Clinical trial results:
A Phase IIb Multi-Center, Randomised, Open Label Study to Assess the Efficacy and Safety of Sequential Treatment with GSK3228836 followed by Pegylated Interferon Alpha 2a in Participants with Chronic Hepatitis B Virus (B-Together)

Summary

EudraCT number	2020-002979-35
Trial protocol	GB PL IT
Global end of trial date	17 February 2023

Results information

Result version number	v1
This version publication date	06 March 2024
First version publication date	06 March 2024

Trial information

Trial identification

Sponsor protocol code	209348

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04676724
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 122685

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford,Middlesex, United Kingdom, TW8 9GS
Public contact	GlaxoSmithKline, GSK Response Center, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.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	06 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy: To investigate the efficacy of two different durations of GSK3228836 followed by up to 24 weeks of PegIFN therapy in participants with CHB on stable NA therapy.

Protection of trial subjects:

None

Background therapy:

Participants were to continue their stable nucleos(t)ide analogue (NA) therapy for the duration of the study.

Evidence for comparator: -

Actual start date of recruitment	28 January 2021
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	Canada: 2
Country: Number of subjects enrolled	China: 15
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Japan: 13
Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Russian Federation: 27
Country: Number of subjects enrolled	South Africa: 1
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 9
Worldwide total number of subjects	108
EEA total number of subjects	21

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	103
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who were on stable NA therapy randomized 1:1 to receive 300 mg/wk GSK3228836 for 24 wks+ PegIFN 180 mcg/wk 24 weeks, on-treatment until wk 48 and off-treatment from Week 48-72 in Arm1 & 300 mg/wk GSK3228836 for 12wks + PegIFN 180 mcg/wk for 24wks, on-treatment until wk 36 and off-treatment follow-up from Weeks 36 to 60 and 72 in arm2.

Pre-assignment

Screening details:

There were 108 participants enrolled in this 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

Are arms mutually exclusive?	Yes
Arm title	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)

Arm description:

Participants on stable NA therapy received 300mg/week GSK3228836 for 24 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 microgram per week (mcg/week) up to 24 weeks.

Arm type	Experimental
Investigational medicinal product name	GSK3228836 and PegINF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 24 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11.

Investigational medicinal product name	PegIFN
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

PegIFN180 180 mcg once a week up to 24 weeks.

Arm title	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)

Arm description:

Participants on stable NA therapy received 300mg/week GSK3228836 for 12 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 mcg/week up to 24 weeks.

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

Dosage and administration details:

PegIFN180 180 mcg once a week up to 24 weeks.

Investigational medicinal product name	GSK3228836 and PegINF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 12 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11.

Number of subjects in period 1	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)
Started	55	53
Completed	49	50
Not completed	6	3
Consent withdrawn by subject	3	2
Physician decision	-	1
Adverse event, non-fatal	2	-
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)
Reporting group description:	
Participants on stable NA therapy received 300mg/week GSK3228836 for 24 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 microgram per week (mcg/week) up to 24 weeks.	
Reporting group title	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)
Reporting group description:	
Participants on stable NA therapy received 300mg/week GSK3228836 for 12 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 mcg/week up to 24 weeks.	

Reporting group values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)	Total
Number of subjects	55	53	108
Age categorical Units: Subjects			
Adults (18-64 years)	50	53	103
From 65-84 years	5	0	5
Age continuous Units: years			
arithmetic mean	45.5	45.5	
standard deviation	± 10.73	± 9.35	-
Sex: Female, Male Units: Participants			
Female	11	20	31
Male	44	33	77
Race/Ethnicity, Customized Units: Subjects			
ASIAN	30	26	56
BLACK OR AFRICAN AMERICAN	3	3	6
WHITE	22	24	46
American Indian or Alaska Native	0	0	0
Mixed Race	0	0	0

End points

End points reporting groups

Reporting group title	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)
Reporting group description:	
Participants on stable NA therapy received 300mg/week GSK3228836 for 24 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 microgram per week (mcg/week) up to 24 weeks.	
Reporting group title	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)
Reporting group description:	
Participants on stable NA therapy received 300mg/week GSK3228836 for 12 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 mcg/week up to 24 weeks.	

Primary: Treatment Arm 1 - Percentage of participants achieving sustained virologic response (SVR) for 24 weeks after end of treatment

End point title	Treatment Arm 1 - Percentage of participants achieving sustained virologic response (SVR) for 24 weeks after end of treatment[1][2]
End point description:	
Sustained virologic response is defined as undetectable levels of Hepatitis B surface antigen (HBsAg) and Hepatitis-B virus deoxy-ribonucleic acid (HBV DNA) on treatment. The SVR was a composite endpoint defined as HBsAg and HBV DNA levels were less than (<) Lower limit of quantitation (LLOQ) at the planned end of sequential treatment of GSK3228836 and PegIFN treatment which is sustained for 24 weeks post-GSK3228836 and PegIFN treatment in the absence of any rescue medication. Intent to Treat (ITT) Set that included all randomized participants. Percentage values are rounded-off.	
End point type	Primary
End point timeframe:	
Up to 24 weeks off treatment (Study Weeks 48 to 72)	

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: This endpoint was descriptive, hence no statistical analysis to report.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	55[3]			
Units: Percentage of Participants	9			

Notes:

[3] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Primary: Treatment Arm 2 - Percentage of Participants Achieving Sustained Virologic Response (SVR) for 24 Weeks After End of Treatment

End point title	Treatment Arm 2 - Percentage of Participants Achieving Sustained Virologic Response (SVR) for 24 Weeks After End of Treatment[4][5]

End point description:

Sustained virologic response is defined as undetectable levels of Hepatitis B surface antigen (HBsAg) and Hepatitis-B virus deoxy-ribonucleic acid (HBV DNA) on treatment. The SVR was a composite endpoint defined as HBsAg and HBV DNA levels were less than (<) Lower limit of quantitation (LLOQ) at the planned end of sequential treatment of GSK3228836 and PegIFN treatment which is sustained for 24 weeks post-GSK3228836 and PegIFN treatment in the absence of any rescue medication. Intent to Treat (ITT) Set that included all randomized participants. Percentage values are rounded-off.

End point type	Primary

End point timeframe:

Up to 24 weeks off treatment (Study Weeks 36 to 60)

Notes:

[4] - 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: This endpoint was descriptive, hence no statistical analysis to report.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[6]			
Units: Percentage of Participants	15			

Notes:

[6] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Percentage of participants achieving HBsAg and HBV DNA < lower limit of quantitation (LLOQ)

End point title	Treatment Arm 1: Percentage of participants achieving HBsAg and HBV DNA < lower limit of quantitation (LLOQ)[7]

End point description:

Percentage of participants achieving HBsAg and HBV DNA <LLOQ were reported. Intent to Treat (ITT) Set that included all randomized participants. Percentage values are rounded-off.

End point type	Secondary

End point timeframe:

End of treatment (up to 48 weeks) and up to 24 weeks off treatment (OTT) follow-up (FUP) (Study Weeks 48 to 72)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[8]			
Units: Percentage of Participants				
End of treatment (up to 48 weeks) n=38	15			
Up to 24 weeks OTT FUP (Study Weeks 48 to 72) n=49	13			

Notes:

[8] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Percentage of Participants with Categorical Changes from Baseline in HBsAg Values

End point title	Treatment Arm 1: Percentage of Participants with Categorical Changes from Baseline in HBsAg Values[9]

End point description:

Participants who achieved a decline in HBsAg values from baseline were reported. Participants were categorized in the following categorical HBsAg decline of <0.5, greater than or equal to (>=) 0.5, >=1, >=1.5, and >=3 log10 international units per milliliter (IU/mL). The 'HBsAg < LLOQ' category is derived based on Absolute/raw HBsAg result. The HBsAg decline categories are based on change from baseline values. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field. Percentage values are rounded-off.

End point type	Secondary

End point timeframe:

Baseline, End of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[10]			
Units: Percentage of Participants				
HBsAg <LLOQ- EOT up to 48 weeks, n=36	18			
HBsAg<LLOQ- 24 Wk OTT (Wks 48 to 72) n=49	13			
HBsAg decline <0.5- EOT up to 48 weeks, n=36	24			
HBsAg decline <0.5- 24 Wk OTT (Wks 48 to 72) n=49	45			

HBsAg decline ≥0.5- EOT up to 48 weeks, n=36	42			
HBsAg decline ≥0.5-24 Wk OTT (Wks 48 to 72) n=49	44			
HBsAg decline ≥1- EOT up to 48 weeks, n=36	33			
HBsAg decline ≥1- 24 Wk OTT (Wks 48 to 72) n=49	36			
HBsAg decline ≥1.5- EOT up to 48 weeks, n=36	27			
HBsAg decline ≥1.5- 24 Wk OTT (Wks 48 to 72) n=49	36			
HBsAg decline ≥3, EOT up to 48 weeks, n=36	20			
HBsAg decline ≥3- 24 Wk OTT (Wks 48 to 72) n=49	27			

Notes:

[10] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Percentage of Participants Achieving HBsAg and HBV DNA < Lower Limit of Quantitation (LLOQ)

End point title	Treatment Arm 2: Percentage of Participants Achieving HBsAg and HBV DNA < Lower Limit of Quantitation (LLOQ)[11]

End point description:

Percentage of participants achieving HBsAg and HBV DNA <LLOQ were reported. Intent to Treat (ITT) Set that included all randomized participants. Percentage values are rounded-off.

End point type	Secondary

End point timeframe:

End of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60) and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	50[12]			
Units: Percentage of Participants				
End of treatment (up to 48 weeks) n=36	15			
Up to 24 weeks OTT FUP (Study Weeks 36 to 60) n=50	17			
Up to 36 weeks OTT FUP (Study Weeks 36 to 72) n=50	15			

Notes:

[12] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Percentage of Participants with Categorical Changes from Baseline in HBsAg Values

End point title	Treatment Arm 2: Percentage of Participants with Categorical Changes from Baseline in HBsAg Values[13]

End point description:

Participants who achieved a decline in HBsAg values from baseline were reported. Participants were categorized in the following categorical HBsAg decline of <0.5, greater than or equal to (>=) 0.5, >=1, >=1.5, and >=3 log10 international units per milliliter (IU/mL). The 'HBsAg < LLOQ' category is derived based on Absolute/raw HBsAg result. The HBsAg decline categories are based on change from baseline values. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

Baseline, End of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60) and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	50[14]			
Units: Percentage of Participants				
HBsAg <LLOQ- EOT up to 36 weeks, n=36	15			
HBsAg<LLOQ-24 Wk OTT (Wks 36 to 60) n=50	17			
HBsAg<LLOQ-36 Wk OTT (Wks 36 to 72) n=50	15			
HBsAg decline <0.5-EOT up to 36 weeks, n=36	26			
HBsAg decline <0.5- 24 Wk OTT (Wks 36 to 60) n=50	42			
HBsAg decline <0.5- 36 Wk OTT (Wks 36 to 72) n=50	43			
HBsAg decline ≥0.5-EOT up to 36 weeks, n=36	42			
HBsAg decline ≥0.5- 24 Wk OTT (Wks 36 to 60) n=50	51			
HBsAg decline ≥0.5- 36 Wk OTT (Wks 36 to 72) n=50	47			

HBsAg decline ≥1- EOT up to 36 weeks, n=36	34			
HBsAg decline ≥1-24 Wk OTT (Wks 36 to 60) n=50	34			
HBsAg decline ≥1- 36 Wk OTT (Wks 36 to 72) n=50	32			
HBsAg decline ≥1.5- EOT up to 36 weeks, n=36	28			
HBsAg decline ≥1.5- 24 Wk OTT (Wks 36 to 60) n=50	23			
HBsAg decline ≥1.5- 36 Wk OTT (Wks 36 to 72) n=50	19			
HBsAg decline ≥3 -EOT up to 36 weeks, n=36	15			
HBsAg decline ≥3- 24 Wk OTT (Wks 36 to 60) n=50	17			
HBsAg decline ≥3- 36 Wk OTT (Wks 36 to 72) n=50	17			

Notes:

[14] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Percentage of Participants with Alanine Aminotransferase (ALT) Normalization

End point title	Treatment Arm 1: Percentage of Participants with Alanine Aminotransferase (ALT) Normalization[15]

End point description:

The ALT normalization (ALT <=upper limit of normal [ULN]) over time in absence of rescue medication in participants with baseline ALT>ULN over time. Participants who achieved ALT normalization were reported. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks) and up to 24 weeks off treatment follow-up (study week 48 to week 72)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	55[16]			
Units: Percentage of Participants				
ALT>ULN, at Baseline n=55	7			
End of Treatment (up to 48 weeks) n=4	0			
Up to 24 weeks OTT FUP (Study Weeks 48 to 72) n=4	4			

Notes:
[16] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of HBe Antibody Levels

End point title	Treatment Arm 1: Absolute values of HBe Antibody Levels[17]

End point description:

Blood samples were collected to assess HBe antibody levels and results reported are for baseline HBeAg positive participants. The unit of measure is Log10 International Units Per Milliliter (IU/mL). Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	14[18]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline n=14	0.52 (± 1.117)			
End of Treatment (up to 48 weeks) n=9	-0.89 (± 0.509)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=13	-0.46 (± 0.793)			

Notes:
[18] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of HBe antibody levels

End point title	Treatment Arm 2: Absolute values of HBe antibody levels[19]

End point description:

Blood samples were collected to assess HBe antibody levels and results reported are for baseline HBeAg positive participants. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of

Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, End of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	14[20]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline n=14	0.69 (± 0.943)			
End of Treatment (up to 36 weeks) n=9	-0.05 (± 0.897)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=12	0.03 (± 0.834)			
36 weeks OTT FUP (Study Weeks 36 to week 72) n=13	0.01 (± 0.724)			

Notes:

[20] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Percentage of Participants with Alanine Aminotransferase (ALT) Normalization

End point title	Treatment Arm 2: Percentage of Participants with Alanine Aminotransferase (ALT) Normalization[21]

End point description:

The ALT normalization (ALT <=upper limit of normal [ULN]) over time in absence of rescue medication in participants with baseline ALT>ULN and ALT data at that visit. Participants who achieved ALT normalization were reported. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, End of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[22]			
Units: Percentage of Participants				
ALT>ULN, at Baseline n=53	19			
End of Treatment (up to 36 weeks) n=7	2			
Up to 24 weeks OTT FUP (Study Weeks 36 to 60) n=9	9			
Up to 36 weeks OTT FUP (Study Weeks 36 to 72) n=9	11			

Notes:

[22] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Mean Change from Baseline in HBe antibody levels

End point title	Treatment Arm 2: Mean Change from Baseline in HBe antibody levels[23]

End point description:

Blood samples were collected to assess HBe antibody levels and results reported are for baseline HBeAg positive participants. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, End of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	13[24]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 36 weeks) n=9	-0.52 (± 0.598)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=12	-0.58 (± 0.766)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=13	-0.65 (± 0.787)			

Notes:

[24] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Mean Change from Baseline in HBe antibody levels

End point title	Treatment Arm 1: Mean Change from Baseline in HBe antibody levels[25]

End point description:

Blood samples were collected to assess HBe antibody levels and results reported are for baseline HBeAg positive participants. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	13[26]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 48 weeks) n=9	-1.04 (± 1.133)			
Up to 24 weeks OTT FUP (study week 48 to 72)- n=13	-0.81 (± 1.044)			

Notes:

[26] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of HBsAg levels

End point title	Treatment Arm 2: Absolute values of HBsAg levels[27]

End point description:

Blood samples were collected from participants to assess HBsAg over time at indicated time points. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed

data reported in the table) were included in the Overall Number of Participants Analyzed field. The unit of measure is log10 International Units Per Milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[28]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline n=53	3.32 (± 0.622)			
End of Treatment (up to 36 weeks) n=36	1.70 (± 0.491)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=49	2.12 (± 1.897)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=48	2.12 (± 1.830)			

Notes:

[28] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of HBsAg levels

End point title	Treatment Arm 1: Absolute values of HBsAg levels[29]

End point description:

Blood samples were collected from participants to assess HBsAg over time at indicated time points. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field. The unit of measure is log10 International Units Per Milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	54[30]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline n=55	3.34 (± 0.555)			
End of Treatment (up to 48 weeks) n=36	1.52 (± 2.071)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=49	1.72 (± 2.043)			

Notes:

[30] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Mean Change from Baseline in HBsAg levels

End point title	Treatment Arm 2: Mean Change from Baseline in HBsAg

End point description:

Blood samples were collected to assess HBsAg change from baselines levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[32]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 36 weeks) n=36	-1.54 (± 1.567)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=49	-1.20 (± 1.458)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=48	-1.20 (± 1.460)			

Notes:
[32] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Mean Change from Baseline in HBsAg levels

End point title	Treatment Arm 1: Mean Change from Baseline in HBsAg

End point description:

Blood samples were collected to assess HBsAg change from baselines levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[34]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 48 weeks) n=36	-1.76 (± 1.726)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=49	-1.58 (± 1.722)			

Notes:

[34] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of HBV DNA levels

End point title	Treatment Arm 1: Absolute values of HBV DNA levels[35]

End point description:

Blood samples were collected to assess HBV DNA levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	55[36]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline n=55	0.64 (± 0.796)			
End of Treatment (up to 48 weeks) n=35	0.97 (± 0.629)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=47	0.17 (± 0.438)			

Notes:

[36] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of HBV DNA levels

End point title	Treatment Arm 2: Absolute values of HBV DNA levels[37]

End point description:

Blood samples were collected to assess HBV DNA levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[38]			
Units: Log10 IU/mL				

arithmetic mean (standard deviation)				
At Baseline n=53	0.57 (± 0.687)			
End of treatment (up to 36 weeks) n=35	0.70 (± 0.700)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=49	0.34 (± 0.579)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=48	0.35 (± 0.587)			

Notes:

[38] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of Hepatitis B virus e-antigen (HBeAg) levels

End point title	Treatment Arm 1: Absolute values of Hepatitis B virus e-antigen (HBeAg) levels[39]

End point description:

Blood samples were collected to assess HBeAg levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	55[40]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline, n=55	14.221 (± 69.3438)			
End of Treatment (up to 48 weeks) n=10	0.250 (± 0.4193)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=15	1.197 (± 2.4945)			

Notes:

[40] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Mean Change from Baseline in HBV DNA Levels

End point title	Treatment Arm 1: Mean Change from Baseline in HBV DNA Levels[41]

End point description:

Blood samples were collected to assess HBV DNA levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	47[42]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of treatment (up to 48 weeks) n=35	0.40 (± 0.945)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=47	-0.39 (± 0.727)			

Notes:

[42] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Mean Change from Baseline in HBV DNA Levels

End point title	Treatment Arm 2: Mean Change from Baseline in HBV DNA Levels[43]

End point description:

Blood samples were collected to assess HBV DNA levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[44]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 36 weeks) n=35	0.21 (± 0.925)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=49	-0.21 (± 0.876)			
up to 36 weeks OTT FUP (study week 36 to 72) n=48	-0.22 (± 0.754)			

Notes:

[44] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Mean Change from Baseline in HBeAg Levels

End point title	Treatment Arm 1: Mean Change from Baseline in HBeAg

End point description:

Blood samples were collected to assess HBeAg levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	15[46]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 48 weeks) n=10	-21.774 (± 65.4276)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=15	-19.482 (± 55.1948)			

Notes:

[46] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of Hepatitis B virus e-antigen (HBeAg) levels

End point title	Treatment Arm 2: Absolute values of Hepatitis B virus e-antigen (HBeAg) levels[47]

End point description:

Blood samples were collected to assess HBeAg levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[48]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Baseline, n=53	8.510 (± 42.1588)			
End of Treatment (up to 36 weeks) n=12	3.008 (± 6.2682)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=14	3.410 (± 6.0421)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=15	2.797 (± 4.8973)			

Notes:

[48] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of HBs Antibody Levels

End point title	Treatment Arm 2: Absolute values of HBs Antibody Levels[49]

End point description:

Blood samples were collected to assess HBs antibody levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[50]			
Units: Log10 IU/L				
arithmetic mean (standard deviation)				
At Baseline, n=53	0.69 (± 0.204)			
End of Treatment (up to 36 weeks) n=35	0.87 (± 0.491)			
Up to 24 weeks OTT FUP (Study Weeks 36 to 60) n=49	0.80 (± 0.521)			
Up to 36 weeks OTT FUP (Study Weeks 36 to 72) n=49	0.76 (± 0.481)			

Notes:

[50] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Mean Change from Baseline in HBeAg Levels

End point title	Treatment Arm 2: Mean Change from Baseline in HBeAg

End point description:

Blood samples were collected to assess HBeAg levels. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	15[52]			
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
End of Treatment (up to 36 weeks) n=12	-5.270 (± 8.8942)			
Up to 24 weeks OTT FUP (study week 36 to 60) n=14	-26.384 (± 80.2108)			
Up to 36 weeks OTT FUP (study week 36 to 72) n=15	-26.345 (± 77.2836)			

Notes:

[52] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of HBs antibody levels

End point title	Treatment Arm 1: Absolute values of HBs antibody levels[53]

End point description:

Blood samples were collected to assess HBs antibody levels. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks) and up to 24 weeks off treatment follow-up (study week 48 to week 72)

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	54[54]			
Units: Log10 IU/L				
arithmetic mean (standard deviation)				
At Baseline, n=54	0.62 (± 0.271)			
End of Treatment (up to 48 weeks), n=36	1.06 (± 0.903)			
Up to 24 weeks OTT FUP (Study Weeks 48 to 72) n=49	0.82 (± 0.718)			

Notes:

[54] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Mean Change from Baseline in HBs antibody levels

End point title	Treatment Arm 2: Mean Change from Baseline in HBs antibody levels[55]

End point description:

Blood samples were collected to assess HBs antibody levels over time. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[56]			
Units: Log10 IU/L				
arithmetic mean (standard deviation)				
End of Treatment (up to 36 weeks) n=35	0.18 (± 0.450)			
Up to 24 weeks OTT FUP (Study Weeks 36 to 60) n=49	0.09 (± 0.487)			
Up to 36 weeks OTT FUP (Study Weeks 36 to 72) n=49	0.05 (± 0.453)			

Notes:

[56] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Mean Change from Baseline in HBs antibody levels

End point title	Treatment Arm 1: Mean Change from Baseline in HBs antibody levels[57]

End point description:

Blood samples were collected to assess HBs antibody levels over time. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	48[58]			
Units: Log10 IU/L				
arithmetic mean (standard deviation)				
End of treatment (up to 48 weeks) n=35	0.42 (± 0.934)			
Up to 24 weeks OTT FUP (Study Weeks 48 to 72) n=48	0.18 (± 0.757)			

Notes:

[58] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Absolute values of ALT

End point title	Treatment Arm 1: Absolute values of ALT[59]

End point description:

Mean values over time for ALT are reported here. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	55[60]			
Units: International units per Liter (IU/L)				
arithmetic mean (standard deviation)				

At Baseline, n=55	22.7 (± 13.97)			
End of Treatment (up to 48 weeks) n=36	53.1 (± 60.61)			
Up to 24 weeks OTT FUP (Study Weeks 48 to 72) n=49	19.2 (± 9.77)			

Notes:

[60] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1: Change from Baseline in ALT

End point title	Treatment Arm 1: Change from Baseline in ALT[61]

End point description:

Blood samples were collected to assess ALT values. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 48 weeks), and up to 24 weeks off treatment follow-up (Study Weeks 48 to 72)

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[62]			
Units: IU/L				
arithmetic mean (standard deviation)				
End of Treatment (up to 48 weeks) n=36	27.6 (± 56.05)			
Up to 24 weeks OTT FUP (study week 48 to 72) n=49	-3.8 (± 9.86)			

Notes:

[62] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2: Absolute values of ALT

End point title	Treatment Arm 2: Absolute values of ALT[63]

End point description:

Mean values over time for ALT are reported here. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the

Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	53[64]			
Units: IU/L				
arithmetic mean (standard deviation)				
At Baseline, n=53	26.9 (± 19.16)			
End of treatment (up to 36 weeks), n=35	55.3 (± 46.60)			
Up to 24 weeks OTT FUP (Study Weeks 36 to 60) n=49	22.1 (± 13.30)			
Up to 36 weeks OTT FUP (Study Weeks 36 to 72) n=48	23.5 (± 15.61)			

Notes:

[64] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Sustained Virologic Response (SVR) up to 24 weeks off-treatment for Comparision of Efficacy Between Different Treatment Durations

End point title	Percentage of Participants Achieving Sustained Virologic Response (SVR) up to 24 weeks off-treatment for Comparision of Efficacy Between Different Treatment Durations

End point description:

Sustained virologic response is defined as undetectable levels of HBsAg and Hepatitis-B virus deoxy-ribonucleic acid (HBV DNA) on treatment. The SVR was a composite endpoint defined as Hepatitis B surface antigen (HBsAg) and Hepatitis B virus (HBV) Deoxyribonucleic acid (DNA) levels were less than (<) Lower limit of quantitation (LLOQ) at the planned end of GSK3228836 treatment which is sustained for 24 weeks post-GSK3228836 treatment in the absence of rescue medication. The point estimate for the difference in SVR and its respective credible interval (CI) were evaluated at 24 weeks off of planned treatment for both arms. The comparison of efficacy is between treatment durations and timepoint corresponds to Week 72 in Arm 1 and Week 60 in Arm 2. 95% CI refers here as credible interval. Intent to Treat (ITT) Set that included all randomized participants.

End point type	Secondary

End point timeframe:

Up to 24 weeks off treatment (Treatment Arm 1: Study Weeks 48 to 72 and Treatment Arm 2: Study Weeks 36 to 60)

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	53		
Units: Percentage of participants	9	15		

Statistical analyses

Statistical analysis title	Treatment Arm 1 Versus Treatment Arm 2
Comparison groups	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks) v GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	other[65]
Parameter estimate	Difference in SVR Rate
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29
upper limit	11

Notes:

[65] - The point estimate of SVR and its 95% highest posterior density Credible Interval (CI) are estimated from a Bayesian model that incorporates the analysis stratification factors and treatment arm.

Secondary: Treatment Arm 2: Change from Baseline in ALT

End point title	Treatment Arm 2: Change from Baseline in ALT[66]

End point description:

Blood samples were collected to assess ALT values. Change from Baseline was defined as value at the indicated time point minus Baseline value. Baseline was the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

At baseline, end of treatment (up to 36 weeks), up to 24 weeks off treatment follow-up (Study Weeks 36 to 60), and up to 36 weeks off treatment follow-up (Study Weeks 36 to 72)

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	49[67]			
Units: IU/L				
arithmetic mean (standard deviation)				
End of treatment (up to 36 weeks), n=35	27.8 (± 40.55)			
Up to 24 weeks OTT FUP (Study Weeks36 to 60) n=49	-4.3 (± 17.50)			
Up to 36 weeks OTT FUP (Study Weeks36 to 72) n=48	-3.1 (± 18.65)			

Notes:

[67] - ITT set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 1 - Median Time to ALT normalization in absence of rescue medication for 24 Weeks Off Treatment

End point title	Treatment Arm 1 - Median Time to ALT normalization in absence of rescue medication for 24 Weeks Off Treatment[68]

End point description:

Time to ALT normalization in absence of rescue medication were measured in participants having Baseline ALT>ULN. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field. The estimate for Median Time to Event (Weeks) is 99999 (non-estimable-NE) for Arm 1 because the survival curve did not reach below 0.5 at the last timepoint. The corresponding 95% CI's upper limit is 99999 (non-estimable-NE) because the number of events in Arm 1 was too small to provide an estimate.

End point type	Secondary

End point timeframe:

Up to 24 weeks off treatment (Study Week 48 to72)

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (24 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	4[69]			
Units: Weeks				
median (confidence interval 95%)	99999 (6.3 to 99999)			

Notes:
[69] - ITT Set

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Arm 2 - Median Time to ALT normalization in absence of rescue medication for 24 Weeks Off Treatment

End point title	Treatment Arm 2 - Median Time to ALT normalization in absence of rescue medication for 24 Weeks Off Treatment[70]

End point description:

Time to ALT normalization in absence of rescue medication were measured in participants having Baseline ALT>ULN. Intent-to-Treat Population. Only those participants who were measured and analyzed (i.e., contributed data reported in the table) were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

Up to 24 weeks off treatment (Study Weeks 36 to 60)

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was descriptive, hence no statistical analysis to report.

End point values	GSK3228836 300 mg (12 weeks) + PegIFN 180 mcg (24 weeks)			
Subject group type	Reporting group			
Number of subjects analysed	10[71]			
Units: Weeks				
median (confidence interval 95%)	4.1 (1.1 to 47.1)			

Notes:

[71] - Intent to Treat (ITT) Set

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 72

Adverse event reporting additional description:

All-cause mortality, Serious adverse events and non-serious adverse events were reported for the Safety Population who were randomized and received at least one dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	GSK3228836 (24 weeks) + PegIFN (24 weeks)

Reporting group description:

Participants on stable NA therapy received 300mg GSK3228836 for 24 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 microgram per week (mcg/week) up to 24 weeks.

Reporting group title	GSK3228836 (12 weeks) + PegIFN (24 weeks)

Reporting group description:

Participants on stable NA therapy received 300mg GSK3228836 for 12 weeks (plus a loading dose on Day 4 and 11), followed by PegIFN 180 microgram per week (mcg/week) up to 24 weeks.

Serious adverse events	GSK3228836 (24 weeks) + PegIFN (24 weeks)	GSK3228836 (12 weeks) + PegIFN (24 weeks)	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 55 (10.91%)	2 / 53 (3.77%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung adenocarcinoma			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Chest injury			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Spinal stenosis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	GSK3228836 (24 weeks) + PegIFN (24 weeks)	GSK3228836 (12 weeks) + PegIFN (24 weeks)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 55 (94.55%)	50 / 53 (94.34%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Uterine leiomyoma			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Varicose vein			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 55 (9.09%)	10 / 53 (18.87%)	
occurrences (all)	8	21	
Chills			
subjects affected / exposed	3 / 55 (5.45%)	1 / 53 (1.89%)	
occurrences (all)	5	2	
Discomfort			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Facial pain			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	9 / 55 (16.36%)	5 / 53 (9.43%)	
occurrences (all)	19	8	
Influenza like illness			

subjects affected / exposed	12 / 55 (21.82%)	8 / 53 (15.09%)	
occurrences (all)	14	12	
Malaise			
subjects affected / exposed	7 / 55 (12.73%)	3 / 53 (5.66%)	
occurrences (all)	11	3	
Pain			
subjects affected / exposed	2 / 55 (3.64%)	2 / 53 (3.77%)	
occurrences (all)	7	2	
Pyrexia			
subjects affected / exposed	17 / 55 (30.91%)	14 / 53 (26.42%)	
occurrences (all)	25	19	
Vaccination site pain			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Injection site pain			
subjects affected / exposed	7 / 55 (12.73%)	11 / 53 (20.75%)	
occurrences (all)	56	102	
Injection site erythema			
subjects affected / exposed	20 / 55 (36.36%)	22 / 53 (41.51%)	
occurrences (all)	112	208	
Injection site pruritus			
subjects affected / exposed	10 / 55 (18.18%)	11 / 53 (20.75%)	
occurrences (all)	36	118	
Injection site induration			
subjects affected / exposed	7 / 55 (12.73%)	3 / 53 (5.66%)	
occurrences (all)	9	17	
Injection site discolouration			
subjects affected / exposed	5 / 55 (9.09%)	3 / 53 (5.66%)	
occurrences (all)	17	12	
Injection site swelling			
subjects affected / exposed	2 / 55 (3.64%)	5 / 53 (9.43%)	
occurrences (all)	8	32	
Injection site bruising			
subjects affected / exposed	2 / 55 (3.64%)	4 / 53 (7.55%)	
occurrences (all)	13	7	
Injection site haematoma			

subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Injection site discomfort			
subjects affected / exposed	1 / 55 (1.82%)	2 / 53 (3.77%)	
occurrences (all)	38	5	
Injection site haemorrhage			
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)	
occurrences (all)	4	1	
Injection site nodule			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Injection site anaesthesia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Injection site warmth			
subjects affected / exposed	1 / 55 (1.82%)	3 / 53 (5.66%)	
occurrences (all)	44	77	
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Prostatitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Pelvic pain			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Heavy menstrual bleeding			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Erectile dysfunction			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Dysmenorrhoea			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Breast swelling			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Throat irritation			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Rhinorrhoea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Pleural effusion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)	
occurrences (all)	2	2	
Nasal obstruction			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Laryngeal discomfort			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Dyspnoea exertional			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Dry throat			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	1 / 55 (1.82%)	2 / 53 (3.77%)	
occurrences (all)	1	3	
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Nervousness			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Mood altered			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Libido decreased			
subjects affected / exposed	1 / 55 (1.82%)	2 / 53 (3.77%)	
occurrences (all)	1	2	
Irritability			
subjects affected / exposed	1 / 55 (1.82%)	3 / 53 (5.66%)	
occurrences (all)	1	4	
Insomnia			
subjects affected / exposed	1 / 55 (1.82%)	4 / 53 (7.55%)	
occurrences (all)	1	6	
Hyposomnia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	2 / 55 (3.64%)	2 / 53 (3.77%)	
occurrences (all)	2	2	

Depressed mood			
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)	
occurrences (all)	2	1	
Anxiety			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 55 (3.64%)	2 / 53 (3.77%)	
occurrences (all)	3	6	
Alanine aminotransferase increased			
subjects affected / exposed	23 / 55 (41.82%)	6 / 53 (11.32%)	
occurrences (all)	36	9	
Antineutrophil cytoplasmic antibody increased			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	2	
Antineutrophil cytoplasmic antibody positive			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	4	0	
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 55 (29.09%)	6 / 53 (11.32%)	
occurrences (all)	21	6	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Blood creatinine increased			
subjects affected / exposed	2 / 55 (3.64%)	2 / 53 (3.77%)	
occurrences (all)	2	2	
Blood phosphorus decreased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	

Blood pressure increased				
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)		
occurrences (all)	1	0		
Blood thyroid stimulating hormone decreased				
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)		
occurrences (all)	1	0		
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)		
occurrences (all)	0	1		
Body temperature increased				
subjects affected / exposed	3 / 55 (5.45%)	4 / 53 (7.55%)		
occurrences (all)	3	8		
C-reactive protein increased				
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)		
occurrences (all)	1	0		
Complement factor C3 decreased				
subjects affected / exposed	7 / 55 (12.73%)	3 / 53 (5.66%)		
occurrences (all)	9	3		
Complement factor C4 decreased				
subjects affected / exposed	8 / 55 (14.55%)	2 / 53 (3.77%)		
occurrences (all)	11	2		
Complement fragment Bb increased				
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)		
occurrences (all)	1	0		
Creatinine renal clearance decreased				
subjects affected / exposed	6 / 55 (10.91%)	4 / 53 (7.55%)		
occurrences (all)	35	24		
Creatinine renal clearance increased				
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)		
occurrences (all)	1	0		
Glomerular filtration rate decreased				
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)		
occurrences (all)	2	2		
Haemoglobin decreased				

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Hepatic enzyme increased			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Hepatitis B DNA increased			
subjects affected / exposed	2 / 55 (3.64%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Monocyte chemotactic protein-1 increased			
subjects affected / exposed	2 / 55 (3.64%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Neutrophil count decreased			
subjects affected / exposed	14 / 55 (25.45%)	8 / 53 (15.09%)	
occurrences (all)	22	12	
Platelet count decreased			
subjects affected / exposed	10 / 55 (18.18%)	5 / 53 (9.43%)	
occurrences (all)	13	5	
Red blood cell count decreased			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Transaminases increased			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	
occurrences (all)	0	5	
Weight decreased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	8 / 55 (14.55%)	4 / 53 (7.55%)	
occurrences (all)	14	7	
Thyroxine increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Ankle fracture			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Head injury			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Joint injury			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Ligament sprain			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Lip injury			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Muscle strain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Wound complication			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Bundle branch block left			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Sinus bradycardia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Sinus tachycardia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Tachycardia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Ventricular extrasystoles			

subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	11	0	
Tension headache			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	8	
Somnolence			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Sensory disturbance			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Presyncope			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Muscle contractions involuntary			
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)	
occurrences (all)	2	3	
Migraine			
subjects affected / exposed	1 / 55 (1.82%)	2 / 53 (3.77%)	
occurrences (all)	1	2	
Hypoaesthesia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	3	0	
Headache			
subjects affected / exposed	7 / 55 (12.73%)	12 / 53 (22.64%)	
occurrences (all)	29	25	
Dizziness			
subjects affected / exposed	3 / 55 (5.45%)	4 / 53 (7.55%)	
occurrences (all)	4	4	
Blood and lymphatic system disorders			
Agranulocytosis			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Coagulopathy			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Iron deficiency anaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	10 / 55 (18.18%)	7 / 53 (13.21%)	
occurrences (all)	18	10	
Neutropenia			
subjects affected / exposed	10 / 55 (18.18%)	12 / 53 (22.64%)	
occurrences (all)	25	21	
Neutrophilia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Pancytopenia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			
subjects affected / exposed	14 / 55 (25.45%)	11 / 53 (20.75%)	
occurrences (all)	20	16	
Anaemia			
subjects affected / exposed	3 / 55 (5.45%)	1 / 53 (1.89%)	
occurrences (all)	3	3	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	2	1	
Ear pruritus			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Tinnitus			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	

Eye disorders			
Cataract			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Dry eye			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Iridocyclitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Meibomian gland dysfunction			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Visual impairment			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Vitreous floaters			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Xerophthalmia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Eye pain			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Abdominal discomfort			
subjects affected / exposed	2 / 55 (3.64%)	1 / 53 (1.89%)	
occurrences (all)	2	1	
Abdominal distension			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Abdominal pain			

subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	12	1	
Abdominal pain upper			
subjects affected / exposed	4 / 55 (7.27%)	4 / 53 (7.55%)	
occurrences (all)	8	4	
Abdominal tenderness			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Anal blister			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Aphthous ulcer			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Colitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	0 / 55 (0.00%)	4 / 53 (7.55%)	
occurrences (all)	0	5	
Diarrhoea			
subjects affected / exposed	3 / 55 (5.45%)	6 / 53 (11.32%)	
occurrences (all)	3	6	
Dry mouth			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Dyspepsia			
subjects affected / exposed	2 / 55 (3.64%)	4 / 53 (7.55%)	
occurrences (all)	3	4	
Gastritis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Gingival bleeding			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Hypoaesthesia oral			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Malocclusion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	8 / 55 (14.55%)	6 / 53 (11.32%)	
occurrences (all)	14	6	
Oral mucosal blistering			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Proctalgia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	2 / 55 (3.64%)	3 / 53 (5.66%)	
occurrences (all)	3	4	
Vomiting			
subjects affected / exposed	2 / 55 (3.64%)	2 / 53 (3.77%)	
occurrences (all)	3	2	
Gingival pain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	3 / 55 (5.45%)	2 / 53 (3.77%)	
occurrences (all)	5	2	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Rash			

subjects affected / exposed	3 / 55 (5.45%)	2 / 53 (3.77%)	
occurrences (all)	5	2	
Rash macular			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Rash papular			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Skin discolouration			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	7	0	
Skin lesion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	3 / 55 (5.45%)	6 / 53 (11.32%)	
occurrences (all)	3	6	
Angioedema			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Dermatitis allergic			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Dermatitis contact			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	
occurrences (all)	0	2	
Dry skin			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Ecchymosis			

subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Erythema			
subjects affected / exposed	2 / 55 (3.64%)	3 / 53 (5.66%)	
occurrences (all)	3	3	
Erythema multiforme			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Nail ridging			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Petechiae			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Pruritus			
subjects affected / exposed	5 / 55 (9.09%)	2 / 53 (3.77%)	
occurrences (all)	5	5	
Psoriasis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Purpura			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Chronic kidney disease			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Renal impairment			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	

Pollakiuria			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Dysuria			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Temporomandibular joint syndrome			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	4 / 55 (7.27%)	9 / 53 (16.98%)	
occurrences (all)	5	13	
Arthritis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	3 / 55 (5.45%)	4 / 53 (7.55%)	
occurrences (all)	9	5	
Flank pain			
subjects affected / exposed	2 / 55 (3.64%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Hip deformity			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Limb discomfort			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	
occurrences (all)	0	4	
Musculoskeletal stiffness			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Myalgia			
subjects affected / exposed	6 / 55 (10.91%)	12 / 53 (22.64%)	
occurrences (all)	9	25	
Neck pain			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	7	
Osteoporosis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	1 / 55 (1.82%)	2 / 53 (3.77%)	
occurrences (all)	2	3	
Spinal osteoarthritis			
subjects affected / exposed	1 / 55 (1.82%)	1 / 53 (1.89%)	
occurrences (all)	1	1	
Spinal pain			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Infections and infestations			
Folliculitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	

Acute sinusitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
COVID-19			
subjects affected / exposed	15 / 55 (27.27%)	5 / 53 (9.43%)	
occurrences (all)	15	5	
Chlamydial infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Cystitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Gingivitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Herpes dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	
Hordeolum			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Influenza			
subjects affected / exposed	0 / 55 (0.00%)	2 / 53 (3.77%)	
occurrences (all)	0	3	
Laryngitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Localised infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	2 / 55 (3.64%)	5 / 53 (9.43%)	
occurrences (all)	2	7	
Oral herpes			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	2	

Otitis media			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Respiratory tract infection viral			
subjects affected / exposed	2 / 55 (3.64%)	4 / 53 (7.55%)	
occurrences (all)	2	5	
Sinusitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 55 (5.45%)	0 / 53 (0.00%)	
occurrences (all)	4	0	
Viral infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Gonorrhoea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Cell death			
subjects affected / exposed	2 / 55 (3.64%)	0 / 53 (0.00%)	
occurrences (all)	2	0	
Decreased appetite			
subjects affected / exposed	7 / 55 (12.73%)	4 / 53 (7.55%)	
occurrences (all)	7	4	
Gout			

subjects affected / exposed	0 / 55 (0.00%)	1 / 53 (1.89%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 53 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 October 2020	Original Protocol
24 September 2021	Protocol Amendment 01: This amendment is considered to be non-substantial based on the criteria set forth in Article 10(a) of Directive 2001/20/Ethics Committee (EC) of the European Parliament and the Council of the European Union because it neither significantly impacts the safety or physical/mental integrity of participants nor the scientific value of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported