Clinical trial results:
A Phase 2b, Multicenter, Double-blind, Active-controlled, Randomized Study to Investigate the Efficacy and Safety of Different Combination Regimens Including JNJ-73763989 and/or JNJ-56136379 for the Treatment of Chronic Hepatitis B Virus Infection

Summary

EudraCT number	2019-000622-22
Trial protocol	GB FR DE CZ ES BE IT
Global end of trial date	26 April 2022

Results information

Result version number	v1 (current)
This version publication date	12 May 2023
First version publication date	12 May 2023

Trial information

Trial identification

Sponsor protocol code	CR108608

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202 South, Raritan, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this trial was to establish the dose-response relationship for antiviral activity of 3 doses of JNJ-73763989 + NA and to evaluate the efficacy of combination regimens of JNJ-73763989 + NA (with and without JNJ-56136379) and of JNJ-56136379+NA.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 August 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Brazil: 4
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	China: 6
Country: Number of subjects enrolled	Czechia: 27
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	Hong Kong: 11
Country: Number of subjects enrolled	Italy: 30
Country: Number of subjects enrolled	Japan: 61
Country: Number of subjects enrolled	Korea, Republic of: 10
Country: Number of subjects enrolled	Malaysia: 18
Country: Number of subjects enrolled	Poland: 37
Country: Number of subjects enrolled	Russian Federation: 62
Country: Number of subjects enrolled	Thailand: 23
Country: Number of subjects enrolled	Turkey: 49
Country: Number of subjects enrolled	United States: 21

Worldwide total number of subjects	470
EEA total number of subjects	173

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	462
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 471 randomised subjects, only 470 subjects were analysed and treated with study drug.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA

Arm description:

Subjects received JNJ-73763989 100 milligrams (mg) as subcutaneous (SC) injection once every 4 weeks along with JNJ-56136379 250 mg as oral tablet once daily and Nucleos(t)ide Analog (NA) (either entecavir [ETV] monohydrate 0.5 mg, tenofovir disoproxil fumarate [TDF] 300 mg, or tenofovir alafenamide [TAF] 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed up to Week 96.

Arm type	Experimental
Investigational medicinal product name	JNJ-73763989
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received JNJ-73763989 100 mg as subcutaneous (SC) injection up to 48 weeks.

Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received NA treatment (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.

Investigational medicinal product name	JNJ-56136379
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-56136379 250 milligrams (mg) orally up to 48 weeks.

Arm title	Arm 2: JNJ-73763989 (200mg) + Placebo + NA

Arm description:

Subjects received JNJ-73763989 200 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Arm type	Experimental

Investigational medicinal product name	JNJ-73763989
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received JNJ-73763989 200 mg as SC injection up to 48 weeks.

Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received NA treatment (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to JNJ-56136379 orally up to 48 weeks.

Arm title	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA

Arm description:

Subjects received JNJ-73763989 100 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Arm type	Experimental
Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received NA treatment (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to JNJ-56136379 orally up to 48 weeks.

Investigational medicinal product name	JNJ-73763989
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received JNJ-73763989 100 mg as SC injection up to 48 weeks.

Arm title	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA

Arm description:

Subjects received JNJ-73763989 40 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once

daily up to 48 weeks. Subjects were followed-up to Week 96.

Arm type	Experimental
Investigational medicinal product name	JNJ-73763989
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received JNJ-73763989 40 mg as SC injection up to 48 weeks.

Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received NA treatment (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to JNJ-56136379 orally up to 48 weeks.

Arm title	Arm 5: Placebo + JNJ-56136379 + NA

Arm description:

Subjects received placebo matching to JNJ-73763989 as SC injection and a fixed dose of JNJ-56136379 250 mg oral tablet once daily along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo matching to JNJ-73763989 as SC injection up to 48 weeks.

Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received NA treatment (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.

Investigational medicinal product name	JNJ-56136379
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received a fixed dose of JNJ-56136379 250 mg tablet orally up to 48 weeks.

Arm title	Arm 6: Placebo + Placebo + NA

Arm description:	
Subjects received placebo matching to JNJ-73763989 as SC injection and placebo matching to JNJ-56136379 tablet orally along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	
Arm type	other
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Subjects received placebo matching to JNJ-73763989 SC injection up to 48 weeks.	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received placebo matching to JNJ-56136379 orally up to 48 weeks.	
Investigational medicinal product name	Nucleos(t)ide Analog (NA)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) orally up to 48 weeks.	

Number of subjects in period 1	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA
Started	95	96	93
Completed	92	90	90
Not completed	3	6	3
Physician decision	-	1	-
Lost to follow-up	-	1	2
Withdrawal by subject	3	4	1

Number of subjects in period 1	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA
Started	93	48	45
Completed	85	45	45
Not completed	8	3	0
Physician decision	-	-	-
Lost to follow-up	1	1	-
Withdrawal by subject	7	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA
Reporting group description:	
Subjects received JNJ-73763989 100 milligrams (mg) as subcutaneous (SC) injection once every 4 weeks along with JNJ-56136379 250 mg as oral tablet once daily and Nucleos(t)ide Analog (NA) (either entecavir [ETV] monohydrate 0.5 mg, tenofovir disoproxil fumarate [TDF] 300 mg, or tenofovir alafenamide [TAF] 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed up to Week 96.	
Reporting group title	Arm 2: JNJ-73763989 (200mg) + Placebo + NA
Reporting group description:	
Subjects received JNJ-73763989 200 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	
Reporting group title	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA
Reporting group description:	
Subjects received JNJ-73763989 100 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	
Reporting group title	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Reporting group description:	
Subjects received JNJ-73763989 40 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	
Reporting group title	Arm 5: Placebo + JNJ-56136379 + NA
Reporting group description:	
Subjects received placebo matching to JNJ-73763989 as SC injection and a fixed dose of JNJ-56136379 250 mg oral tablet once daily along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	
Reporting group title	Arm 6: Placebo + Placebo + NA
Reporting group description:	
Subjects received placebo matching to JNJ-73763989 as SC injection and placebo matching to JNJ-56136379 tablet orally along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.	

Reporting group values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA
Number of subjects	95	96	93
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	94	95	89
From 65 to 84 years	1	1	4
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	42.8	42.9	43
standard deviation	± 10.72	± 10.9	± 11.3

Title for Gender Units: subjects			
Female	24	35	38
Male	71	61	55

Reporting group values	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA
Number of subjects	93	48	45
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	93	46	45
From 65 to 84 years	0	2	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	42.2	43.9	43.8
standard deviation	± 10.92	± 9.8	± 9.99
Title for Gender Units: subjects			
Female	32	11	20
Male	61	37	25

Reporting group values	Total		
Number of subjects	470		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	462		
From 65 to 84 years	8		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	160		
Male	310		

End points

End points reporting groups

Reporting group title	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA

Reporting group description:

Subjects received JNJ-73763989 100 milligrams (mg) as subcutaneous (SC) injection once every 4 weeks along with JNJ-56136379 250 mg as oral tablet once daily and Nucleos(t)ide Analog (NA) (either entecavir [ETV] monohydrate 0.5 mg, tenofovir disoproxil fumarate [TDF] 300 mg, or tenofovir alafenamide [TAF] 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed up to Week 96.

Reporting group title	Arm 2: JNJ-73763989 (200mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 200 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Reporting group title	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 100 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Reporting group title	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 40 mg as SC injection once every 4 weeks along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Reporting group title	Arm 5: Placebo + JNJ-56136379 + NA

Reporting group description:

Subjects received placebo matching to JNJ-73763989 as SC injection and a fixed dose of JNJ-56136379 250 mg oral tablet once daily along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Reporting group title	Arm 6: Placebo + Placebo + NA

Reporting group description:

Subjects received placebo matching to JNJ-73763989 as SC injection and placebo matching to JNJ-56136379 tablet orally along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally once daily up to 48 weeks. Subjects were followed-up to Week 96.

Primary: Percentage of Subjects Meeting the Nucleos(t)ide Analog (NA) Treatment Completion Criteria at Week 48

End point title	Percentage of Subjects Meeting the Nucleos(t)ide Analog (NA) Treatment Completion Criteria at Week 48

End point description:

Percentage of subject meeting the NA treatment completion criteria at Week 48 was reported. NA completion criteria: subjects had alanine transaminase (ALT) less than (<) 3*upper limit of normal range (ULN); subjects had hepatitis B virus deoxyribonucleic acid (HBV DNA) < lower limit of quantification (LLOQ); subjects had hepatitis B e antigen (HBeAg)-negative; subjects had hepatitis B surface antigen (HBsAg) <10 international units per millilitre (IU/mL). Modified Intent-to-Treat (mITT) analysis set included all subjects who were randomised in the study and received at least one dose of study treatment. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Primary

End point timeframe:

Week 48

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	89	90	90	87
Units: Percentage of subject				
number (confidence interval 90%)	9.4 (4.36 to 14.36)	19.1 (12.76 to 27.06)	16.3 (10.33 to 23.99)	5.5 (2.19 to 11.21)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	45		
Units: Percentage of subject				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	2.2 (0.11 to 10.11)		

Statistical analyses

Statistical analysis title	NA versus JNJ-56136379+NA
Comparison groups	Arm 6: Placebo + Placebo + NA v Arm 5: Placebo + JNJ-56136379 + NA
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.848
Method	Mantel-Haenszel
Parameter estimate	Difference of proportions
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.97
upper limit	1.38

Statistical analysis title	NA versus JNJ3989 (100mg)+JNJ6379+NA
Comparison groups	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA v Arm 6: Placebo + Placebo + NA

Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027
Method	Mantel-Haenszel
Parameter estimate	Difference of proportions
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.07
upper limit	13.68

Statistical analysis title	JNJ-73763989+JNJ-56136379+NA V/S JNJ-56136379+NA
Comparison groups	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA v Arm 5: Placebo + JNJ-56136379 + NA
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.917
Method	Mantel-Haenszel
Parameter estimate	Difference of proportions
Confidence interval	
level	90 %
sides	2-sided
lower limit	4.16
upper limit	14.07

Statistical analysis title	JNJ-73763989+JNJ-56136379+NA V/S JNJ-73763989+NA
Comparison groups	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA v Arm 3: JNJ-73763989 (100 mg) + Placebo + NA
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.917
Method	Mantel-Haenszel
Parameter estimate	Difference of proportions
Confidence interval	
level	90 %
sides	2-sided
lower limit	-14.67
upper limit	1.25

Secondary: Percentage of Subjects with Adverse Events (AE)

End point title	Percentage of Subjects with Adverse Events (AE)

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a medicinal (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. Safety analysis set included all subjects who received at least one dose of any of the study treatments. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Up to 48 weeks, F-U: Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	96	93	93
Units: Percentage of subjects				
number (not applicable)				
Double blind (DB) (n=95,96,93,93,48,45)	71.6	64.6	71.0	74.2
Follow-up (F-U) Phase (n=92,95,91,90,47,45)	46.7	42.1	54.9	45.6

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (not applicable)				
Double blind (DB) (n=95,96,93,93,48,45)	85.4	66.7		
Follow-up (F-U) Phase (n=92,95,91,90,47,45)	55.3	31.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Serious Adverse Events (SAE)

End point title	Percentage of Subjects with Serious Adverse Events (SAE)

End point description:

SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product, and is medically important. Safety analysis set included all subjects who received at least one dose of any of the study treatments. Here, 'n' (number analysed)

represents number of subjects evaluable at the specified category.

End point type	Secondary

End point timeframe:

DB: Up to 48 weeks, F-U: Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	96	93	93
Units: Percentage of subjects				
number (not applicable)				
DB Phase (n=95,96,93,93,48,45)	2.1	3.1	2.2	1.1
Follow-up Phase (n=92,95,91,90,47,45)	3.3	5.3	3.3	1.1

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (not applicable)				
DB Phase (n=95,96,93,93,48,45)	4.2	0		
Follow-up Phase (n=92,95,91,90,47,45)	2.1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in Clinical Laboratory Tests

End point title	Percentage of Subjects with Abnormalities in Clinical Laboratory Tests

End point description:

Percentage of subjects with abnormalities in clinical laboratory tests were reported. Abnormality was determined at the investigator's discretion. Safety analysis set included all subjects who received at least one dose of any of the study treatments. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified category. AL: Abnormal low; AH: Abnormal high; M.C: Mean corpuscular; GGT: Gamma Glutamyl Transferase; E.C: Epithelial cells. Here, '99999' indicated that data was not available due to less number of subjects.

End point type	Secondary

End point timeframe:

DB: Up to 48 weeks, F-U: Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	96	93	93
Units: Percentage of subjects				
number (not applicable)				
DB:Basophils AL (n=93,94,93,92,48,45)	0	0	0	0
DB:Basophils AH (n=93,94,93,92,48,45)	1.1	2.1	1.1	2.2
F-U:Basophils AL (n=93,92,90,87,46,44)	0	0	0	0
F-U:Basophils AH (n=93,92,90,87,46,44)	2.2	0	1.1	0
DB:Eosinophils AL (n=93,94,93,92,48,45)	0	0	0	0
DB:Eosinophils AH (n=93,94,93,92,48,45)	3.2	0	1.1	3.3
F-U:Eosinophils AL (n=93,92,90,87,46,44)	0	0	0	0
F-U:Eosinophils AH (n=93,92,90,87,46,44)	1.1	1.1	1.1	1.1
DB:Ery. M.C HGB Conc. AL (n=93,94,93,92,48,45)	10.8	13.8	26.9	14.1
DB:Ery. M.C HGB Conc. AH (n=93,94,93,92,48,45)	0	0	0	0
F-U:Ery. M.C HGB Conc. AL (n=93,92,90,87,46,44)	13.0	17.4	24.4	18.4
F-U:Ery. M.C HGB Conc. AH (n=93,92,90,87,46,44)	0	0	0	0
DB:Ery. M.C Hemoglobin AL (n=93,94,93,92,48,45)	3.2	4.3	7.5	6.5
DB:Ery. M.C Hemoglobin AH (n=93,94,93,92,48,45)	7.5	1.1	1.1	1.1
F-U::Ery. M.C Hemoglobin AL (n=93,92,90,87,46,44)	7.5	8.7	6.7	8.0
F-U::Ery. M.C Hemoglobin AH (n=93,92,90,87,46,44)	4.3	1.1	0	1.1
DB:Ery. M.C Volume AL (n=93,94,93,92,48,45)	3.2	4.3	7.5	6.5
DB:Ery. M.C Volume AH (n=93,94,93,92,48,45)	29.0	19.1	15.1	16.3
F-U:Ery. M.C Volume AL (n=93,92,90,87,46,44)	4.3	6.5	7.8	6.9
F-U:Ery. M.C Volume AH (n=93,92,90,87,46,44)	16.3	12.0	13.3	13.8
DB:Erythrocytes AL (n=93,94,93,92,48,45)	20.4	14.9	24.7	15.2
DB:Erythrocytes AH (n=93,94,93,92,48,45)	0	0	3.2	3.3
F-U:Erythrocytes AL (n=93,92,90,87,46,44)	18.3	13.0	21.1	19.5
F-U:Erythrocytes AH (n=93,92,90,87,46,44)	0	0	1.1	3.4

DB:Hematocrit AL(n=93,94,93,92,48,45)	7.5	10.6	14.0	8.7
DB:Hematocrit AH (n=93,94,93,92,48,45)	1.1	0	1.1	0
F-U:Hematocrit AL (n=93,92,90,87,46,44)	6.5	13.0	10.0	11.5
F-U: Hematocrit AH (n=93,92,90,87,46,44)	1.1	1.1	0	0
DB:Lymphocytes Atypical AL (n=5,6,2,4,2,2)	0	0	0	0
DB:Lymphocytes Atypical AH (n=5,6,2,4,2,2)	80.0	100.0	100.0	100.0
F-U:Lymphocytes Atypical AL (n=2,4,1,0,2,0)	0	0	0	99999
F-U:Lymphocytes Atypical AH (n=2,4,1,0,2,0)	100.0	100.0	100.0	99999
DB:Lymphocyte Atypical/Leukocyte AL(n=5,6,2,4,2,1)	0	0	0	0
DB:Lymphocyte Atypical/Leukocyte AH(n=5,6,2,4,2,1)	80.0	100.0	100.0	100.0
F-U:LymphocyteAtypical/Leukocyte AL(n=2,4,1,0,1,0)	0	0	0	99999
F-U:LymphocyteAtypical/Leukocyte AH(n=2,4,1,0,1,0)	100.0	100.0	100.0	99999
F-U:Metamyelocytes AL(n=1,0,0,0,0,0)	0	99999	99999	99999
F-U:Metamyelocytes AH (n=1,0,0,0,0,0)	100.0	99999	99999	99999
DB:Monocytes AL (n=93,94,93,92,48,45)	10.8	12.8	5.4	5.4
DB:Monocytes AH (n=93,94,93,92,48,45)	1.1	2.1	0	0
F-U:Monocytes AL (n=93,92,90,87,46,44)	4.3	7.6	7.8	1.1
F-U:Monocytes AH (n=93,92,90,87,46,44)	0	1.1	1.1	0
F-U:Myelocytes AL (n=1,0,1,0,0,0)	0	99999	0	99999
F-U:Myelocytes AH (n=1,0,1,0,0,0)	100.0	99999	100.0	99999
DB:Neutrophils, Segmented AL (n=93,94,93,92,48,45)	36.6	24.5	23.7	25.0
DB:Neutrophils, Segmented AH (n=93,94,93,92,48,45)	5.4	4.3	6.5	6.5
F-U:Neutrophils,Segmented AL(n=93,92,90,87,46,44)	30.1	23.9	18.9	26.4
F-U:Neutrophils,Segmented AH(n=93,92,90,87,46,44)	3.2	4.3	2.2	2.3
DB:Reticulocytes AL (n=91,92,91,89,46,45)	34.1	27.2	26.4	24.7
DB:Reticulocytes AH (n=91,92,91,89,46,45)	4.4	0	0	2.2
F-U:Reticulocytes AL (n=92,92,90,86,46,44)	27.2	32.6	24.4	20.9
F-U:Reticulocytes AH (n=92,92,90,86,46,44)	3.3	4.3	4.4	1.2
DB:Serum Alpha Fetoprotein AL(n=87,91,88,89,46,43)	0	0	0	0
DB:Serum Alpha Fetoprotein AH(n=87,91,88,89,46,43)	1.1	3.3	0	0
F-U:Serum AlphaFetoprotein AL(n=89,85,85,86,46,45)	0	0	0	0
F-U:Serum AlphaFetoprotein AH(n=89,85,85,86,46,45)	1.1	2.4	0	1.2

F-U:Serum Chloride AL (n=94,94,90,88,46,45)	0	0	0	0
F-U:Serum Chloride AH (n=94,94,90,88,46,45)	1.1	2.1	1.1	0
DB:Serum GGT AL(n=93,96,93,93,48,45)	1.1	3.1	5.4	8.6
DB:Serum GGT AH(n=93,96,93,93,48,45)	10.8	3.1	3.2	2.2
F-U:Serum GGT AL(n=94,94,90,88,46,45)	1.1	3.2	3.3	9.1
F-U:Serum GGT AH(n=94,94,90,88,46,45)	4.3	2.1	6.7	3.4
DB:Serum HDL Cholesterol AL(n=93,96,93,93,48.45)	6.5	18.8	24.7	28.0
DB:Serum HDL Cholesterol AH(n=93,96,93,93,48.45)	50.5	15.6	11.8	6.5
F-U:Serum HDL Cholesterol AL(n=94,94,90,88,46,45)	18.1	20.2	15.6	28.4
F-U:Serum HDL Cholesterol AH(n=94,94,90,88,46,45)	23.4	12.8	10.0	8.0
DB:Indirect Bilirubin AL(n=93,96,93,93,48,45)	0	0	0	0
DB:Indirect Bilirubin AH(n=93,96,93,93,48,45)	7.5	3.1	4.3	6.5
F-U:Indirect Bilirubin AL(n=92,94,90,88,46,45)	0	0	0	0
F-U:Indirect Bilirubin AH(n=92,94,90,88,46,45)	6.5	1.1	2.2	8.0
DB:Lactate Dehydrogenase AL(n=93,94,93,92,48,45)	0	0	0	0
DB:Lactate Dehydrogenase AH(n=93,94,93,92,48,45)	9.7	11.7	3.2	8.7
F-U:Lactate Dehydrogenase AL(n=92,94,90,88,46,45)	0	0	0	0
F-U:Lactate Dehydrogenase AH(n=92,94,90,88,46,45)	6.5	7.4	7.8	9.1
DB:Serum Protein AL(n=93,96,93,93,48,45)	5.4	3.1	0	0
DB:Serum Protein AH(n=93,96,93,93,48,45)	2.2	3.1	4.3	3.2
F-U:Serum Protein AL(n=94,94,90,88,46,45)	0	0	0	0
F-U:Serum Protein AH(n=94,94,90,88,46,45)	4.3	1.1	2.2	2.3
DB:Urea Nitrogen AL (n=93,96,93,93,48,45)	6.50	0	0	0
DB:Urea Nitrogen AH (n=93,96,93,93,48,45)	6.5	4.2	3.2	5.4
F-U:Urea Nitrogen AL (n=94,94,90,88,46,45)	0	0	0	0
F-U:Urea Nitrogen AH (n=94,94,90,88,46,45)	6.4	4.3	2.2	1.1
DB:Urine Granular Casts AL(n=1,0,0,1,0,0)	0	99999	99999	0
DB:Urine Granular Casts AH(n=1,0,0,1,0,0)	100.0	99999	99999	100.0
DB:Urine Hyaline Casts AL(n=3,5,3,4,2,6)	0	0	0	0
DB:Urine Hyaline Casts AH(n=3,5,3,4,2,6)	100.0	60.0	100.0	100.0
F-U:Urine Hyaline Casts AL(n=1,0,0,0,0,0)	0	99999	99999	99999

F-U:Urine Hyaline Casts AH(n=1,0,0,0,0,0)	100.0	99999	99999	99999
DB:Urine Leukocytes AL(n=47,48,42,39,21,22)	0	0	0	0
DB:Urine Leukocytes AH(n=47,48,42,39,21,22)	8.5	6.3	9.5	2.6
F-U:Urine Leukocytes AL(n=8,7,9,11,4,0)	0	0	0	0
F-U:Urine Leukocytes AH(n=8,7,9,11,4,0)	0	0	0	0
DB:Urine Specific Gravity AL(n=61,61,53,54,29,25)	1.6	0	3.8	3.7
DB:Urine Specific Gravity AH(n=61,61,53,54,29,25)	1.6	11.5	1.9	5.6
F-U:Urine Specific Gravity AL(n=17,15,18,15,8,0))	5.9	0	5.6	0
F-U:Urine Specific Gravity AH(n=17,15,18,15,8,0))	5.9	0	0	0
DB:Urine Squamous Epithelial cellAL(n=1,3,4,2,2,2)	0	0	0	0
DB:Urine Squamous Epithelial cellAH(n=1,3,4,2,2,2)	100.0	66.7	75.0	50.0
DB:Urine T.E Cells AL(n=0,1,1,2,1,1)	99999	0	0	0
DB:Urine Transitinoal E.C AH(n=0,1,1,2,1,1)	99999	100.0	100.0	100.0
DB:Urine Tubular E.C AL(n=0,0,0,1,0,0)	99999	99999	99999	0
DB:Urine Tubular E.C AH (n=0,0,0,1,0,0)	99999	99999	99999	100.0

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (not applicable)				
DB:Basophils AL (n=93,94,93,92,48,45)	0	0		
DB:Basophils AH (n=93,94,93,92,48,45)	2.1	0		
F-U:Basophils AL (n=93,92,90,87,46,44)	0	0		
F-U:Basophils AH (n=93,92,90,87,46,44)	0	0		
DB:Eosinophils AL (n=93,94,93,92,48,45)	0	0		
DB:Eosinophils AH (n=93,94,93,92,48,45)	14.6	2.2		
F-U:Eosinophils AL (n=93,92,90,87,46,44)	0	0		
F-U:Eosinophils AH (n=93,92,90,87,46,44)	2.2	0		
DB:Ery. M.C HGB Conc. AL (n=93,94,93,92,48,45)	16.7	22.2		
DB:Ery. M.C HGB Conc. AH (n=93,94,93,92,48,45)	0	0		
F-U:Ery. M.C HGB Conc. AL (n=93,92,90,87,46,44)	13.0	22.7		

F-U:Ery. M.C HGB Conc. AH (n=93,92,90,87,46,44)	0	0		
DB:Ery. M.C Hemoglobin AL (n=93,94,93,92,48,45)	6.3	11.1		
DB:Ery. M.C Hemoglobin AH (n=93,94,93,92,48,45)	6.3	2.2		
F-U::Ery. M.C Hemoglobin AL (n=93,92,90,87,46,44)	2.2	6.8		
F-U::Ery. M.C Hemoglobin AH (n=93,92,90,87,46,44)	2.2	2.3		
DB:Ery. M.C Volume AL (n=93,94,93,92,48,45)	6.3	8.9		
DB:Ery. M.C Volume AH (n=93,94,93,92,48,45)	29.2	13.3		
F-U:Ery. M.C Volume AL (n=93,92,90,87,46,44)	2.2	4.5		
F-U:Ery. M.C Volume AH (n=93,92,90,87,46,44)	19.6	9.1		
DB:Erythrocytes AL (n=93,94,93,92,48,45)	27.1	22.2		
DB:Erythrocytes AH (n=93,94,93,92,48,45)	0	2.2		
F-U:Erythrocytes AL (n=93,92,90,87,46,44)	21.7	13.6		
F-U:Erythrocytes AH (n=93,92,90,87,46,44)	0	0		
DB:Hematocrit AL(n=93,94,93,92,48,45)	10.4	13.3		
DB:Hematocrit AH (n=93,94,93,92,48,45)	2.1	2.2		
F-U:Hematocrit AL (n=93,92,90,87,46,44)	13.0	11.4		
F-U: Hematocrit AH (n=93,92,90,87,46,44)	0	0		
DB:Lymphocytes Atypical AL (n=5,6,2,4,2,2)	0	0		
DB:Lymphocytes Atypical AH (n=5,6,2,4,2,2)	100.0	100.0		
F-U:Lymphocytes Atypical AL (n=2,4,1,0,2,0)	0	99999		
F-U:Lymphocytes Atypical AH (n=2,4,1,0,2,0)	100.0	99999		
DB:Lymphocyte Atypical/Leukocyte AL(n=5,6,2,4,2,1)	0	0		
DB:Lymphocyte Atypical/Leukocyte AH(n=5,6,2,4,2,1)	100.0	100.0		
F-U:LymphocyteAtypical/Leukocyte AL(n=2,4,1,0,1,0)	0	99999		
F-U:LymphocyteAtypical/Leukocyte AH(n=2,4,1,0,1,0)	100.0	99999		
F-U:Metamyelocytes AL(n=1,0,0,0,0,0)	99999	99999		
F-U:Metamyelocytes AH (n=1,0,0,0,0,0)	99999	99999		
DB:Monocytes AL (n=93,94,93,92,48,45)	4.2	8.9		
DB:Monocytes AH (n=93,94,93,92,48,45)	6.3	0		
F-U:Monocytes AL (n=93,92,90,87,46,44)	4.3	0		
F-U:Monocytes AH (n=93,92,90,87,46,44)	0	0		
F-U:Myelocytes AL (n=1,0,1,0,0,0)	99999	99999		

F-U:Myelocytes AH (n=1,0,1,0,0,0)	99999	99999		
DB:Neutrophils, Segmented AL (n=93,94,93,92,48,45)	35.4	33.3		
DB:Neutrophils, Segmented AH (n=93,94,93,92,48,45)	4.2	4.4		
F-U:Neutrophils,Segmented AL(n=93,92,90,87,46,44)	17.4	20.5		
F-U:Neutrophils,Segmented AH(n=93,92,90,87,46,44)	4.3	0		
DB:Reticulocytes AL (n=91,92,91,89,46,45)	41.3	37.8		
DB:Reticulocytes AH (n=91,92,91,89,46,45)	0	2.2		
F-U:Reticulocytes AL (n=92,92,90,86,46,44)	30.4	13.6		
F-U:Reticulocytes AH (n=92,92,90,86,46,44)	0	2.3		
DB:Serum Alpha Fetoprotein AL(n=87,91,88,89,46,43)	0	0		
DB:Serum Alpha Fetoprotein AH(n=87,91,88,89,46,43)	0	0		
F-U:Serum AlphaFetoprotein AL(n=89,85,85,86,46,45)	0	0		
F-U:Serum AlphaFetoprotein AH(n=89,85,85,86,46,45)	0	0		
F-U:Serum Chloride AL (n=94,94,90,88,46,45)	0	0		
F-U:Serum Chloride AH (n=94,94,90,88,46,45)	0	0		
DB:Serum GGT AL(n=93,96,93,93,48,45)	2.1	8.9		
DB:Serum GGT AH(n=93,96,93,93,48,45)	6.3	4.4		
F-U:Serum GGT AL(n=94,94,90,88,46,45)	8.7	4.4		
F-U:Serum GGT AH(n=94,94,90,88,46,45)	4.3	0		
DB:Serum HDL Cholesterol AL(n=93,96,93,93,48.45)	8.3	37.8		
DB:Serum HDL Cholesterol AH(n=93,96,93,93,48.45)	41.7	8.9		
F-U:Serum HDL Cholesterol AL(n=94,94,90,88,46,45)	19.6	17.8		
F-U:Serum HDL Cholesterol AH(n=94,94,90,88,46,45)	19.6	2.2		
DB:Indirect Bilirubin AL(n=93,96,93,93,48,45)	0	0		
DB:Indirect Bilirubin AH(n=93,96,93,93,48,45)	8.3	2.2		
F-U:Indirect Bilirubin AL(n=92,94,90,88,46,45)	0	0		
F-U:Indirect Bilirubin AH(n=92,94,90,88,46,45)	6.5	2.2		
DB:Lactate Dehydrogenase AL(n=93,94,93,92,48,45)	0	0		
DB:Lactate Dehydrogenase AH(n=93,94,93,92,48,45)	14.6	4.4		
F-U:Lactate Dehydrogenase AL(n=92,94,90,88,46,45)	0	0		
F-U:Lactate Dehydrogenase AH(n=92,94,90,88,46,45)	13.0	6.7		

DB:Serum Protein AL(n=93,96,93,93,48,45)	2.1	0		
DB:Serum Protein AH(n=93,96,93,93,48,45)	7	6.7		
F-U:Serum Protein AL(n=94,94,90,88,46,45)	0	0		
F-U:Serum Protein AH(n=94,94,90,88,46,45)	2.2	2.2		
DB:Urea Nitrogen AL (n=93,96,93,93,48,45)	0	0		
DB:Urea Nitrogen AH (n=93,96,93,93,48,45)	6.3	6.7		
F-U:Urea Nitrogen AL (n=94,94,90,88,46,45)	0	0		
F-U:Urea Nitrogen AH (n=94,94,90,88,46,45)	8.7	0		
DB:Urine Granular Casts AL(n=1,0,0,1,0,0)	99999	99999		
DB:Urine Granular Casts AH(n=1,0,0,1,0,0)	99999	99999		
DB:Urine Hyaline Casts AL(n=3,5,3,4,2,6)	0	0		
DB:Urine Hyaline Casts AH(n=3,5,3,4,2,6)	100.0	100.0		
F-U:Urine Hyaline Casts AL(n=1,0,0,0,0,0)	99999	99999		
F-U:Urine Hyaline Casts AH(n=1,0,0,0,0,0)	99999	99999		
DB:Urine Leukocytes AL(n=47,48,42,39,21,22)	0	0		
DB:Urine Leukocytes AH(n=47,48,42,39,21,22)	9.5	9.1		
F-U:Urine Leukocytes AL(n=8,7,9,11,4,0)	0	99999		
F-U:Urine Leukocytes AH(n=8,7,9,11,4,0)	25.0	99999		
DB:Urine Specific Gravity AL(n=61,61,53,54,29,25)	0	0		
DB:Urine Specific Gravity AH(n=61,61,53,54,29,25)	3.4	24.0		
F-U:Urine Specific Gravity AL(n=17,15,18,15,8,0))	0	99999		
F-U:Urine Specific Gravity AH(n=17,15,18,15,8,0))	0	99999		
DB:Urine Squamous Epithelial cellAL(n=1,3,4,2,2,2)	0	0		
DB:Urine Squamous Epithelial cellAH(n=1,3,4,2,2,2)	50.0	50.0		
DB:Urine T.E Cells AL(n=0,1,1,2,1,1)	0	0		
DB:Urine Transitinoal E.C AH(n=0,1,1,2,1,1)	100.0	100.0		
DB:Urine Tubular E.C AL(n=0,0,0,1,0,0)	99999	99999		
DB:Urine Tubular E.C AH (n=0,0,0,1,0,0)	99999	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in Electrocardiogram (ECG)

End point title	Percentage of Subjects with Abnormalities in Electrocardiogram (ECG)

End point description:

Percentage of subjects with abnormalities in ECG parameters (heart rate, PR interval, QRS duration, and QTcF interval) were reported. Abnormality criteria: Heart rate abnormally low (AL): <45 beats per minute (bpm); Hear rate abnormally high (AH):>=120 bpm; PR interval AH:>220 msec; QRS duration AH:>120 msec; QTcF borderline prolonged (BP) QT: 450 msec to <=480 msec. Safety analysis set included all subjects who received at least one dose of any of the study treatments. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints. PP: Pathologically prolonged.

End point type	Secondary

End point timeframe:

DB: Up to 48 weeks, F-U: Wek 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	95	91	92
Units: Percentage of subjects				
number (not applicable)				
DB: Heart Rate AL (n=93,95,91,92,47,45	0	2.1	1.1	3.3
DB: Heart Rate AH (n=93,95,91,92,47,45	0	0	0	0
F-U: Heart Rate AL (n=92,84,83,84,46,1)	0	0	0	0
F-U: Heart Rate AH (n=92,84,93,84,46,1)	0	0	0	0
DB: PR interval AH (n=93,95,91,92,47,45)	1.1	0	3.3	1.1
F-U: PR interval AH (n=92,84,83,84,46,1)	0	0	1.2	0
DB: QRS duration AH (n=93,95,91,92,47,45)	2.2	1.1	1.1	0
F-U: QRS duration AH (n=92,84,83,84,46,1)	2.2	0	0	0
DB: QTcF interval BP-QT(n=93,95,91,92,47,45)	2.2	2.1	3.3	1.1
DB:QTcF interval prolonged QT(n=93,95,91,92,47,45)	0	0	0	0
DB: QTcF interval PP-QT(n=93,95,91,92,47,45)	0	0	0	0
F-U: QTcF interval BP-QT (n=92,84,83,84,46,1)	1.1	0	2.4	1.2
F-U:QTcF interval prolonged QT(n=92,84,83,84,46,1)	0	0	0	0
F-U: QTcF interval PP-QT (n=92,84,83,84,46,1)	0	0	0	0

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	45		
Units: Percentage of subjects				
number (not applicable)				
DB: Heart Rate AL (n=93,95,91,92,47,45	0	0		
DB: Heart Rate AH (n=93,95,91,92,47,45	0	0		
F-U: Heart Rate AL (n=92,84,83,84,46,1)	2.2	0		
F-U: Heart Rate AH (n=92,84,93,84,46,1)	0	0		
DB: PR interval AH (n=93,95,91,92,47,45)	4.3	2.2		
F-U: PR interval AH (n=92,84,83,84,46,1)	0	0		
DB: QRS duration AH (n=93,95,91,92,47,45)	0	2.2		
F-U: QRS duration AH (n=92,84,83,84,46,1)	0	0		
DB: QTcF interval BP-QT(n=93,95,91,92,47,45)	0	2.2		
DB:QTcF interval prolonged QT(n=93,95,91,92,47,45)	0	0		
DB: QTcF interval PP-QT(n=93,95,91,92,47,45)	0	0		
F-U: QTcF interval BP-QT (n=92,84,83,84,46,1)	0	0		
F-U:QTcF interval prolonged QT(n=92,84,83,84,46,1)	0	0		
F-U: QTcF interval PP-QT (n=92,84,83,84,46,1)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in Vital Signs

End point title	Percentage of Subjects with Abnormalities in Vital Signs

End point description:

Percentage of subjects with abnormalities in vital signs parameters (pulse rate, diastolic and systolic blood pressure) were reported. Abnormality criteria: Pulse rate AL:<=45 bpm; Systolic blood pressure (SBP) AL: <=90 millimeters of mercury (mmHg), mild:>140 mmHg - <160 mmHg; moderate:>=160 mmHg - <180 mmHg; Diastolic blood pressure (DBP): AL: <=150 mmHg; mild:>90 mmHg - <100 mmHg; moderate: >=100 mmHg - <110 mmHg; severe:>=110 mmHg. Abnormality was determined at the investigator's discretion. Safety analysis set included all subjects who received at least one dose of any of the study treatments. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represented number of subjects evaluable at the specified category.

End point type	Secondary
End point timeframe:	
DB: Up to 48 weeks, F-U: Week 48 up to Week 96	

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	96	93	93
Units: Percentage of subjects				
number (not applicable)				
DB:Pulse rate AL (n=93,96,93,93,48,45)	1.1	4.2	2.2	2.2
DB:Pulse rate AH (n=93,96,93,93,48,45)	0	2.1	1.1	2.2
FU:Pulse rate AL (n=94,94,90,88,46,45)	1.1	0	1.1	2.3
FU:Pulse rate AH (n=94,94,90,88,46,45)	0	0	0	1.1
DB: DBP AL (n=93,96,93,93,48,45)	4.3	1.0	4.3	4.3
DB: DBP mild (n=93,96,93,93,48,45)	20.4	18.8	12.9	14.0
DB: DBP moderate (n=93,96,93,93,48,45)	4.3	4.2	3.2	3.2
DB: DBP severe (n=93,96,93,93,48,45)	0	0	0	1.1
FU: DBP AL (n=94,94,90,88,46,45)	1.1	1.1	0	1.1
FU: DBP mild (n=94,94,90,88,46,45)	10.16	10.16	4.4	12.5
FU: DBP moderate (n=94,94,90,88,46,45)	1.1	2.1	4.4	1.1
DB: SBP AL(n=93,96,93,93,48,45)	0	6.3	2.2	6.5
DB: SBP mild (n=93,96,93,93,48,45)	23.7	18.8	12.9	22.6
DB: SBP moderate (n=93,96,93,93,48,45)	4.3	3.1	4.3	2.2
FU: SBP AL (n=94,94,90,88,46,45)	3.2	2.1	1.1	4.5
FU: SBP mild (n=94,94,90,88,46,45)	12.8	12.8	11.1	10.2
FU: SBP moderate (n=94,94,90,88,46,45)	0	2.1	2.2	2.1

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (not applicable)				
DB:Pulse rate AL (n=93,96,93,93,48,45)	0	0		
DB:Pulse rate AH (n=93,96,93,93,48,45)	0	0		
FU:Pulse rate AL (n=94,94,90,88,46,45)	0	0		

FU:Pulse rate AH (n=94,94,90,88,46,45)	0	0		
DB: DBP AL (n=93,96,93,93,48,45)	0	2.2		
DB: DBP mild (n=93,96,93,93,48,45)	0	6.7		
DB: DBP moderate (n=93,96,93,93,48,45)	0	0		
DB: DBP severe (n=93,96,93,93,48,45)	0	0		
FU: DBP AL (n=94,94,90,88,46,45)	0	0		
FU: DBP mild (n=94,94,90,88,46,45)	0	8.9		
FU: DBP moderate (n=94,94,90,88,46,45)	0	0		
DB: SBP AL(n=93,96,93,93,48,45)	0	4.4		
DB: SBP mild (n=93,96,93,93,48,45)	0	17.8		
DB: SBP moderate (n=93,96,93,93,48,45)	0	2.2		
FU: SBP AL (n=94,94,90,88,46,45)	0	0		
FU: SBP mild (n=94,94,90,88,46,45)	0	4.4		
FU: SBP moderate (n=94,94,90,88,46,45)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Seroclearance 24 Weeks After Completion of all Study Intervention at Week 48

End point title	Percentage of Subjects with HBsAg Seroclearance 24 Weeks After Completion of all Study Intervention at Week 48

End point description:

Percentage of subjects with HBsAg seroclearance 24 weeks after completion of all study intervention at week 48 were reported. HBsAg Seroclearance was defined as HBsAg <LLOQ. Responder was defined as a subject who achieved functional cure at Week 72 if the subject met the criteria for stopping NA treatment at Week 48, had HBsAg seroclearance at Week 72. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Week 72

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	85	83	82	83
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 3.46)	0.0 (0.00 to 3.54)	0.0 (0.00 to 3.59)	0.0 (0.00 to 3.54)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.30)	2.2 (0.11 to 10.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Seroclearance 48 Weeks After Completion of all Study Intervention at Week 48.

End point title	Percentage of Subjects with HBsAg Seroclearance 48 Weeks After Completion of all Study Intervention at Week 48.

End point description:

Percentage of subjects with HBsAg seroclearance 48 weeks after completion of all study intervention at Week 48 were reported. HBsAg Seroclearance was defined as HBsAg <LLOQ. A responder was defined as a subject who achieved HBsAg seroclearance at Week 96 if the subject completed 48 weeks of treatment, met the criteria for stopping NA treatment at Week 48, did not require NA re-treatment between Week 48 and Week 96, and had HBsAg seroclearance at Week 96. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 3.14)	1.1 (0.05 to 4.95)	0.0 (0.00 to 3.20)	0.0 (0.00 to 3.24)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	2.2 (0.11 to 10.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBV DNA <LLOQ 24 and 48 Weeks After Completion of all Study Intervention at Week 48

End point title	Percentage of Subjects with HBV DNA <LLOQ 24 and 48 Weeks After Completion of all Study Intervention at Week 48

End point description:

Percentage of subject who completed all study intervention at week 48 and reached HBV DNA <LLOQ at follow-up weeks 24 and 48 were reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analyzed) represents number of subjects evaluable at the specified timepoint.

End point type	Secondary

End point timeframe:

Weeks 72 and 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)				
F-U: Week 72 (n=94,94,92,91,48,45)	5.3 (2.12 to 10.86)	16.0 (10.10 to 23.50)	7.6 (3.63 to 13.82)	1.1 (0.06 to 5.11)
FU: Week 96 (n=94,94,92,91,48,45)	6.4 (2.82 to 12.21)	9.6 (5.09 to 16.11)	5.4 (2.17 to 11.09)	1.1 (0.06 to 5.11)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)				

F-U: Week 72 (n=94,94,92,91,48,45)	0.0 (0.00 to 6.05)	4.4 (0.80 to 13.34)		
FU: Week 96 (n=94,94,92,91,48,45)	2.1 (0.11 to 9.51)	0.0 (0.00 to 6.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Seroclearance After Completion of NA Treatment at Weeks 60, 84 and 96

End point title	Percentage of Subjects with HBsAg Seroclearance After Completion of NA Treatment at Weeks 60, 84 and 96

End point description:

Percentage of subjects with HBsAg seroclearance after completion of NA treatment at Weeks 60, 84 and 96 were reported. A responder was defined as a subject who achieved HBsAg seroclearance at Week 96 if the subject completed 48 weeks of treatment, met the criteria for stopping NA treatment at Week 48, did not require NA re-treatment between Week 48 and Week 96, and had HBsAg seroclearance at Week 96. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'n' (number analysed) represented number of subjects evaluable at the specified timepoints. Here, '99999' indicated that data was not available as no subject was analysed.

End point type	Secondary

End point timeframe:

Weeks 60, 84 and 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of of subjects				
number (confidence interval 90%)				
Week 96 (n=94,94,92,9148,45)	0.0 (0.00 to 3.14)	1.1 (0.05 to 4.95)	0.0 (0.00 to 3.20)	0.0 (0.00 to 3.24)
Week 60 (n=9,22,18,5,0,1)	0.0 (0.00 to 28.31)	9.1 (1.64 to 25.95)	0.0 (0.00 to 15.33)	0.0 (0.00 to 45.07)
Week 84 (n=10,22,14,5,0,1)	0.0 (0.00 to 25.89)	9.1 (1.64 to 25.95)	0.0 (0.00 to 19.26)	0.0 (0.00 to 45.07)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of of subjects				

number (confidence interval 90%)				
Week 96 (n=94,94,92,9148,45)	0.0 (0.00 to 6.05)	2.2 (0.11 to 10.11)		
Week 60 (n=9,22,18,5,0,1)	99999 (99999 to 99999)	0.0 (0.00 to 95.00)		
Week 84 (n=10,22,14,5,0,1)	99999 (99999 to 99999)	100.0 (5.0 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Meeting the NA Treatment Completion Criteria

End point title	Percentage of Subjects Meeting the NA Treatment Completion Criteria

End point description:

Percentage of subjects meeting the NA treatment completion criteria was reported. NA completion criteria: subjects had ALT 3*ULN; subjects had HBV DNA <LLOQ; subjects was HBeAg-negative; subjects had HBsAg <10 IU/mL. A responder was defined as a subject who stopped NA at Week 48 and met the NA treatment completion criteria at any time during the follow-up phase, regardless of the treatment duration. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)	11.7 (6.70 to 18.63)	26.6 (19.21 to 35.12)	16.3 (10.33 to 23.99)	4.4 (1.52 to 9.78)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	2.2 (0.11 to 10.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Required NA Re-treatment During Follow-up

End point title	Percentage of Subjects who Required NA Re-treatment During Follow-up

End point description:

Percentage of subjects who required NA re-treatment during follow-up were reported. Responder was defined as a subject who met the criteria for NA re-treatment at any time during follow-up, for those subjects who met the NA treatment completion criteria at any time during the study and actually stopped NA treatment. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)	1.1 (0.05 to 4.95)	1.1 (0.05 to 4.95)	2.2 (0.39 to 6.69)	0.0 (0.00 to 3.24)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	0.0 (0.00 to 6.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Flares

End point title	Percentage of Subjects with Flares

End point description:

Percentage of subjects with flare (virologic, biochemical, and clinical) was reported. Virologic flare: confirmed HBV DNA >peak threshold; biochemical Flare: confirmed ALT and/or AST increase of 3*ULN and 3*nadir; clinical flare: confirmed HBV DNA >peak threshold and confirmed ALT and/or AST increase of 3*ULN and 3*nadir. Virologic and clinical flare was assessed only for those subjects who were off-treatment and had HBV DNA<LLOQ at the last observed time point on all study treatments and biochemical flares was identified on treatment and off treatment, respectively. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'n' (number analysed) represents number of subjects evaluable at the specified category.

End point type	Secondary

End point timeframe:

Follow-up phase (Week 48 up to Week 96)

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)				
Biochemical: On NA (n=94,94,92,91,48,45	0.0 (0.00 to 3.14)	0.0 (0.00 to 3.14)	0.0 (0.00 to 3.20)	0.0 (0.00 to 3.24)
Biochemical: Off NA (n=33,40,40,18,10,10)	0.0 (0.00 to 8.68)	2.5 (1.13 to 11.32)	0.0 (0.00 to 7.22)	0.0 (0.00 to 14.59)
Virologic HBVDNA>200:Off NA(n=30,37,37,14,9,10)	13.3 (4.69 to 27.96)	24.3 (13.32 to 38.61)	21.6 (11.24 to 35.64)	14.3 (2.60 to 38.54)
Virologic HBVDNA>2000:Off NA(n=30,37,37,14,9,10)	3.3 (0.17 to 14.86)	2.7 (0.14 to 12.19)	8.1 (2.25 to 19.64)	7.1 (0.37 to 29.67)
Virologic HBVDNA>20000:Off NA(n=30,37,37,14,9,10)	3.0 (0.17 to 14.86)	2.7 (0.14 to 12.19)	5.4 (0.97 to 16.05)	0.0 (0.00 to 19.26)
Clinical HBVDNA>200:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 9.50)	0.0 (0.00 to 7.78)	0.0 (0.00 to 7.78)	0.0 (0.00 to 19.26)
Clinical HBVDNA>2000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 9.50)	0.0 (0.00 to 7.78)	0.0 (0.00 to 7.78)	0.0 (0.00 to 19.26)
Clinical HBVDNA>20000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 9.50)	2.7 (0.14 to 12.19)	0.0 (0.00 to 7.78)	0.0 (0.00 to 19.26)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)				

Biochemical: On NA (n=94,94,92,91,48,45	2.1 (0.11 to 9.51)	0.0 (0.00 to 6.44)		
Biochemical: Off NA (n=33,40,40,18,10,10)	0.0 (0.00 to 25.89)	0.0 (0.00 to 25.89)		
Virologic HBVDNA>200:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 28.31)	0.0 (0.00 to 25.89)		
Virologic HBVDNA>2000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 28.21)	10.0 (0.51 to 39.42)		
Virologic HBVDNA>20000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 8.31)	0.0 (0.00 to 25.89)		
Clinical HBVDNA>200:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 28.31)	0.0 (0.00 to 25.89)		
Clinical HBVDNA>2000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 28.31)	0.0 (0.00 to 25.89)		
Clinical HBVDNA>20000:Off NA(n=30,37,37,14,9,10)	0.0 (0.00 to 28.31)	0.0 (0.00 to 25.89)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with (Sustained) Reduction, Suppression, and/or Seroclearance Considering Single and Multiple Marker

End point title	Number of Subjects with (Sustained) Reduction, Suppression, and/or Seroclearance Considering Single and Multiple Marker

End point description:

Number of subjects with (sustained) reduction, suppression and/or seroclearance considering single and multiple marker was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 12, 24, 36 and 48

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Subjects				
Week 12 (n=94,94,92,91,48,45)	10	25	17	5
Week 24 (n=94,94,92,91,48,45)	10	24	16	5
Week 36 (n=94,94,92,91,48,45)	9	23	18	5
Week 48 (n=94,94,92,91,48,45)	10	23	18	5

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Subjects				
Week 12 (n=94,94,92,91,48,45)	1	1		
Week 24 (n=94,94,92,91,48,45)	1	1		
Week 36 (n=94,94,92,91,48,45)	1	1		
Week 48 (n=94,94,92,91,48,45)	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Seroconversion

End point title	Percentage of Subjects with HBsAg Seroconversion

End point description:

HBsAg seroconversion was defined as achieving HBsAg seroclearance (HBsAg (quantitative) <LLOQ) together with an appearance of anti-HBs antibodies (baseline anti-HBs antibodies [quantitative] <LLOQ and a post-baseline assessment greater than or equal to [>=] LLOQ). mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Week 48, Follow-up Weeks 60, 72, and 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	87	89	83	85
Units: Percentage of subjects				
number (not applicable)				
DB: Week 48 (n=86,89,83,85,44,42)	0.0	1.1	0.0	0.0
F-U: Week 60 (n=85,83,78,81,45,41)	0.0	0.0	0.0	0.0
F-U: Week 72 (n=83,82,76,82,45,42)	0.0	0.0	1.3	0.0
F-U: Week 96 (n=87,81,80,80,42,42)	0.0	1.2	0.0	0.0

End point values	Arm 5: Placebo + JNJ-56136379 +	Arm 6: Placebo + Placebo + NA		

	NA			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	42		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 48 (n=86,89,83,85,44,42)	0.0	0.0		
F-U: Week 60 (n=85,83,78,81,45,41)	0.0	0.0		
F-U: Week 72 (n=83,82,76,82,45,42)	0.0	2.4		
F-U: Week 96 (n=87,81,80,80,42,42)	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBeAg Seroconversion

End point title	Percentage of Subjects with HBeAg Seroconversion

End point description:

HBeAg seroconversion was defined as achieving HBeAg seroclearance (HBeAg [quantitative] <LLOQ) together with an appearance of anti-HBe antibodies (baseline anti-HBe antibodies [qualitative] with a "negative" result and a post-baseline assessment with "positive" result. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Week 48, Follow-up Weeks 60, 72, and 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	28	23	25
Units: Percentage of subjects				
number (not applicable)				
DB: Week 48 (n=25, 28, 23, 24, 13, 11)	4.0	3.6	8.7	0
F-U: Week 60 (n=23, 27, 22, 23, 14, 10)	4.3	7.4	4.5	0
F-U: Week 72 (n=24, 27, 22, 25, 14, 11)	4.2	3.7	9.1	0
F-U: Week 96 (n=25, 27, 23, 24, 13, 11)	8.0	14.8	13.0	4.2

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	11		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 48 (n=25, 28, 23, 24, 13, 11)	0	18.2		
F-U: Week 60 (n=23, 27, 22, 23, 14, 10)	0	20.0		
F-U: Week 72 (n=24, 27, 22, 25, 14, 11)	0	18.2		
F-U: Week 96 (n=25, 27, 23, 24, 13, 11)	7.7	18.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HBsAg Levels

End point title	Change From Baseline in HBsAg Levels

End point description:

Change from baseline in HBsAg levels was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'n' (number analysed) represents number of subjects evaluable at the specified category. Log IU/mL: Log international units per millilitre

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=94,94,92,91,48,45)	3.66 (± 0.691)	3.83 (± 0.721)	3.70 (± 0.778)	3.81 (± 0.678)
DB: Week 12 (n=92,92,86,88,45,45)	-0.96 (± 0.533)	-1.51 (± 0.790)	-1.24 (± 0.646)	-0.82 (± 0.361)
DB: Week 24 (n=91,92,88,88,45,44)	-1.52 (± 0.582)	-2.22 (± 0.768)	-1.84 (± 0.612)	-1.26 (± 0.430)
DB: Week 48 (n=87,91,88,86,45,44)	-1.76 (± 0.643)	-2.58 (± 0.996)	-2.09 (± 0.665)	-1.50 (± 0.470)
F-U: Week 60 (n=87,85,84,83,46,1)	-1.59 (± 0.613)	-2.21 (± 0.975)	-1.75 (± 0.699)	-1.22 (± 0.456)

F-U: Week 72 (n=85,83,82,84,46,45)	-1.38 (± 0.630)	-1.85 (± 0.927)	-1.50 (± 0.783)	-1.01 (± 0.487)
F-U: Week 96 (n=89,82,85,82,44,45)	-1.04 (± 0.634)	-1.39 (± 0.895)	-1.15 (± 0.744)	-0.74 (± 0.497)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=94,94,92,91,48,45)	3.63 (± 0.681)	3.83 (± 0.714)		
DB: Week 12 (n=92,92,86,88,45,45)	-0.01 (± 0.286)	-0.07 (± 0.244)		
DB: Week 24 (n=91,92,88,88,45,44)	-0.05 (± 0.356)	-0.12 (± 0.350)		
DB: Week 48 (n=87,91,88,86,45,44)	-0.07 (± 0.354)	-0.22 (± 0.854)		
F-U: Week 60 (n=87,85,84,83,46,1)	-0.12 (± 0.367)	-0.21 (± 0.747)		
F-U: Week 72 (n=85,83,82,84,46,45)	-0.15 (± 0.366)	-0.26 (± 1.032)		
F-U: Week 96 (n=89,82,85,82,44,45)	-0.14 (± 0.360)	-0.25 (± 1.031)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HBeAg Levels

End point title	Change From Baseline in HBeAg Levels

End point description:

Change from baseline in HBeAg levels was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints. log10 IU/mL: Log10 international units per millilitre

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	25	30
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=27,30,25,30,15,13)	1.22 (± 1.494)	1.60 (± 1.449)	1.68 (± 1.540)	1.26 (± 1.318)
DB: Week 12 (n=27,27,23,29,13,10)	-0.82 (± 0.746)	-0.90 (± 0.629)	-0.95 (± 0.502)	-0.44 (± 0.273)
DB: Week 24 (n=27,29,25,30,,13,13)	-1.00 (± 0.880)	-1.17 (± 0.832)	-1.12 (± 0.636)	-0.54 (± 0.372)
DB: Week 48 (n=26,28,24,27,14,13)	-1.43 (± 1.194)	-1.50 (± 1.142)	-1.53 (± 0.999)	-0.78 (± 0.550)
F-U: Week 60 (n=25,27,24,27,15,12	-1.40 (± 1.253)	-1.61 (± 1.168)	-1.32 (± 0.763)	-0.83 (± 0.600)
F-U: Week 72 (n=25,27,23,28,15,13)	-1.50 (± 1.276)	-1.67 (± 1.303)	-1.44 (± 1.000)	-0.80 (± 0.687)
F-U: Week 96 (n=26,27,24,26,14,13)	-1.55 (± 1.334)	-1.58 (± 1.325)	-1.43 (± 1.092)	-0.84 (± 0.710)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=27,30,25,30,15,13)	0.81 (± 1.261)	1.03 (± 1.435)		
DB: Week 12 (n=27,27,23,29,13,10)	-0.60 (± 0.652)	-0.32 (± 0.425)		
DB: Week 24 (n=27,29,25,30,,13,13)	-0.77 (± 0.817)	-0.59 (± 0.782)		
DB: Week 48 (n=26,28,24,27,14,13)	-0.84 (± 0.876)	-0.96 (± 1.325)		
F-U: Week 60 (n=25,27,24,27,15,12	-0.87 (± 0.874)	-1.03 (± 1.384)		
F-U: Week 72 (n=25,27,23,28,15,13)	-0.95 (± 0.891)	-0.97 (± 1.361)		
F-U: Week 96 (n=26,27,24,26,14,13)	-1.21 (± 1.104)	-1.07 (± 1.357)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HBV DNA Levels

End point title	Change from Baseline in HBV DNA Levels

End point description:

Change from baseline in HBV DNA levels were reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified category.

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	35	33	33
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=33,35,33,33,18,16)	5.97 (± 1.989)	6.64 (± 1.972)	6.34 (± 1.778)	6.10 (± 1.916)
DB: Week 12 (n=32,34,33,31,16,16)	-4.13 (± 1.267)	-3.90 (± 1.221)	-3.83 (± 1.079)	-3.72 (± 1.008)
DB: Week 24 (n=32,33,32,31,16,16)	-4.59 (± 1.532)	-5.03 (± 1.441)	-4.68 (± 1.199)	-4.53 (± 1.273)
DB: Week 48 (n=30,32,32,30,15,16)	-4.85 (± 1.896)	-5.28 (± 1.663)	-5.18 (± 1.669)	-4.86 (± 1.605)
F-U: Week 60 (n=31,32,28,31,17,16)	-4.85 (± 1.910)	-5.39 (± 1.673)	-5.27 (± 1.759)	-4.95 (± 1.602)
F-U: Week 72 (n=30,31,29,31,17,16)	-4.97 (± 1.912)	-5.40 (± 1.849)	-5.25 (± 1.727)	-5.04 (± 1.606)
F-U: Week 96 (n=31,30,29,28,17,16)	-4.96 (± 2.010)	-5.45 (± 1.948)	-5.18 (± 2.004)	-5.06 (± 1.693)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: log10 IU/mL				
arithmetic mean (standard deviation)				
DB: Baseline (n=33,35,33,33,18,16)	6.48 (± 2.008)	6.39 (± 1.922)		
DB: Week 12 (n=32,34,33,31,16,16)	-4.28 (± 1.052)	-3.64 (± 1.365)		
DB: Week 24 (n=32,33,32,31,16,16)	-5.08 (± 1.566)	-4.34 (± 1.457)		
DB: Week 48 (n=30,32,32,30,15,16)	-5.71 (± 1.578)	-4.68 (± 1.970)		
F-U: Week 60 (n=31,32,28,31,17,16)	-5.40 (± 1.808)	-4.67 (± 2.028)		
F-U: Week 72 (n=30,31,29,31,17,16)	-5.49 (± 1.845)	-4.81 (± 1.903)		

F-U: Week 96 (n=31,30,29,28,17,16)	-5.63 (± 1.827)	-4.95 (± 1.963)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve HBsAg Seroclearance

End point title	Time to Achieve HBsAg Seroclearance

End point description:

Time to HBsAg seroclearance (defined as HBsAg level <LLOQ) was defined as the number of days between the date of first study treatment intake and the date of the first occurrence of HBsAg seroclearance. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, '99999' indicated that data was not evaluable due to less number of events.

End point type	Secondary

End point timeframe:

Up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Hours				
median (confidence interval 90%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Hours				
median (confidence interval 90%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve HBeAg Seroclearance

End point title	Time to Achieve HBeAg Seroclearance

End point description:

Time to HBeAg seroclearance (defined as HBeAg level <LLOQ) was defined as the number of days between the date of first study treatment intake and the date of the first occurrence of HBeAg seroclearance. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, '99999' indicated that data was not evaluable due to less number of events. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	25	30
Units: Hour				
median (confidence interval 90%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: Hour				
median (confidence interval 90%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Value <100 IU/mL

End point title	Percentage of Subjects with HBsAg Value <100 IU/mL

End point description:

Percentage of subjects with HBsAg value <100 IU/mL was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'n'

(number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (not applicable)				
DB: Baseline (n=94,94,92,92,48,45)	0	1.1	1.1	0
DB: Week 12 (n=92,92,86,88,45,45)	19.6	33.7	30.2	15.9
DB: Week 24 (n=91,92,88,88,45,44)	42.9	65.2	59.1	25.0
DB: Week 48 (n=87,91,88,86,45,44)	57.5	74.7	69.3	36.0
F-U: Week 60 (n=87,85,84,83,46,45)	54.0	61.2	56.0	22.9
F-U: Week 72 (n=85,83,82,84,46,45)	43.5	47.0	37.8	14.3
F-U: Week 96 (n=89,82,85,82,44,45)	21.3	35.4	28.2	9.8

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (not applicable)				
DB: Baseline (n=94,94,92,92,48,45)	0	0		
DB: Week 12 (n=92,92,86,88,45,45)	0	0		
DB: Week 24 (n=91,92,88,88,45,44)	0	0		
DB: Week 48 (n=87,91,88,86,45,44)	0	2.3		
F-U: Week 60 (n=87,85,84,83,46,45)	0	2.2		
F-U: Week 72 (n=85,83,82,84,46,45)	0	2.2		
F-U: Week 96 (n=89,82,85,82,44,45)	0	2.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Value >1 log10 IU/mL Reduction from Baseline

End point title	Percentage of Subjects with HBsAg Value >1 log10 IU/mL Reduction from Baseline

End point description:

Percentage of subjects with HBsAg value >1 log10 IU/mL reduction from baseline was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	92	88	88
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=92,92,86,88,45,45)	40.2	72.8	60.5	27.3
DB: Week 24 (n=91,92,88,88,45,44)	84.6	97.8	93.2	71.6
DB: Week 48 (n=87,91,88,86,45,44)	93.1	97.8	97.7	82.6
F-U: Week 60 (n=87,85,84,83,46,45)	86.2	94.1	90.5	67.5
F-U: Week 72 (n=85,83,82,84,46,45)	71.8	84.4	73.2	46.6
F-U: Week 96 (n=89,82,85,82,44,45)	41.6	63.4	49.4	20.7

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	45		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=92,92,86,88,45,45)	2.2	0		
DB: Week 24 (n=91,92,88,88,45,44)	4.4	4.5		
DB: Week 48 (n=87,91,88,86,45,44)	4.4	4.5		
F-U: Week 60 (n=87,85,84,83,46,45)	4.3	4.4		
F-U: Week 72 (n=85,83,82,84,46,45)	4.3	6.7		
F-U: Week 96 (n=89,82,85,82,44,45)	4.5	4.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of HBeAg-positive Subjects with HBeAg Levels <LLOQ

End point title	Percentage of HBeAg-positive Subjects with HBeAg Levels <LLOQ

End point description:

Percentage of HBeAg-positive subjects with HBeAg levels <LLOQ was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	29	25	30
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=27,27,23,29,13,10)	7.4	3.7	17.4	6.9
DB: Week 24 (n=27,29,25,30,13,13)	7.4	3.4	16.0	6.7
DB: Week 48 (n=26,28,24,27,14,13)	19.2	7.1	20.8	11.1
F-U: Week 60 (n=25,27,24,27,15,12)	12.0	11.1	16.7	7.4
F-U: Week 72 (n=25,27,23,28,15,13)	8.0	11.1	21.7	10.7
F-U: Week 96 (n=26,27,24,26,14,13)	15.4	14.8	20.8	11.5

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=27,27,23,29,13,10)	7.7	0		
DB: Week 24 (n=27,29,25,30,13,13)	7.7	0		
DB: Week 48 (n=26,28,24,27,14,13)	7.1	15.4		
F-U: Week 60 (n=25,27,24,27,15,12)	6.7	16.7		
F-U: Week 72 (n=25,27,23,28,15,13)	6.7	15.4		
F-U: Week 96 (n=26,27,24,26,14,13)	21.4	15.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of HBeAg-positive Subjects with HBeAg Levels >1 log10 IU/mL

End point title	Percentage of HBeAg-positive Subjects with HBeAg Levels >1 log10 IU/mL

End point description:

Percentage of HBeAg-positive subjects with HBeAg levels >1 log10 IU/mL was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	29	25	30
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=27,27,23,29,13,10)	33.3	33.3	39.1	3.4
DB: Week 24 (n=27,29,25,30,13,13)	44.4	48.3	60.0	10.0
DB: Week 48 (n=26,28,24,27,14,13)	50.0	53.6	66.7	25.9
F-U: Week 60 (n=25,27,24,27,15,12)	52.0	63.3	62.5	37.0
F-U: Week 72 (n=25,27,23,28,15,13)	56.0	59.3	65.2	35.7
F-U: Week 96 (n=26,27,24,26,14,13)	53.8	59.3	58.3	42.3

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=27,27,23,29,13,10)	23.1	10.0		
DB: Week 24 (n=27,29,25,30,13,13)	30.8	23.1		
DB: Week 48 (n=26,28,24,27,14,13)	35.7	30.8		
F-U: Week 60 (n=25,27,24,27,15,12)	40.0	33.3		
F-U: Week 72 (n=25,27,23,28,15,13)	40.0	30.8		
F-U: Week 96 (n=26,27,24,26,14,13)	42.9	30.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBV DNA Levels <LLOQ

End point title	Percentage of Subjects with HBV DNA Levels <LLOQ

End point description:

Percentage of subjects with HBV DNA levels <LLOQ was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analyzed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	92	88	88
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=92,92,86,88,45,45)	78.3	71.7	76.7	70.5
DB: Week 24 (n=91,92,88,88,45,44)	84.6	80.4	81.8	83.0
DB: Week 48 (n=88,91,88,87,45,45)	92.0	85.7	86.4	90.8
F-U: Week 60 (n=88,85,83,85,46,45)	88.6	85.9	79.5	85.9
F-U: Week 72 (n=86,85,83,84,46,45)	89.5	81.2	81.9	86.9
F-U: Week 96 (n=89,82,85,80,44,45)	94.4	75.6	80.0	87.5

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	45		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 (n=92,92,86,88,45,45)	73.3	75.6		
DB: Week 24 (n=91,92,88,88,45,44)	80.0	77.3		

DB: Week 48 (n=88,91,88,87,45,45)	95.6	93.3		
F-U: Week 60 (n=88,85,83,85,46,45)	93.5	93.3		
F-U: Week 72 (n=86,85,83,84,46,45)	95.7	91.1		
F-U: Week 96 (n=89,82,85,80,44,45)	95.5	93.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Decrease from Baseline in ALT at EOT (Week 48) in Subjects With Elevated ALT at Baseline

End point title	Mean Decrease from Baseline in ALT at EOT (Week 48) in Subjects With Elevated ALT at Baseline

End point description:

Mean decrease from baseline in ALT at EOT (Week 48) in subjects With elevated ALT at baseline was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 48

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	32	37	34
Units: Units per liter (U/L)				
arithmetic mean (standard deviation)	-72.77 (± 106.851)	-65.47 (± 110.213)	-37.51 (± 63.468)	-42.53 (± 41.767)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Units per liter (U/L)				
arithmetic mean (standard deviation)	-17.68 (± 272.44)	-49.28 (± 85.374)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with ALT Normalization

End point title	Percentage of Subjects with ALT Normalization

End point description:

Percentage of subjects with ALT normalization was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment. Here, 'N' (number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

DB: Baseline, Weeks 12, 24, 48; F-U: Weeks 60, 72, 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	32	37	34
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 On-treatment (n=35,31,36,31,16,17)	54.3	41.9	58.3	64.5
DB: Week 24 On-treatment (n=34,30,36,33,17,18)	61.8	43.3	69.4	78.8
DB: Week 48 On-treatment (n=33,30,35,31,16,17)	60.6	46.7	65.7	83.9
F-U: Week 60 On-treatment (n=33,28,33,33,18,18)	0	3.6	12.1	0
F-U: Week 72 On-treatment (n=32,28,33,33,18,18)	0	3.6	12.1	0
F-U: Week 96 On-treatment (n=33,26,34,30,18,18)	21.2	11.5	35.3	10.0
F-U: Week 60 Off-treatment (n=33,28,33,33,18,18)	0	3.6	12.1	0
F-U: Week 72 Off-treatment (n=32,28,33,33,18,18)	0	3.6	12.1	0
F-U: Week 96 Off-treatment (n=33,26,34,30,18,18)	21.2	11.5	35.3	10.0

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Percentage of subjects				
number (not applicable)				
DB: Week 12 On-treatment (n=35,31,36,31,16,17)	56.3	47.1		

DB: Week 24 On-treatment (n=34,30,36,33,17,18)	76.5	55.6		
DB: Week 48 On-treatment (n=33,30,35,31,16,17)	87.5	58.8		
F-U: Week 60 On-treatment (n=33,28,33,33,18,18)	0	5.6		
F-U: Week 72 On-treatment (n=32,28,33,33,18,18)	0	5.6		
F-U: Week 96 On-treatment (n=33,26,34,30,18,18)	16.7	11.1		
F-U: Week 60 Off-treatment (n=33,28,33,33,18,18)	0	5.6		
F-U: Week 72 Off-treatment (n=32,28,33,33,18,18)	0	5.6		
F-U: Week 96 Off-treatment (n=33,26,34,30,18,18)	16.7	11.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Virologic Breakthrough

End point title	Percentage of Subjects with Virologic Breakthrough

End point description:

Virologic breakthrough was defined as having a confirmed on-treatment HBV DNA increase by >1 log10 from nadir (that is, lowest value during treatment) or a confirmed HBV DNA level >200 IU/mL in subjects who had on-treatment HBV DNA level below the LLOQ. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)	2.1 (0.38 to 6.55)	2.1 (0.38 to 6.55)	2.2 (0.39 to 6.69)	2.2 (0.39 to 6.76)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	2.2 (0.11 to 10.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Undetectable HBV DNA Levels After Re-start of NA Treatment During Follow-up

End point title	Percentage of Subjects with Undetectable HBV DNA Levels After Re-start of NA Treatment During Follow-up

End point description:

Percentage of subjects with undetectable HBV DNA levels after re-start of NA treatment during follow-up was reported. mITT analysis set included all subjects who were randomised in the study and received at least one dose of study treatment excluding those subjects impacted by the pandemic defined as those subjects who, because of COVID-19 or similar pandemics related reasons, withdrew prematurely from the study prior to Week 44.

End point type	Secondary

End point timeframe:

Week 48 up to Week 96

End point values	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 (250 mg) + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	94	92	91
Units: Percentage of subjects				
number (confidence interval 90%)	1.1 (0.05 to 4.95)	1.1 (0.05 to 4.95)	1.1 (0.06 to 5.05)	0.0 (0.00 to 3.24)

End point values	Arm 5: Placebo + JNJ-56136379 + NA	Arm 6: Placebo + Placebo + NA		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	45		
Units: Percentage of subjects				
number (confidence interval 90%)	0.0 (0.00 to 6.05)	0.0 (0.00 to 6.44)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 150 weeks

Adverse event reporting additional description:

Safety analysis set included all subjects who received at least one dose of any of the study treatments.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Arm 6: Placebo + Placebo + NA

Reporting group description:

Subjects received placebo matching to JNJ-73763989 as SC injection and placebo matching to JNJ-56136379 tablet orally along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally up to 48 weeks.

Reporting group title	Arm 5: Placebo + JNJ-56136379 + NA

Reporting group description:

Subjects received placebo matching to JNJ-73763989 as SC injection and a fixed dose of JNJ-56136379 250 mg tablet orally along with NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally up to 48 weeks.

Reporting group title	Arm 2: JNJ-73763989 (200mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 200 mg as SC injection along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally up to 48 weeks.

Reporting group title	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 100 mg as SC injection along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablets orally up to 48 weeks.

Reporting group title	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 + NA

Reporting group description:

Subjects received JNJ-73763989 100 mg as subcutaneous (SC) injection along JNJ-56136379 250 milligrams (mg) orally and Nucleos(t)ide Analog (NA) (either Entecavir [ETV] monohydrate 0.5 mg, Tenofovir disoproxil fumarate [TDF] 300 mg, or Tenofovir alafenamide [TAF] 25 mg) tablet orally up to 48 weeks.

Reporting group title	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA

Reporting group description:

Subjects received JNJ-73763989 40 mg as SC injection along with placebo matching to JNJ-56136379 tablet orally and NA (either ETV 0.5 mg, TDF 300 mg, or TAF 25 mg) tablet orally up to 48 weeks.

Serious adverse events	Arm 6: Placebo + Placebo + NA	Arm 5: Placebo + JNJ-56136379 + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 45 (0.00%)	3 / 48 (6.25%)	8 / 96 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			

Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular Carcinoma			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fracture Displacement			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			

subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary Artery Disease			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Myoclonus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal Detachment			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Melaena			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Polyps			

subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Gallbladder Cholesterolosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal Colic			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cystitis			

subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 Pneumonia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 93 (7.53%)	5 / 95 (5.26%)	2 / 93 (2.15%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Aspartate Aminotransferase Increased			

subjects affected / exposed	0 / 93 (0.00%)	1 / 95 (1.05%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 93 (0.00%)	1 / 95 (1.05%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma			
subjects affected / exposed	0 / 93 (0.00%)	2 / 95 (2.11%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular Carcinoma			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fracture Displacement			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	1 / 93 (1.08%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ligament Rupture			
subjects affected / exposed	2 / 93 (2.15%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary Artery Disease			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Myoclonus			
subjects affected / exposed	1 / 93 (1.08%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal Detachment			
subjects affected / exposed	1 / 93 (1.08%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Melaena			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Polyps			
subjects affected / exposed	1 / 93 (1.08%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Gallbladder Cholesterolosis			

subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal Colic			
subjects affected / exposed	0 / 93 (0.00%)	1 / 95 (1.05%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 93 (0.00%)	1 / 95 (1.05%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19 Pneumonia			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Covid-19			
subjects affected / exposed	0 / 93 (0.00%)	1 / 95 (1.05%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 93 (1.08%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Arm 6: Placebo + Placebo + NA	Arm 5: Placebo + JNJ-56136379 + NA	Arm 2: JNJ-73763989 (200mg) + Placebo + NA
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 45 (55.56%)	36 / 48 (75.00%)	60 / 96 (62.50%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 45 (2.22%)	3 / 48 (6.25%)	4 / 96 (4.17%)
occurrences (all)	1	5	6
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 45 (2.22%)	3 / 48 (6.25%)	2 / 96 (2.08%)
occurrences (all)	1	6	2
Glomerular Filtration Rate Decreased			
subjects affected / exposed	1 / 45 (2.22%)	3 / 48 (6.25%)	2 / 96 (2.08%)
occurrences (all)	1	5	2
Vascular disorders			

Hypertension			
subjects affected / exposed	2 / 45 (4.44%)	1 / 48 (2.08%)	4 / 96 (4.17%)
occurrences (all)	2	1	4
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 45 (15.56%)	5 / 48 (10.42%)	16 / 96 (16.67%)
occurrences (all)	9	7	27
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 45 (6.67%)	2 / 48 (4.17%)	3 / 96 (3.13%)
occurrences (all)	4	3	3
Neutropenia			
subjects affected / exposed	0 / 45 (0.00%)	3 / 48 (6.25%)	1 / 96 (1.04%)
occurrences (all)	0	3	1
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	0 / 45 (0.00%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 45 (4.44%)	5 / 48 (10.42%)	7 / 96 (7.29%)
occurrences (all)	3	8	7
Fatigue			
subjects affected / exposed	3 / 45 (6.67%)	6 / 48 (12.50%)	3 / 96 (3.13%)
occurrences (all)	3	8	3
Asthenia			
subjects affected / exposed	4 / 45 (8.89%)	4 / 48 (8.33%)	6 / 96 (6.25%)
occurrences (all)	5	4	10
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	2 / 45 (4.44%)	3 / 48 (6.25%)	5 / 96 (5.21%)
occurrences (all)	3	3	5
Abdominal Pain			
subjects affected / exposed	2 / 45 (4.44%)	1 / 48 (2.08%)	0 / 96 (0.00%)
occurrences (all)	2	1	0
Nausea			

subjects affected / exposed	1 / 45 (2.22%)	6 / 48 (12.50%)	7 / 96 (7.29%)
occurrences (all)	1	6	9
Diarrhoea			
subjects affected / exposed	2 / 45 (4.44%)	3 / 48 (6.25%)	4 / 96 (4.17%)
occurrences (all)	2	5	4
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 48 (0.00%)	2 / 96 (2.08%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 45 (6.67%)	2 / 48 (4.17%)	7 / 96 (7.29%)
occurrences (all)	3	2	7
Oropharyngeal Pain			
subjects affected / exposed	1 / 45 (2.22%)	4 / 48 (8.33%)	2 / 96 (2.08%)
occurrences (all)	1	5	2
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 45 (0.00%)	3 / 48 (6.25%)	2 / 96 (2.08%)
occurrences (all)	0	3	2
Alopecia			
subjects affected / exposed	1 / 45 (2.22%)	2 / 48 (4.17%)	0 / 96 (0.00%)
occurrences (all)	1	4	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 45 (2.22%)	3 / 48 (6.25%)	4 / 96 (4.17%)
occurrences (all)	1	3	4
Back Pain			
subjects affected / exposed	1 / 45 (2.22%)	4 / 48 (8.33%)	6 / 96 (6.25%)
occurrences (all)	3	5	9
Myalgia			
subjects affected / exposed	3 / 45 (6.67%)	4 / 48 (8.33%)	6 / 96 (6.25%)
occurrences (all)	3	5	7
Infections and infestations			
Covid-19			

subjects affected / exposed	6 / 45 (13.33%)	6 / 48 (12.50%)	12 / 96 (12.50%)
occurrences (all)	6	6	12
Nasopharyngitis			
subjects affected / exposed	1 / 45 (2.22%)	4 / 48 (8.33%)	6 / 96 (6.25%)
occurrences (all)	1	6	6
Rhinitis			
subjects affected / exposed	0 / 45 (0.00%)	3 / 48 (6.25%)	1 / 96 (1.04%)
occurrences (all)	0	3	1
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 45 (2.22%)	3 / 48 (6.25%)	4 / 96 (4.17%)
occurrences (all)	1	3	4

Non-serious adverse events	Arm 3: JNJ-73763989 (100 mg) + Placebo + NA	Arm 1: JNJ-73763989 (100 mg) + JNJ-56136379 + NA	Arm 4: JNJ-73763989 (40 mg) + Placebo + NA
Total subjects affected by non-serious adverse events			
subjects affected / exposed	63 / 93 (67.74%)	62 / 95 (65.26%)	50 / 93 (53.76%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 93 (1.08%)	6 / 95 (6.32%)	1 / 93 (1.08%)
occurrences (all)	1	9	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 93 (0.00%)	3 / 95 (3.16%)	2 / 93 (2.15%)
occurrences (all)	0	3	3
Glomerular Filtration Rate Decreased			
subjects affected / exposed	5 / 93 (5.38%)	11 / 95 (11.58%)	5 / 93 (5.38%)
occurrences (all)	6	16	6
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 93 (1.08%)	5 / 95 (5.26%)	1 / 93 (1.08%)
occurrences (all)	1	6	1
Nervous system disorders			
Headache			
subjects affected / exposed	19 / 93 (20.43%)	13 / 95 (13.68%)	14 / 93 (15.05%)
occurrences (all)	29	20	22
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 93 (3.23%)	3 / 95 (3.16%)	3 / 93 (3.23%)
occurrences (all)	5	4	3
Neutropenia			
subjects affected / exposed	0 / 93 (0.00%)	0 / 95 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	7 / 93 (7.53%)	2 / 95 (2.11%)	2 / 93 (2.15%)
occurrences (all)	38	6	11
Pyrexia			
subjects affected / exposed	4 / 93 (4.30%)	4 / 95 (4.21%)	4 / 93 (4.30%)
occurrences (all)	4	5	4
Fatigue			
subjects affected / exposed	5 / 93 (5.38%)	8 / 95 (8.42%)	7 / 93 (7.53%)
occurrences (all)	5	9	8
Asthenia			
subjects affected / exposed	5 / 93 (5.38%)	3 / 95 (3.16%)	3 / 93 (3.23%)
occurrences (all)	9	3	3
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	2 / 93 (2.15%)	3 / 95 (3.16%)	3 / 93 (3.23%)
occurrences (all)	4	3	4
Abdominal Pain			
subjects affected / exposed	5 / 93 (5.38%)	2 / 95 (2.11%)	5 / 93 (5.38%)
occurrences (all)	5	2	5
Nausea			
subjects affected / exposed	6 / 93 (6.45%)	4 / 95 (4.21%)	6 / 93 (6.45%)
occurrences (all)	6	7	7
Diarrhoea			
subjects affected / exposed	11 / 93 (11.83%)	5 / 95 (5.26%)	7 / 93 (7.53%)
occurrences (all)	11	5	8
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	5 / 93 (5.38%)	1 / 95 (1.05%)	3 / 93 (3.23%)
occurrences (all)	8	1	3

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 93 (3.23%)	6 / 95 (6.32%)	3 / 93 (3.23%)
occurrences (all)	4	7	4
Oropharyngeal Pain			
subjects affected / exposed	4 / 93 (4.30%)	3 / 95 (3.16%)	1 / 93 (1.08%)
occurrences (all)	4	3	2
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	3 / 93 (3.23%)	5 / 95 (5.26%)	0 / 93 (0.00%)
occurrences (all)	3	6	0
Alopecia			
subjects affected / exposed	0 / 93 (0.00%)	5 / 95 (5.26%)	0 / 93 (0.00%)
occurrences (all)	0	5	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 93 (6.45%)	6 / 95 (6.32%)	7 / 93 (7.53%)
occurrences (all)	6	6	7
Back Pain			
subjects affected / exposed	9 / 93 (9.68%)	7 / 95 (7.37%)	8 / 93 (8.60%)
occurrences (all)	11	7	13
Myalgia			
subjects affected / exposed	8 / 93 (8.60%)	6 / 95 (6.32%)	4 / 93 (4.30%)
occurrences (all)	8	9	4
Infections and infestations			
Covid-19			
subjects affected / exposed	11 / 93 (11.83%)	8 / 95 (8.42%)	11 / 93 (11.83%)
occurrences (all)	11	9	11
Nasopharyngitis			
subjects affected / exposed	12 / 93 (12.90%)	9 / 95 (9.47%)	8 / 93 (8.60%)
occurrences (all)	12	10	10
Rhinitis			
subjects affected / exposed	1 / 93 (1.08%)	1 / 95 (1.05%)	2 / 93 (2.15%)
occurrences (all)	1	2	2
Upper Respiratory Tract Infection			

subjects affected / exposed occurrences (all)	5 / 93 (5.38%) 8	2 / 95 (2.11%) 2	3 / 93 (3.23%) 3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2019	The main purpose of this amendment-1 was to add liver ultrasound with increased risk for hepatocellular carcinoma (HCC), a timeframe of 30 days prior to screening was added for the use of contraception by female subjects of childbearing potential, exclusion criteria as well as the description of the unblinding procedure were updated, breast cancer resistance protein (BCRP) inhibitors were added as disallowed concomitant medications, and description on control of the Type 1 error rate for multiple testing was updated.
27 January 2020	The main purpose of this amendment-2 was to include the following main changes: based on a nonclinical finding from the preliminary results of the 3-month combination toxicity study with JNJ-56136379 and JNJ-73763989 in the rat, hematologic abnormalities were included as an event of special interest, to trigger a mandatory higher visit frequency with unscheduled visits in case of significant on-treatment reduction in hematologic parameters, and treatment discontinuation criteria were included in relation to hematological abnormalities as precautionary measure.
30 September 2021	The main purpose of this amendment-3 was to include the following main changes: after a severe alanine aminotransferase (ALT) flare in a virologically suppressed hepatitis B e antigen (HBeAg)-negative subject randomised to the control arm in the REEF-2 (73763989PAHPB2002) study, a new nucleos(t)ide analog (NA) re-treatment criterion was added for subjects who discontinued NA treatment at Week 48 or during the follow-up phase; in addition, more frequent monitoring for participants who discontinued NA treatment was included.
24 November 2021	The main purpose of this amendment-4 was to include the additional changes to the criteria for posttreatment monitoring and for NA re-treatment for subjects discontinued NA treatment, to further protect the safety of study subjects.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported