Clinical trial results:
A Phase 2, Open-label, Multicenter Study to Assess Efficacy, Safety, Tolerability, and Pharmacokinetics of Treatment With JNJ-73763989, Nucleos(t)ide Analogs, and Pegylated Interferon Alpha-2a in Patients With Chronic Hepatitis B Virus Infection

Summary

EudraCT number	2021-002450-81
Trial protocol	ES PL
Global end of trial date	29 December 2021

Results information

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

Trial information

Trial identification

Sponsor protocol code	73763989PAHPB2007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05005507
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 US Highway 202, Raritan, NJ, United States, 08869-1420
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	29 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy in terms of hepatitis B surface antigen (HBsAg) changes from baseline for the treatment regimens of 24 weeks of JNJ-73763989 (JNJ-3989) + 24 weeks of nucleos(t)ide analog (NA) + 12 or 24 weeks of pegylated interferon alpha-2a (PegIFN-alpha-2a) (with immediate or delayed start of PegIFN-alpha-2a treatment), as compared to NA standard of care treatment.

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	03 November 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Only 1 subject was enrolled in the study in Arm 1: JNJ-73763989 + nucleos(t)ide analog (NA) + pegylated interferon alpha-2a (PegIFN-alpha-2a). Subjects were also planned to be enrolled in Arms 2 and 3 but were not enrolled as the study discontinued prematurely based on a strategic decision and not for safety reasons. None completed the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a

Arm description:

Subject received JNJ-73763989 200 milligrams (mg) subcutaneous (SC) injection on Day 1 plus NA treatment (entecavir [ETV] 0.5 mg tablet) orally once daily from Day 1 to Day 16 plus pegylated interferon alpha-2a (PegIFN-alpha-2a) 180 micrograms (mcg) SC injection on Days 1, 8, and 15.

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

Dosage and administration details:

JNJ-73763989 200 mg injection was administered subcutaneously on Day 1.

Investigational medicinal product name	PegIFN-alpha-2a
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PegIFN-alpha-2a 180 mcg injection was administered subcutaneously on Days 1, 8, and 15.

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

Dosage and administration details:

NA treatment entecavir (ETV) 0.5 mg tablet was administered orally once daily from Day 1 to Day 16.

Number of subjects in period 1	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-
Started	1
Completed	0
Not completed	1
Premature discontinuation of study	1

Baseline characteristics

Reporting groups	
Reporting group title	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a

Reporting group description:

Subject received JNJ-73763989 200 milligrams (mg) subcutaneous (SC) injection on Day 1 plus NA treatment (entecavir [ETV] 0.5 mg tablet) orally once daily from Day 1 to Day 16 plus pegylated interferon alpha-2a (PegIFN-alpha-2a) 180 micrograms (mcg) SC injection on Days 1, 8, and 15.

Reporting group values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-	Total	
Number of subjects	1	1	
Age Categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	1	1	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	46		
standard deviation	± 0	-	
Gender Categorical Units: Subjects			
Female	0	0	
Male	1	1	

End points

End points reporting groups

Reporting group title	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a

Reporting group description:

Subject received JNJ-73763989 200 milligrams (mg) subcutaneous (SC) injection on Day 1 plus NA treatment (entecavir [ETV] 0.5 mg tablet) orally once daily from Day 1 to Day 16 plus pegylated interferon alpha-2a (PegIFN-alpha-2a) 180 micrograms (mcg) SC injection on Days 1, 8, and 15.

Primary: Percentage of Subjects with a Reduction of at least 2log10 International Units Per Millilitre (IU/mL) in Hepatitis B Surface Antigen (HBsAg) Levels from Baseline at Week 24 (End of Study Intervention [EOSI])

End point title	Percentage of Subjects with a Reduction of at least 2log10 International Units Per Millilitre (IU/mL) in Hepatitis B Surface Antigen (HBsAg) Levels from Baseline at Week 24 (End of Study Intervention [EOSI])[1]

End point description:

Percentage of subjects with a reduction of at least 2log10 IU/mL in HBsAg levels from baseline at Week 24 (EOSI) were reported. Full analysis set (FAS) included all subjects who were randomly assigned to an intervention arm in the intervention-specific appendix (ISA) and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Primary

End point timeframe:

Week 24

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[2] - This endpoint was not assessed due to premature termination of the study prior to Week 24.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Adverse Events (AEs)

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

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Safety analysis set included all subjects who received at least 1 dose of

study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

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

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

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. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	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 including hematology, blood biochemistry, blood coagulation, urinalysis, urine chemistry, renal biomarkers) were reported. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in 12-Lead Electrocardiograms (ECGs)

End point title	Percentage of Subjects with Abnormalities in 12-Lead Electrocardiograms (ECGs)

End point description:

Percentage of subjects with abnormalities in 12-Lead ECGs were reported. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	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 were reported. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in Ophthalmologic Examination

End point title	Percentage of Subjects with Abnormalities in Ophthalmologic Examination

End point description:

Percentage of subjects with abnormalities in ophthalmologic examination were reported. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Weeks 8 and 20

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[3]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[3] - This endpoint was not assessed due to premature termination of the study prior to Weeks 8 and 20.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormalities in Physical Examination

End point title	Percentage of Subjects with Abnormalities in Physical Examination

End point description:

Percentage of subjects with abnormalities in physical examination were reported. Safety analysis set included all subjects who received at least 1 dose of study intervention within the ISA. Subjects were analysed according to the study intervention they actually received.

End point type	Secondary

End point timeframe:

Week 24

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[4]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[4] - This endpoint was not assessed due to premature termination of the study prior to Week 24.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Meeting the Protocol- defined Nucleos(t)ide Analog (NA) Treatment Completion Criteria Based on the Week 24 (EOSI) or Follow-up (FU) Week 2 Results

End point title	Percentage of Subjects Meeting the Protocol- defined Nucleos(t)ide Analog (NA) Treatment Completion Criteria Based on the Week 24 (EOSI) or Follow-up (FU) Week 2 Results

End point description:

Percentage of subjects meeting the protocol- defined NA treatment completion criteria based on the Week 24 (EOSI) or FU Week 2 results were reported. NA treatment completion criteria were as follows: (a) subject had ALT <3*upper limits of normal (ULN); (b) subject had HBV DNA <20 IU/mL; (c) subject was HBeAg-negative; (d) subject had HBsAg <10 International units per milliliter (IU/mL). FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Week 24 (EOSI) and FU Week 2

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[5]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[5] - Endpoint was not assessed due to premature termination of study prior Week 24 (EOSI) and FU Week 2.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg Seroclearance at FU Weeks 24 and 48 without Re-starting NA Treatment

End point title	Percentage of Subjects with HBsAg Seroclearance at FU Weeks 24 and 48 without Re-starting NA Treatment

End point description:

Percentage of subjects with HBsAg seroclearance at FU Weeks 24 and 48 without re-starting NA treatment were reported. Seroclearance of HBsAg is defined as a (quantitative) HBsAg level <LLOQ. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Follow-up Weeks 24 and 48

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[6] - This endpoint was not assessed due to premature termination of study prior to FU Weeks 24 and 48.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Hepatitis B Virus (HBV) Deoxyribonucleic Acid (DNA) < (Less Than) Lower Limit of Quantification (LLOQ) at FU Weeks 24 and 48 Without Re-starting NA Treatment

End point title	Percentage of Subjects with Hepatitis B Virus (HBV) Deoxyribonucleic Acid (DNA) < (Less Than) Lower Limit of Quantification (LLOQ) at FU Weeks 24 and 48 Without Re-starting NA Treatment

End point description:

Percentage of subjects with HBV DNA <LLOQ at FU Weeks 24 and 48 without re-starting NA treatment were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

FU Weeks 24 and 48

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[7]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[7] - This endpoint was not assessed due to premature termination of study prior to FU Weeks 24 and 48.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Virologic Flares

End point title	Percentage of Subjects with Virologic Flares

End point description:

Percentage of subjects with virologic flares were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Biochemical Flares

End point title	Percentage of Subjects with Biochemical Flares

End point description:

Percentage of subjects with biochemical flares were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 1 month 26 days

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Requiring NA Re-treatment

End point title	Percentage of Subjects Requiring NA Re-treatment

End point description:

Percentage of subjects requiring NA re-treatment were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 72 weeks

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[8]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[8] - This endpoint was not assessed due to premature termination of the study prior to 72 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with HBsAg, Hepatitis B e Antigen (HBeAg), HBV DNA, and Alanine Aminotransferase (ALT) Levels Below/Above Different Cut-offs Over Time

End point title	Percentage of Subjects with HBsAg, Hepatitis B e Antigen (HBeAg), HBV DNA, and Alanine Aminotransferase (ALT) Levels Below/Above Different Cut-offs Over Time

End point description:

Percentage of subjects with HBsAg, HBeAg, HBV DNA, and ALT levels below/above different cut-offs over time were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 72 weeks

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[9] - This endpoint was not assessed due to premature termination of the study prior to 72 weeks.

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:

Percentage of subjects with HBsAg seroconversion were reported. Seroconversion of HBsAg is defined as having achieved HBsAg seroclearance and appearance of
anti-HBs antibodies. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analyzed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 72 weeks

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[10]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[10] - This endpoint was not performed due to premature termination of the study prior to 72 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HBsAg Over Time

End point title	Change from Baseline in HBsAg Over Time

End point description:

Change from baseline in HBsAg over time were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Baseline up to Week 72

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[11]			
Units: IU/mL				
arithmetic mean (standard deviation)	()			

Notes:

[11] - This endpoint was not assessed due to premature termination of the study prior to Week 72.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve HBV DNA <LLOQ

End point title	Time to Achieve HBV DNA <LLOQ

End point description:

Time to achieve HBV DNA <LLOQ were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 72 weeks

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[12]			
Units: hours				
median (full range (min-max))	(to)			

Notes:

[12] - This endpoint was not assessed due to premature termination of the study prior to 72 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve HBsAg Seroclearance/ Seroconversion

End point title	Time to Achieve HBsAg Seroclearance/ Seroconversion

End point description:

Time to achieve HBsAg seroclearance/ seroconversion were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to 72 weeks

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[13]			
Units: hours				
median (full range (min-max))	(to)			

Notes:

[13] - This endpoint was not performed due to premature termination of the study prior to 72 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of JNJ-73763989 (JNJ-73763924 and JNJ-73763976)

End point title	Serum Concentration of JNJ-73763989 (JNJ-73763924 and JNJ-73763976)

End point description:

Serum concentration of JNJ-73763989 (JNJ-73763924 and JNJ-73763976) were reported. Pharmacokinetics (PK) analysis set included all subjects who received at least 1 dose of study intervention and have at least 1 valid blood sample drawn for PK analysis.

End point type	Secondary

End point timeframe:

Days 1, 29, 85, 113, 169

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[14]			
Units: nanograms per millilitre (ng/mL)				
arithmetic mean (standard deviation)	()			

Notes:

[14] - This endpoint was not assessed due to premature termination of the study.

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:

Percentage of subjects with virologic breakthrough were reported. FAS included all subjects who were randomly assigned to an intervention arm in the ISA and received at least 1 dose of study intervention. Subjects were analysed according to the study intervention they were randomly assigned to.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Percentage of subjects				
number (not applicable)				

Notes:

[15] - This endpoint was not assessed due to premature termination of the study prior to Week 24.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of NA (Entecavir [ETV])

End point title	Serum Concentration of NA (Entecavir [ETV])

End point description:

Serum concentration of NA (ETV) were reported. PK analysis set included all subjects who received at least 1 dose of study intervention and have at least 1 valid blood sample drawn for PK analysis.

End point type	Secondary

End point timeframe:

Days 1, 29, 85, 113, 169

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[16]			
Units: ng/mL				
arithmetic mean (standard deviation)	()			

Notes:

[16] - This endpoint was not assessed due to premature termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of PegIFN-alpha-2a

End point title	Serum Concentration of PegIFN-alpha-2a

End point description:

Serum concentration of PegIFN-alpha-2a were reported. PK analysis set included all subjects who received at least 1 dose of study intervention and have at least 1 valid blood sample drawn for PK analysis.

End point type	Secondary

End point timeframe:

Days 1, 29, 85, 113, 169

End point values	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a			
Subject group type	Reporting group			
Number of subjects analysed	0[17]			
Units: ng/mL				
arithmetic mean (standard deviation)	()			

Notes:

[17] - This endpoint was not assessed due to premature termination of the study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Up to 1 month 26 days

Adverse event reporting additional description:

Safety analysis set included all subjects who received at least 1 dose of study intervention within this intervention-specific appendix (ISA). Subjects were analysed according to the study intervention they actually received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-2a

Reporting group description:

Subject received JNJ-73763989 200 milligrams (mg) subcutaneous (SC) injection on Day 1 plus NA treatment (entecavir [ETV] 0.5 mg tablet) orally once daily from Day 1 to Day 16 plus pegylated interferon alpha-2a (PegIFN-alpha-2a) 180 micrograms (mcg) SC injection on Days 1, 8, and 15.

Serious adverse events	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Arm 1: JNJ-73763989+nucleos(t)ide analog (NA)+PegIFN-alpha-		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Data could not be reported as only 1 subject was enrolled in the study who did not experience any non-serious adverse event.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 October 2021	The primary reasons for this amendment was to include pre-specified nucleos(t)ide analog (NA) treatment completion criteria, and to add a new NA re-treatment criterion and more frequent monitoring for subjects who met the NA treatment completion criteria based on the Week 24 (or Follow-up Week 2) results and discontinued NA treatment during follow-up.
01 December 2021	The primary reason for this amendment was to update the criteria for post-treatment monitoring and for nucleos(t)ide analog (NA) re-treatment for subjects who discontinued NA treatment at Follow-up Week 2.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported