF; TDF)	Phase 2

Condition	Intervention	Phase
	Drug: Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) Drug: Entecavir (ETV) Drug: TDF placebo Drug: FTC/TDF placebo Drug: ETV placebo	

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety/Efficacy Study
Official Title: A Phase 2, Double-Blind, Multi-center, Randomized Study Comparing Tenofovir Disoproxil Fumarate, Emtricitabine Plus Tenofovir Disoproxil Fumarate, and Entecavir in the Treatment of Chronic Hepatitis B Subjects With Decompensated Liver Disease and in the Prevention of Hepatitis B Recurrence Post-Transplantation

Further study details as provided by Gilead Sciences:

Primary Outcome Measure:

- Percent Probability of Tolerability Failure [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  Tolerability failure was defined as permanent discontinuation of study drug due to a treatment-emergent adverse event (AE), including any subject who temporarily discontinued study drug due to an AE and did not restart. Results are expressed as proportions of participants who experience tolerability failure using the Kaplan-Meier (KM) method of estimation.
- Percent Probability of a Confirmed Increase in Serum Creatinine of ≥ 0.5 mg/dL From Baseline or a Confirmed Serum Phosphorus Level < 2.0 mg/dL [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  Results are expressed as proportions of participants who experience a confirmed increase in serum creatinine of ≥ 0.5 mg/dL from baseline or a confirmed serum phosphorus level < 2.0 mg/dL using the KM method of estimation.

Secondary Outcome Measures:

- Median Time-averaged Change (DAVG) in Plasma Hepatitis B Virus (HBV) Deoxyribonucleic Acid (DNA) Levels at 48 Weeks Relative to Baseline [Time Frame: Baseline to 48 weeks] [Designated as safety issue: No]
  Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 48 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
- Median DAVG in Plasma HBV DNA Levels at 96 Weeks Relative to Baseline [Time Frame: Baseline to 96 weeks] [Designated as safety issue: No]
  Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 96 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
- Median DAVG in Plasma HBV DNA Levels at 144 Weeks Relative to Baseline [Time Frame: Baseline to 144 weeks] [Designated as safety issue: No]
  Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 144 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
- Median DAVG in Plasma HBV DNA Levels at 168 Weeks Relative to Baseline [Time Frame: Baseline to 168 weeks] [Designated as safety issue: No]
  Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 168 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
- Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 48 [Time Frame: Week 48] [Designated as safety issue: No]
  The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 48 was summarized.
- Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 96 [Time Frame: Week 96] [Designated as safety issue: No]

The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 96 was summarized.

- Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 144 [Time Frame: Week 144] [Designated as safety issue: No]
  The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 144 was summarized.
- Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 168 [Time Frame: Week 168] [Designated as safety issue: No]
  The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 168 was summarized.
- Percentage of Participants With Normalized Alanine Aminotransferase (ALT) (for Subjects With Elevated ALT at Baseline) at Week 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  Normalized ALT is defined as having a baseline ALT value > the upper limit of the normal range (ULN), and a decrease in ALT value to ≤ ULN at the given time point.
- Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 96 [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
- Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
- Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 168 [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
- Percentage of Participants With an Increase in Child-Pugh Turcotte (CPT) Score of ≥ 2 Points at Weeks 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
- Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 96 [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
- Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
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- Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 168 [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
- Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
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- Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
- Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 168 [Time Frame: Baseline to Week 168] [Designated as safety issue: No]

CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.

- Median Change in Model for End-Stage Liver Disease (MELD) Score From Baseline at Week 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
- Median Change in MELD Score From Baseline at Week 96 [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
- Median Change in MELD Score From Baseline at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
- Median Change in MELD Score From Baseline at Week 168 [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
- Percentage of Participants With Hepatitis B Early Antigen (HBeAg) Loss and HBeAg Seroconversion at Week 48 (for Participants Who Were HBeAg Positive at Baseline) [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
- Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 96 (for Participants Who Were HBeAg Positive at Baseline) [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
- Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 144 (for Participants Who Were HBeAg Positive at Baseline) [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
- Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 168 (for Participants Who Were HBeAg Positive at Baseline) [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
- Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Loss and HBsAg Seroconversion at Week 48 [Time Frame: Baseline to Week 48] [Designated as safety issue: No]
  Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
- Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 96 [Time Frame: Baseline to Week 96] [Designated as safety issue: No]
  Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
- Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 144 [Time Frame: Baseline to Week 144] [Designated as safety issue: No]
  Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
- Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 168 [Time Frame: Baseline to Week 168] [Designated as safety issue: No]

Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.

- In the Subset of Participants Undergoing Liver Transplantation, Time to Recurrence of Hepatitis B, Defined as 2 Consecutive Plasma HBV DNA Concentrations ≥ 400 Copies/mL or 2 Consecutive HBsAg(+) Results [Time Frame: Baseline to Week 168] [Designated as safety issue: No]

Other Pre-specified Outcome Measures:

- Percentage of Participants With Only Baseline Adefovir Dipivoxil Resistance (ADV-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  ADV resistance mutations are defined as the presence of the rtA181T/V HBV gene mutation and/or the rtN236T HBV gene mutation.
- Percentage of Participants With Only Baseline Lamivudine-resistance (LAM-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  LAM resistance mutations are defined as the presence of the rtM204V/I HBV gene mutation with or without the rtL180M HBV gene mutation.
- Percentage of Participants With Baseline ADV-R + LAM-R Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks [Time Frame: Baseline to Week 168] [Designated as safety issue: No]
  ADV resistance mutation + LAM resistance mutations are defined as the presence of the rtA181T/V HBV gene mutation and/or the rtN236T HBV gene mutation, and the rtM204V/I HBV gene mutation with or without the rtL180M HBV gene mutation.

Enrollment: 112
Study Start Date: April 2006
Primary Completion Date: April 2011
Study Completion Date: April 2011

Arms	Assigned Interventions
Experimental: Tenofovir DF TDF 300 mg + FTC/TDF placebo + ETV placebo once daily (QD)	Drug: Tenofovir disoproxil fumarate (tenofovir DF; TDF) 300-mg tablet QD Other Names: Viread Drug: FTC/TDF placebo Placebo to match FTC/TDF QD Drug: ETV placebo Placebo to match ETV QD
Experimental: FTC/TDF FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo QD	Drug: Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) FTC 200 mg/TDF 300 mg fixed-dose combination (FDC) tablet QD Other Names: Truvada Drug: TDF placebo Placebo to match TDF QD Drug: ETV placebo Placebo to match ETV QD

Arms	Assigned Interventions
Experimental: Entecavir ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo QD	Drug: Entecavir (ETV) 0.5-mg or 1-mg tablet QD Other Names: Baraclude Drug: TDF placebo Placebo to match TDF QD Drug: FTC/TDF placebo Placebo to match FTC/TDF QD

Eligibility

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

Criteria

Inclusion Criteria:

A participant was required to meet all of the following inclusion criteria to be eligible for participation in the study:

- Chronic Hepatitis B infection
- 18 through 69 years of age, inclusive
- HBV DNA ≥ 1000 copies/mL
- Decompensated liver disease with all of the following:
  - CPT score of 7-12 (inclusive) OR history of CPT score ≥ 7 and any CPT at screen ≤ 12
  - Serum alanine aminotransferase (ALT) < 10 x the upper limit of the normal range (ULN)
  - Hemoglobin ≥ 7.5 g/dL
  - Total white blood cell (WBC) count ≥ 1,500/mm^3
  - Platelet count ≥ 30,000/mm^3
- Alpha-fetoprotein ≤ 20 ng/mL and ultrasound or other imaging with no evidence of hepatocellular carcinoma (HCC), or alpha-fetoprotein of 21-50 ng/mL and computed tomography (CT)/magnetic resonance imaging (MRI) scan with no evidence of HCC, within 6 months of screening
- Calculated creatinine clearance ≥ 50 mL/min
- Negative human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis D virus (HDV) serologies
- Less than 24 months of total prior adefovir dipivoxil exposure
- Willing and able to provide written informed consent

Exclusion Criteria:

A participant who met any of the following exclusion criteria could not be enrolled in the study:

- Pregnant women, women who were breastfeeding or who believed they may have wished to become pregnant during the course of the study
- Males and females of reproductive potential who were unwilling to use an effective method of contraception during the study

- Prior use of TDF or ETV
- History of variceal bleeding, hepatorenal syndrome, Grade 3 or 4 hepatic encephalopathy, or spontaneous bacterial peritonitis within 60 days of screening
- Grade 2 hepatic encephalopathy at screening
- History of solid organ or bone marrow transplant
- Current use of hepatotoxic drugs, nephrotoxic drugs, or drugs that interfere with renal tubular secretion
- Current therapy with immunomodulators (eg, corticosteroids, interleukin-2, etc.) or investigational drugs
- Diagnosis of proximal tubulopathy
- Use of investigational agent within 30 days prior to screening
- Known hypersensitivity to TDF, FTC, ETV, or formulation excipients of any of the study drug products

Contacts and Locations

Locations

United States, California

Pfleger Liver Institute

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California Pacific Medical Center Research Institute

San Francisco, California, United States, 94115

United States, Florida

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United States, Illinois

Rush Presbyterian - St. Luke's Medical Center

Chicago, Illinois, United States, 60612

United States, Michigan

Henry Ford Hospital and Health System

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United States, New York

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Investigators

Study Director:	John Flaherty, PharmD	Gilead Sciences, Inc.

More Information

Results Publications:

Liaw YF, Sheen IS, Lee CM, Akarca US, Papatheodoridis GV, Suet-Hing Wong F, Chang TT, Horban A, Wang C, Kwan P, Buti M, Prieto M, Berg T, Kitrinos K, Peschell K, Mondou E, Frederick D, Rousseau F, Schiff ER. Tenofovir disoproxil fumarate (TDF), emtricitabine/TDF, and entecavir in patients with decompensated chronic hepatitis B liver disease. Hepatology. 2011 Jan;53(1):62-72. doi: 10.1002/hep.23952. Epub 2010 Oct 27.

Responsible Party:	Gilead Sciences
Study ID Numbers:	GS-US-174-0108
Health Authority:	United States: Food and Drug Administration

Participant Flow

Recruitment Details	Of the 112 participants randomized, 43 were in Taiwan or Singapore, 43 were in Europe (Turkey, Spain, Germany, Greece, Poland, Italy, or France), and 26 were in the US or Canada. The first participant was screened on 04 April 2006, and the last participant was randomized on 03 January 2008. Last participant observation date was 12 April 2011.
Pre-Assignment Details	196 participants screened; 112 randomized and treated (full analysis set; randomized analysis set). Subjects without adequate decrease in HBV DNA at Week 8 could start open-label FTC/TDF. Subjects with virologic breakthrough or HBV DNA levels > 400 copies/mL at ≥ 24 weeks could have received other therapy that may have included open-label FTC/TDF.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive double-blind (DB) TDF 300 mg + FTC)/TDF placebo + ETV placebo at baseline, and may have been unblinded (due to either lack of adequate decrease of HBV DNA or virologic breakthrough) and switched to open-label (OL) FTC/TDF (this study enrolled participants with decompensated liver disease, and early intervention strategies were provided if profound viral suppression was not achieved quickly).
FTC/TDF	Participants in this group were randomized to receive DB FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline, and may have been unblinded (due to either lack of adequate decrease of HBV DNA or virologic breakthrough) and switched to OL FTC/TDF.
Entecavir	Participants in this group were randomized to receive DB ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline, and may have been unblinded (due to either lack of adequate decrease of HBV DNA or virologic breakthrough) and switched to OL FTC/TDF.

Overall Study

	Tenofovir DF	FTC/TDF	Entecavir
Started	45	45	22
Completed	28 [1]	37 [2]	16 [3]
Not Completed	17	8	6
Lost to Follow-up	0	0	1
Physician Decision	4	1	0
Protocol Violation	1	1	0

	Tenofovir DF	FTC/TDF	Entecavir
Withdrawal by Subject	5	1	3
Adverse Event	5	2	2
Lack of Efficacy	2	3	0

[1] 22 completed while taking DB TDF; 6 completed following switch from DB TDF to OL FTC/TDF.
[2] 34 completed while taking DB FTC/TDF; 3 completed following switch from DB TDF to OL FTC/TDF.
[3] 13 completed while taking DB ETV; 3 completed following switch from DB ETV to OL FTC/TDF.

Baseline Characteristics

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Baseline Measures

	Tenofovir DF	FTC/TDF	Entecavir	Total
Number of Participants	45	45	22	112
Age, Continuous [units: years] Mean (Standard Deviation)	53 (8.8)	49 (10.1)	52 (12.0)	51 (10.0)
Gender, Male/Female [units: participants]				
Female	8	5	5	18
Male	37	40	17	94
Region of Enrollment [units: participants]				
France	0	0	1	1
United States	10	2	2	14

	Tenofovir DF	FTC/TDF	Entecavir	Total
Taiwan	13	16	9	38
Greece	4	1	1	6
Canada	4	7	1	12
Poland	2	2	2	6
Spain	2	6	2	10
Singapore	1	3	1	5
Turkey	4	6	2	12
Germany	4	1	1	6
Italy	1	1	0	2
Race [units: participants]				
Asian	23	24	13	60
Black	1	1	0	2
Other	2	0	1	3
White	19	20	8	47
Ethnicity [units: participants]				
Hispanic or Latino	2	1	0	3
Not Hispanic or Latino	39	39	21	99
Not Permitted	4	5	1	10
Weight [units: kg] Mean (Standard Deviation)	78.1 (17.02)	74.4 (15.41)	77.3 (16.64)	76.5 (16.26)
Height [units: cm] Mean (Standard Deviation)	168.3 (7.98)	168.4 (8.47)	167.1 (8.39)	168.1 (8.20)
BMI [units: kg/m^2] Mean (Standard Deviation)	27.6 (5.67)	26.2 (5.07)	27.6 (5.27)	27.0 (5.35)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percent Probability of Tolerability Failure
Measure Description	Tolerability failure was defined as permanent discontinuation of study drug due to a treatment-emergent adverse event (AE), including any subject who temporarily discontinued study drug due to an AE and did not restart. Results are expressed as proportions of participants who experience tolerability failure using the Kaplan-Meier (KM) method of estimation.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Full analysis set (all randomized subjects who received at least one dose of study drug)

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
TDF or FTC/TDF	Participants in this group include all participants who received TDF or FTC/TDF during the study.
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Measured Values

	Tenofovir DF	FTC/TDF	TDF or FTC/TDF	Entecavir
Number of Participants Analyzed	45	45	90	22
Percent Probability of Tolerability Failure [units: percent probability (KM estimate)] Number (95% Confidence Interval)	18 (5.8 to 30.6)	4 (0.0 to 10.4)	11 (4.1 to 17.7)	14 (0.0 to 29.5)

2. Primary Outcome Measure:

Measure Title	Percent Probability of a Confirmed Increase in Serum Creatinine of ≥ 0.5 mg/dL From Baseline or a Confirmed Serum Phosphorus Level < 2.0 mg/dL

Measure Description	Results are expressed as proportions of participants who experience a confirmed increase in serum creatinine of ≥ 0.5 mg/dL from baseline or a confirmed serum phosphorus level < 2.0 mg/dL using the KM method of estimation.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description
Full analysis set

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
TDF or FTC/TDF	Participants in this group include all participants who received TDF or FTC/TDF during the study.
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Measured Values

	Tenofovir DF	FTC/TDF	TDF or FTC/TDF	Entecavir
Number of Participants Analyzed	45	45	90	22
Percent Probability of a Confirmed Increase in Serum Creatinine of ≥ 0.5 mg/dL From Baseline or a Confirmed Serum Phosphorus Level < 2.0 mg/dL [units: percent probability (KM estimate)] Number (95% Confidence Interval)	15 (3.9 to 25.9)	14 (3.6 to 24.4)	14 (6.8 to 22.0)	10 (0.0 to 22.8)

3. Secondary Outcome Measure:

Measure Title	Median Time-averaged Change (DAVG) in Plasma Hepatitis B Virus (HBV) Deoxyribonucleic Acid (DNA) Levels at 48 Weeks Relative to Baseline
Measure Description	Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 48 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
Time Frame	Baseline to 48 weeks

Safety Issue?	No

Analysis Population Description

Participants with HBV DNA measurements at Week 48 were included in this analysis.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	36	38	18	92
Median Time-averaged Change (DAVG) in Plasma Hepatitis B Virus (HBV) Deoxyribonucleic Acid (DNA) Levels at 48 Weeks Relative to Baseline [units: log_10 copies/mL] Median (Inter-Quartile Range)	-2.93 (-3.84 to -2.18)	-3.45 (-4.73 to -2.02)	-3.61 (-4.51 to -1.31)	-3.19 (-4.52 to -2.08)

4. Secondary Outcome Measure:

Measure Title	Median DAVG in Plasma HBV DNA Levels at 96 Weeks Relative to Baseline
Measure Description	Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 96 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
Time Frame	Baseline to 96 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set; data collected for participants who underwent liver transplant prior to Week 96 were excluded.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	34	35	16	85
Median DAVG in Plasma HBV DNA Levels at 96 Weeks Relative to Baseline [units: log_10 copies/mL] Median (Inter-Quartile Range)	-3.06 (-4.17 to -2.18)	-4.06 (-4.97 to -2.38)	-3.32 (-4.82 to -1.26)	-3.40 (-4.81 to -2.14)

5. Secondary Outcome Measure:

Measure Title	Median DAVG in Plasma HBV DNA Levels at 144 Weeks Relative to Baseline
Measure Description	Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 144 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
Time Frame	Baseline to 144 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set; data collected for participants who underwent liver transplant prior to Week 144 were excluded.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline

	Description
FTC/TDF	Participants in this group were randomized to receive FTC 200mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	28	34	15	77
Median DAVG in Plasma HBV DNA Levels at 144 Weeks Relative to Baseline [units: log _10 copies/mL] Median (Inter-Quartile Range)	-3.07 (-4.36 to -2.00)	-3.82 (-4.99 to -2.06)	-3.76 (-5.00 to -1.33)	-3.49 (-4.91 to -2.05)

6. Secondary Outcome Measure:

Measure Title	Median DAVG in Plasma HBV DNA Levels at 168 Weeks Relative to Baseline
Measure Description	Change from baseline was evaluated by subtracting baseline HBV DNA log_10 copies/mL from Week 168 HBV DNA log_10 copies/mL. DAVG is defined as the area of the trapezoid under the response-time curve divided by time to the last available evaluation of the patient minus the baseline value.
Time Frame	Baseline to 168 weeks
Safety Issue?	No

Analysis Population Description

Full analysis set; data collected for participants who underwent liver transplant prior to Week 168 were excluded.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

	Description
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	26	31	15	72
Median DAVG in Plasma HBV DNA Levels at 168 Weeks Relative to Baseline [units: log_10 copies/mL] Median (Inter-Quartile Range)	-3.16 (-4.57 to -1.97)	-4.06 (-5.15 to -2.42)	-3.77 (-5.02 to -1.33)	-3.66 (-4.99 to -2.10)

7. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 48
Measure Description	The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 48 was summarized.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure analysis (participants who did not complete treatment or changed from double-blind to open-label treatment up to the time point were considered as failing to meet efficacy response criteria [defined as not achieving viral suppression of < 400 copies/mL]).

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	44	41	22	107

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 48 [units: percentage of participants]	70.5	87.8	72.7	77.6

8. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 96
Measure Description	The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 96 was summarized.
Time Frame	Week 96
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	44	39	21	104
Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 96 [units: percentage of participants]	59.1	79.5	57.1	66.3

9. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 144
Measure Description	The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 144 was summarized.
Time Frame	Week 144
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	44	40	21	105
Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 144 [units: percentage of participants]	50.0	77.5	52.4	61.0

10. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 168
Measure Description	The percentage of participants with plasma HBV DNA < 400 copies/mL at Week 168 was summarized.
Time Frame	Week 168
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	42	37	21	100
Percentage of Participants With Plasma HBV DNA < 400 Copies/mL at Week 168 [units: percentage of participants]	50.0	75.7	52.4	60.0

11. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Normalized Alanine Aminotransferase (ALT) (for Subjects With Elevated ALT at Baseline) at Week 48
Measure Description	Normalized ALT is defined as having a baseline ALT value > the upper limit of the normal range (ULN), and a decrease in ALT value to ≤ ULN at the given time point.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Biochemically evaluable analysis set (subjects in full analysis set with abnormal baseline alanine aminotransferase [ALT] values); noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	26	25	17	68
Percentage of Participants With Normalized Alanine Aminotransferase (ALT) (for Subjects With Elevated ALT at Baseline) at Week 48 [units: percentage of participants]	46.2	64.0	41.2	51.5

12. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 96
Measure Description	Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Biochemically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline

	Description
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	26	24	16	66
Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 96 [units: percentage of participants]	50.0	58.3	31.3	48.5

13. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 144
Measure Description	Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description

Biochemically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	26	25	16	67
Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 144 [units: percentage of participants]	34.6	64.0	37.5	46.3

14. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 168
Measure Description	Normalized ALT is defined as having a baseline ALT value > ULN, and a decrease in ALT value to ≤ ULN at the given time point.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Biochemically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	24	25	16	65
Percentage of Participants With Normalized ALT (for Subjects With Elevated ALT at Baseline) at Week 168 [units: percentage of participants]	29.2	60.0	37.5	43.1

15. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Increase in Child-Pugh Turcotte (CPT) Score of ≥ 2 Points at Weeks 48
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	43	38	22	103
Percentage of Participants With an Increase in Child-Pugh Turcotte (CPT) Score of ≥ 2 Points at Weeks 48 [units: percentage of participants]	0.0	2.6	0.0	1.0

16. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 96

Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	43	38	20	101
Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 96 [units: percentage of participants]	0.0	0.0	0.0	0.0

17. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 144
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description
Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	43	40	21	104
Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 144 [units: percentage of participants]	0.0	2.5	0.0	1.0

18. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 168
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description
Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline

	Description
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	41	36	21	98
Percentage of Participants With an Increase in CPT Score of ≥ 2 Points at Week 168 [units: percentage of participants]	2.4	0.0	0.0	1.0

19. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 48
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

CPT evaluable analysis set (subjects with CPT scores ≥ 7 at baseline; because the minimum CPT score was 5, only these subjects were evaluable for analyses of ≥ 2-point decrease in CPT score); noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

	Description
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	27	25	12	64
Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 48 [units: percentage of participants]	25.9	48.0	41.7	37.5

20. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 96
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

CPT evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	26	25	10	61
Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 96 [units: percentage of participants]	23.1	52.0	50.0	39.3

21. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 144
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description

CPT evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	27	27	11	65
Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 144 [units: percentage of participants]	25.9	51.9	45.5	40.0

22. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 168
Measure Description	CPT scores, widely used to grade the severity of cirrhosis and to determine the need for liver transplantation, are calculated based on a combination of laboratory values and clinical features. CPT scores can range from 5 to 15, with higher scores indicating a greater severity of disease.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

CPT evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	25	24	11	60
Percentage of Participants With a Decrease in CPT Score of ≥ 2 Points From Baseline at Week 168 [units: percentage of participants]	24.0	45.8	45.5	36.7

23. Secondary Outcome Measure:

Measure Title	Median Change in Model for End-Stage Liver Disease (MELD) Score From Baseline at Week 48

Measure Description	MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Subjects in the full analysis set with an available score at the visit

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	35	35	19	89
Median Change in Model for End-Stage Liver Disease (MELD) Score From Baseline at Week 48 [units: units on a scale] Median (Inter-Quartile Range)	-2.0 (-3.0 to 0.0)	-2.0 (-4.0 to 0.0)	-2.0 (-4.0 to -1.0)	-2.0 (-3.0 to 0.0)

24. Secondary Outcome Measure:

Measure Title	Median Change in MELD Score From Baseline at Week 96
Measure Description	MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description
Subjects in the full analysis set with an available score at the visit

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	33	33	15	81
Median Change in MELD Score From Baseline at Week 96 [units: units on a scale] Median (Inter-Quartile Range)	-2.0 (-3.0 to 1.0)	-3.0 (-4.0 to 0.0)	-3.0 (-4.0 to -1.0)	-2.0 (-4.0 to 0.0)

25. Secondary Outcome Measure:

Measure Title	Median Change in MELD Score From Baseline at Week 144
Measure Description	MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description
Subjects in the full analysis set with an available score at the visit

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline

	Description
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	28	34	15	77
Median Change in MELD Score From Baseline at Week 144 [units: units on a scale] Median (Inter-Quartile Range)	-2.0 (-3.5 to -0.5)	-1.5 (-6.0 to 0.0)	-2.0 (-5.0 to -1.0)	-2.0 (-4.0 to 0.0)

26. Secondary Outcome Measure:

Measure Title	Median Change in MELD Score From Baseline at Week 168
Measure Description	MELD scores, used to assess prognosis and suitability for transplant, are calculated based on laboratory values only and can range from 6 to 40, with higher scores indicating greater disease severity.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Subjects in the full analysis set with an available score at the visit

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

	Description
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	25	30	15	70
Median Change in MELD Score From Baseline at Week 168 [units: units on a scale] Median (Inter-Quartile Range)	-2.0 (-4.0 to -1.0)	-2.0 (-4.0 to 0.0)	-2.0 (-5.0 to 0.0)	-2.0 (-4.0 to 0.0)

27. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis B Early Antigen (HBeAg) Loss and HBeAg Seroconversion at Week 48 (for Participants Who Were HBeAg Positive at Baseline)
Measure Description	Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Serologically evaluable analysis set (subjects in full analysis set with positive hepatitis B early antigen [HBeAg] at baseline); noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	14	15	7	36
Percentage of Participants With Hepatitis B Early Antigen (HBeAg) Loss and HBeAg Seroconversion at Week 48 (for Participants Who Were HBeAg Positive at Baseline) [units: percentage of participants]				
HBeAg Loss	21.4	26.7	0.0	19.4
HBeAg Seroconversion	21.4	13.3	0.0	13.9

28. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 96 (for Participants Who Were HBeAg Positive at Baseline)
Measure Description	Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Serologically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	14	15	6	35
Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 96 (for Participants Who Were HBeAg Positive at Baseline) [units: percentage of participants]				
HBeAg Loss	14.3	33.3	0.0	20.0
HBeAg Seroconversion	14.3	13.3	0.0	11.4

29. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 144 (for Participants Who Were HBeAg Positive at Baseline)
Measure Description	Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description

Serologically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	14	15	6	35
Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 144 (for Participants Who Were HBeAg Positive at Baseline) [units: percentage of participants]				
HBeAg Loss	14.3	33.3	16.7	22.9
HBeAg Seroconversion	14.3	13.3	0.0	11.4

30. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 168 (for Participants Who Were HBeAg Positive at Baseline)
Measure Description	Loss of HBeAg was defined as change of detectable HBeAg from positive to negative. HBeAg seroconversion was defined as change of detectable antibody to HBeAg from negative to positive.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Serologically evaluable analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	13	14	6	33
Percentage of Participants With HBeAg Loss and HBeAg Seroconversion at Week 168 (for Participants Who Were HBeAg Positive at Baseline) [units: percentage of participants]				
HBeAg Loss	23.1	35.7	16.7	27.3
HBeAg Seroconversion	23.1	21.4	0.0	18.2

31. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Loss and HBsAg Seroconversion at Week 48
Measure Description	Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	43	41	22	106

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Loss and HBsAg Seroconversion at Week 48 [units: percentage of participants]				
HBsAg Loss	0.0	0.0	0.0	0.0
HBsAg Seroconversion	0.0	0.0	0.0	0.0

32. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 96
Measure Description	Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	44	39	21	104
Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 96				

	Tenofovir DF	FTC/TDF	Entecavir	Overall
[units: percentage of participants]				
HBsAg Loss	0.0	0.0	0.0	0.0
HBsAg Seroconversion	0.0	0.0	0.0	0.0

33. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 144
Measure Description	Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
Time Frame	Baseline to Week 144
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	43	38	21	102
Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 144 [units: percentage of participants]				
HBsAg Loss	0.0	0.0	0.0	0.0
HBsAg Seroconversion	0.0	0.0	0.0	0.0

34. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 168
Measure Description	Loss of HBsAg was defined as change of detectable HBsAg from positive to negative. HBsAg seroconversion was defined as change of detectable antibody to HBsAg from negative to positive.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Full analysis set; noncompleters/switch = failure

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	41	36	21	98
Percentage of Participants With HBsAg Loss and HBsAg Seroconversion at Week 168 [units: percentage of participants]				
HBsAg Loss	0.0	0.0	0.0	0.0
HBsAg Seroconversion	0.0	0.0	0.0	0.0

35. Secondary Outcome Measure:

Measure Title	In the Subset of Participants Undergoing Liver Transplantation, Time to Recurrence of Hepatitis B, Defined as 2 Consecutive Plasma HBV DNA Concentrations ≥ 400 Copies/mL or 2 Consecutive HBsAg(+) Results
Measure Description	
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Liver transplantation analysis set

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline
Overall	Participants in this group includes all participants from TDF, FTC/TDF, and ETV groups

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir	Overall
Number of Participants Analyzed	3	7	1	11
In the Subset of Participants Undergoing Liver Transplantation, Time to Recurrence of Hepatitis B, Defined as 2 Consecutive Plasma HBV DNA Concentrations ≥ 400 Copies/mL or 2 Consecutive HBsAg(+) Results [units: Days]	NA [1]	NA [1]	NA [1]	NA [1]

[1] No participant in this category experienced Hepatitis B Recurrence.

36. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Participants With Only Baseline Adefovir Dipivoxil Resistance (ADV-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks

Measure Description	ADV resistance mutations are defined as the presence of the rtA181T/V HBV gene mutation and/or the rtN236T HBV gene mutation.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Participants in the full analysis set with ADV resistance mutation at baseline were included in this analysis.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir
Number of Participants Analyzed	1	1	0
Percentage of Participants With Only Baseline Adefovir Dipivoxil Resistance (ADV-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks [units: percentage of participants]	100	100	

37. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Participants With Only Baseline Lamivudine-resistance (LAM-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks
Measure Description	LAM resistance mutations are defined as the presence of the rtM204V/I HBV gene mutation with or without the rtL180M HBV gene mutation.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Patients in the full analysis set with LAM resistance mutation at baseline were included in this analysis.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir
Number of Participants Analyzed	5	8	3
Percentage of Participants With Only Baseline Lamivudine-resistance (LAM-R) Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks [units: percentage of participants]	100	100	100

38. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Participants With Baseline ADV-R + LAM-R Mutations Achieving HBV DNA < 400 Copies/mL by 168 Weeks
Measure Description	ADV resistance mutation + LAM resistance mutations are defined as the presence of the rtA181T/V HBV gene mutation and/or the rtN236T HBV gene mutation, and the rtM204V/I HBV gene mutation with or without the rtL180M HBV gene mutation.
Time Frame	Baseline to Week 168
Safety Issue?	No

Analysis Population Description

Participants in the full analysis set with both ADV and LAM resistance mutations at baseline were included in this analysis.

Reporting Groups

	Description
Tenofovir DF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo at baseline

	Description
FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo at baseline
Entecavir	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo at baseline

Measured Values

	Tenofovir DF	FTC/TDF	Entecavir
Number of Participants Analyzed	2	0	0
Percentage of Participants With Baseline ADV-R + LAM-R Mutations Achieving HBV DNA < 400 Copies/ mL by 168 Weeks [units: percentage of participants]	50		

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Double Blind TDF	Participants in this group were randomized to receive TDF 300 mg + FTC/TDF placebo + ETV placebo
Double Blind FTC/TDF	Participants in this group were randomized to receive FTC 200 mg/TDF 300 mg + TDF placebo + ETV placebo
Double Blind ETV	Participants in this group were randomized to receive ETV 0.5 mg or 1 mg + TDF placebo + FTC/TDF placebo
Open Label FTC/TDF	Participants in this group were randomized to receive TDF, FTC/TDF, or ETV at the beginning of the study, but switched to open label FTC/TDF during the study.
All TDF	Participants in this group received a TDF-containing treatment (all double-blind TDF, FTC/TDF, or open-label FTC/TDF) during the study.

Serious Adverse Events

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	21/45 (46.67%)	25/45 (55.56%)	11/22 (50%)	4/12 (33.33%)	50/93 (53.76%)
Blood and lymphatic system disorders					
Thrombocytopenia	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Ear and labyrinth disorders					
Sudden hearing loss	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Gastrointestinal disorders					
Abdominal distension	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Abdominal hernia	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Abdominal pain	3/45 (6.67%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Ascites	3/45 (6.67%)	3/45 (6.67%)	1/22 (4.55%)	1/12 (8.33%)	7/93 (7.53%)
Gastric varices haemorrhage	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Gastrointestinal haemorrhage	1/45 (2.22%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	2/93 (2.15%)
Gastrointestinal motility disorder	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Haematemesis	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Inguinal hernia	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Inguinal hernia, obstructive	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Melaena	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Nausea	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Oesophageal varices haemorrhage	3/45 (6.67%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Pancreatitis acute	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Small intestinal obstruction	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Upper gastrointestinal haemorrhage	2/45 (4.44%)	2/45 (4.44%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Vomiting	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
General disorders					
Asthenia	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Generalized oedema	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Oedema	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Pyrexia	1/45 (2.22%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	2/93 (2.15%)
Hepatobiliary disorders					
Cholestasis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Chronic hepatic failure	1/45 (2.22%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	2/93 (2.15%)
Hepatic cirrhosis	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hepatic failure	1/45 (2.22%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	2/93 (2.15%)
Hepatic function abnormal	2/45 (4.44%)	5/45 (11.11%)	2/22 (9.09%)	0/12 (0%)	7/93 (7.53%)
Hepatic lesion	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hepatitis acute	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Hepatorenal syndrome	1/45 (2.22%)	2/45 (4.44%)	0/22 (0%)	0/12 (0%)	3/93 (3.23%)
Porcelain gallbladder	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Immune system disorders					
Contrast media allergy	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hypersensitivity	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Liver transplant rejection	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Infections and infestations					
Anal abscess	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Bacteraemia	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Cellulitis	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Gastroenteritis viral	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hepatitis B	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Laryngitis	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Lower respiratory tract infection	0/45 (0%)	2/45 (4.44%)	0/22 (0%)	0/12 (0%)	2/93 (2.15%)
Necrotising fasciitis	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Osteomyelitis	0/45 (0%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	1/93 (1.08%)
Peritonitis bacterial	2/45 (4.44%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	5/93 (5.38%)
Pharyngitis	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Pneumococcal sepsis	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Pneumonia	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Pyelonephritis acute	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Scrotal abscess	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Sepsis	1/45 (2.22%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	4/93 (4.3%)
Septic shock	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Subcutaneous abscess	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Wound infection	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Injury, poisoning and procedural complications					
Allergic transfusion reaction	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Biliary anastomosis complication	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Device failure	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Multiple fractures	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Overdose	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Post procedural haematoma	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Road traffic accident	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Thermal burn	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Traumatic spinal cord compression	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Investigations					
Alanine aminotransferase increased	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Creatinine renal clearance decreased	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Metabolism and nutrition disorders					
Diabetic ketoacidosis	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Fluid overload	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hypovolaemia	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Musculoskeletal and connective tissue disorders					
Intervertebral disc protrusion	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Musculoskeletal chest pain	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Hepatic neoplasm malignant	8/45 (17.78%)	3/45 (6.67%)	2/22 (9.09%)	1/12 (8.33%)	12/93 (12.9%)
Hodgkin's disease	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Nervous system disorders					
Basal ganglia haemorrhage	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Cerebral haemorrhage	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Cerebral infarction	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Cerebrospinal fluid rhinorrhoea	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Depressed level of consciousness	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Encephalopathy	1/45 (2.22%)	2/45 (4.44%)	0/22 (0%)	0/12 (0%)	3/93 (3.23%)
Headache	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Hepatic encephalopathy	3/45 (6.67%)	1/45 (2.22%)	2/22 (9.09%)	0/12 (0%)	4/93 (4.3%)
Subarachnoid haemorrhage	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Psychiatric disorders					
Mental status change	2/45 (4.44%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	2/93 (2.15%)
Schizophreniform disorder	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Renal and urinary disorders					
Calculus Ureteric	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Hydronephrosis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Nephrolithiasis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Renal aneurysm	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Renal failure	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Renal failure acute	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Reproductive system and breast disorders					
Postmenopausal hemorrhage	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Respiratory, thoracic and mediastinal disorders					
Chronic obstructive pulmonary disease	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Hydrothorax	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Nasal disorder	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Pleural effusion	0/45 (0%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	1/93 (1.08%)
Vascular disorders					
Aortic dissection	0/45 (0%)	0/45 (0%)	1/22 (4.55%)	0/12 (0%)	0/93 (0%)
Circulatory collapse	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)
Hypotension	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	1/93 (1.08%)

Other Adverse Events

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

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	41/45 (91.11%)	44/45 (97.78%)	20/22 (90.91%)	9/12 (75%)	89/93 (95.7%)
Blood and lymphatic system disorders					
Anaemia	2/45 (4.44%)	6/45 (13.33%)	2/22 (9.09%)	0/12 (0%)	8/93 (8.6%)
Leukopenia	0/45 (0%)	0/45 (0%)	2/22 (9.09%)	0/12 (0%)	0/93 (0%)
Thrombocytopenia	3/45 (6.67%)	3/45 (6.67%)	2/22 (9.09%)	0/12 (0%)	6/93 (6.45%)
Ear and labyrinth disorders					
Sudden hearing loss	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Vertigo	2/45 (4.44%)	0/45 (0%)	2/22 (9.09%)	1/12 (8.33%)	3/93 (3.23%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders					
Abdominal distension	5/45 (11.11%)	4/45 (8.89%)	2/22 (9.09%)	1/12 (8.33%)	10/93 (10.75%)
Abdominal pain	6/45 (13.33%)	4/45 (8.89%)	3/22 (13.64%)	1/12 (8.33%)	11/93 (11.83%)
Abdominal pain upper	9/45 (20%)	7/45 (15.56%)	2/22 (9.09%)	2/12 (16.67%)	18/93 (19.35%)
Ascites	8/45 (17.78%)	4/45 (8.89%)	6/22 (27.27%)	1/12 (8.33%)	13/93 (13.98%)
Constipation	3/45 (6.67%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	6/93 (6.45%)
Diarrhoea	4/45 (8.89%)	1/45 (2.22%)	5/22 (22.73%)	1/12 (8.33%)	5/93 (5.38%)
Duodenal ulcer	0/45 (0%)	2/45 (4.44%)	2/22 (9.09%)	0/12 (0%)	2/93 (2.15%)
Dyspepsia	1/45 (2.22%)	6/45 (13.33%)	1/22 (4.55%)	1/12 (8.33%)	8/93 (8.6%)
Gastritis	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	2/12 (16.67%)	3/93 (3.23%)
Haemorrhoids	1/45 (2.22%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	3/93 (3.23%)
Hiatus hernia	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Inguinal hernia	3/45 (6.67%)	2/45 (4.44%)	0/22 (0%)	0/12 (0%)	5/93 (5.38%)
Nausea	9/45 (20%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	12/93 (12.9%)
Oesophageal varices haemorrhage	3/45 (6.67%)	1/45 (2.22%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Upper gastrointestinal haemorrhage	2/45 (4.44%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	5/93 (5.38%)
Vomiting	6/45 (13.33%)	2/45 (4.44%)	2/22 (9.09%)	1/12 (8.33%)	9/93 (9.68%)
General disorders					
Asthenia	5/45 (11.11%)	2/45 (4.44%)	2/22 (9.09%)	0/12 (0%)	7/93 (7.53%)
Chest pain	1/45 (2.22%)	0/45 (0%)	1/22 (4.55%)	1/12 (8.33%)	2/93 (2.15%)
Fatigue	2/45 (4.44%)	2/45 (4.44%)	2/22 (9.09%)	0/12 (0%)	4/93 (4.3%)
Oedema peripheral	8/45 (17.78%)	3/45 (6.67%)	5/22 (22.73%)	0/12 (0%)	11/93 (11.83%)
Pyrexia	6/45 (13.33%)	5/45 (11.11%)	4/22 (18.18%)	0/12 (0%)	11/93 (11.83%)
Hepatobiliary disorders					
Cholangitis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Cholelithiasis	2/45 (4.44%)	4/45 (8.89%)	0/22 (0%)	0/12 (0%)	6/93 (6.45%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cholestasis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Gallbladder polyp	0/45 (0%)	0/45 (0%)	2/22 (9.09%)	1/12 (8.33%)	1/93 (1.08%)
Hepatic function abnormal	2/45 (4.44%)	5/45 (11.11%)	2/22 (9.09%)	0/12 (0%)	7/93 (7.53%)
Hepatic steatosis	1/45 (2.22%)	1/45 (2.22%)	0/22 (0%)	2/12 (16.67%)	4/93 (4.3%)
Hepatitis acute	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Hepatomegaly	2/45 (4.44%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	3/93 (3.23%)
Jaundice	1/45 (2.22%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Portal hypertension	2/45 (4.44%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	4/93 (4.3%)
Immune system disorders					
Seasonal allergy	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	2/93 (2.15%)
Infections and infestations					
Bronchitis	3/45 (6.67%)	1/45 (2.22%)	2/22 (9.09%)	1/12 (8.33%)	5/93 (5.38%)
Influenza	1/45 (2.22%)	2/45 (4.44%)	0/22 (0%)	1/12 (8.33%)	4/93 (4.3%)
Nasopharyngitis	5/45 (11.11%)	7/45 (15.56%)	1/22 (4.55%)	0/12 (0%)	12/93 (12.9%)
Peritonitis bacterial	2/45 (4.44%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	5/93 (5.38%)
Pyelonephritis acute	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Rhinitis	0/45 (0%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	3/93 (3.23%)
Sepsis	2/45 (4.44%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	5/93 (5.38%)
Upper respiratory tract infection	4/45 (8.89%)	4/45 (8.89%)	2/22 (9.09%)	2/12 (16.67%)	9/93 (9.68%)
Urinary tract infection	4/45 (8.89%)	2/45 (4.44%)	1/22 (4.55%)	1/12 (8.33%)	7/93 (7.53%)
Wound infection	0/45 (0%)	0/45 (0%)	2/22 (9.09%)	0/12 (0%)	0/93 (0%)
Injury, poisoning and procedural complications					
Biliary anastomosis complication	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Investigations					
Cardiac murmur	2/45 (4.44%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	4/93 (4.3%)
Creatinine renal clearance increased	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Metabolism and nutrition disorders					
Diabetes mellitus	5/45 (11.11%)	2/45 (4.44%)	2/22 (9.09%)	1/12 (8.33%)	8/93 (8.6%)
Hyperglycaemia	3/45 (6.67%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	3/93 (3.23%)
Hypokalaemia	0/45 (0%)	4/45 (8.89%)	3/22 (13.64%)	0/12 (0%)	4/93 (4.3%)
Iron deficiency	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Musculoskeletal and connective tissue disorders					
Arthralgia	4/45 (8.89%)	5/45 (11.11%)	2/22 (9.09%)	0/12 (0%)	9/93 (9.68%)
Back pain	5/45 (11.11%)	2/45 (4.44%)	0/22 (0%)	0/12 (0%)	7/93 (7.53%)
Intervertebral disc protrusion	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Muscle spasms	3/45 (6.67%)	1/45 (2.22%)	2/22 (9.09%)	0/12 (0%)	4/93 (4.3%)
Musculoskeletal pain	1/45 (2.22%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	4/93 (4.3%)
Myalgia	5/45 (11.11%)	3/45 (6.67%)	1/22 (4.55%)	0/12 (0%)	8/93 (8.6%)
Pain in extremity	1/45 (2.22%)	2/45 (4.44%)	1/22 (4.55%)	1/12 (8.33%)	4/93 (4.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Hepatic neoplasm malignant	8/45 (17.78%)	3/45 (6.67%)	2/22 (9.09%)	1/12 (8.33%)	12/93 (12.9%)
Nervous system disorders					
Dizziness	6/45 (13.33%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	9/93 (9.68%)
Encephalopathy	3/45 (6.67%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	6/93 (6.45%)
Headache	4/45 (8.89%)	3/45 (6.67%)	5/22 (22.73%)	1/12 (8.33%)	8/93 (8.6%)
Hepatic encephalopathy	5/45 (11.11%)	2/45 (4.44%)	3/22 (13.64%)	0/12 (0%)	7/93 (7.53%)
Psychiatric disorders					
Anxiety	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	2/93 (2.15%)
Depression	2/45 (4.44%)	1/45 (2.22%)	1/22 (4.55%)	1/12 (8.33%)	4/93 (4.3%)
Insomnia	9/45 (20%)	4/45 (8.89%)	4/22 (18.18%)	1/12 (8.33%)	14/93 (15.05%)
Renal and urinary disorders					
Calculus Ureteric	0/45 (0%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	2/93 (2.15%)

	Double Blind TDF	Double Blind FTC/TDF	Double Blind ETV	Open Label FTC/TDF	All TDF
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hydronephrosis	0/45 (0%)	1/45 (2.22%)	1/22 (4.55%)	1/12 (8.33%)	2/93 (2.15%)
Micturition disorder	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Nephrolithiasis	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	2/93 (2.15%)
Renal failure	2/45 (4.44%)	0/45 (0%)	1/22 (4.55%)	1/12 (8.33%)	3/93 (3.23%)
Reproductive system and breast disorders					
Gynaecomastia	2/45 (4.44%)	3/45 (6.67%)	1/22 (4.55%)	1/12 (8.33%)	6/93 (6.45%)
Respiratory, thoracic and mediastinal disorders					
Chronic obstructrive pulmonary disease	1/45 (2.22%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Cough	2/45 (4.44%)	4/45 (8.89%)	4/22 (18.18%)	2/12 (16.67%)	8/93 (8.6%)
Dyspnoea	1/45 (2.22%)	1/45 (2.22%)	0/22 (0%)	1/12 (8.33%)	3/93 (3.23%)
Dyspnoea exertional	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Nasal disorder	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Pharyngolaryngeal pain	1/45 (2.22%)	3/45 (6.67%)	0/22 (0%)	0/12 (0%)	4/93 (4.3%)
Skin and subcutaneous tissue disorders					
Pruritis	7/45 (15.56%)	6/45 (13.33%)	2/22 (9.09%)	0/12 (0%)	13/93 (13.98%)
Psoriasis	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Rash	4/45 (8.89%)	5/45 (11.11%)	1/22 (4.55%)	1/12 (8.33%)	10/93 (10.75%)
Rash pruritic	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Scar pain	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Skin hyperpigmentation	0/45 (0%)	0/45 (0%)	0/22 (0%)	1/12 (8.33%)	1/93 (1.08%)
Vascular disorders					
Hypertension	1/45 (2.22%)	5/45 (11.11%)	0/22 (0%)	1/12 (8.33%)	7/93 (7.53%)
Hypotension	4/45 (8.89%)	0/45 (0%)	0/22 (0%)	0/12 (0%)	4/93 (4.3%)

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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