Clinical trial results:
A Phase IIIb randomized open-label study of nirsevimab (versus no intervention) in preventing hospitalizations due to respiratory syncytial virus in infants (HARMONIE)

Summary

EudraCT number	2022-000099-20
Trial protocol	FR DE
Global end of trial date	09 April 2025

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	VAS00006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05437510
WHO universal trial number (UTN)	U1111-1272-2514

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur
Sponsor organisation address	14 Espace Henry Vallée, Lyon, France, 69007
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.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	18 June 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 April 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of nirsevimab in preventing respiratory syncytial virus (RSV) lower respiratory tract infection (LRTI) hospitalization compared to no intervention.

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 August 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 2177
Country: Number of subjects enrolled	Germany: 1789
Country: Number of subjects enrolled	United Kingdom: 4091
Worldwide total number of subjects	8057
EEA total number of subjects	3966

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	1865
Infants and toddlers (28 days-23 months)	6192
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 235 investigational sites. Total 8057 participants were enrolled and randomized in 1:1 ratio to nirsevimab or no intervention group between 08 August 2022 to 28 February 2023.

Pre-assignment

Screening details:

Participants were followed up for safety for 12-months (366 days) (for France, Germany, and United Kingdom[UK] non-reconsented participants) and for 24 months (731 days) (for UK participants who consented to take part into study extension [UK reconsented participants]). As pre-specified in protocol and SAP, results are presented by treatment group.

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	Nirsevimab

Arm description:

Participants received nirsevimab 50 milligrams (mg) (if weight <5 kilograms [kg]) or 100 mg (if weight ≥5 kg) as a single intramuscular (IM) injection on Day 1.

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

Dosage and administration details:

Nirsevimab was administered as a single IM injection of 50 mg (if weight <5 kg) or 100 mg (if weight ≥5 kg) on Day 1.

Arm title	No Intervention

Arm description:

Participants received no RSV preventive intervention on Day 1.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Nirsevimab	No Intervention
Started	4038	4019
Randomized and treated	4015	1 [1]
Participants Entered Study Extension	1142 [2]	1084 [3]
Completed	3747	3631
Not completed	291	388
Adverse event, non-fatal	2	1

Protocol Deviation	1	6
Withdrawal by Parent/Guardian	23	23
Lost to follow-up	265	358

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 1 participant of the no intervention group wrongly received the study intervention.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: UK participants who consented to take part into optional 12-month study extension.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: UK participants who consented to take part into optional 12-month study extension.

Baseline characteristics

Reporting groups	
Reporting group title	Nirsevimab
Reporting group description:	
Participants received nirsevimab 50 milligrams (mg) (if weight <5 kilograms [kg]) or 100 mg (if weight ≥5 kg) as a single intramuscular (IM) injection on Day 1.	
Reporting group title	No Intervention
Reporting group description:	
Participants received no RSV preventive intervention on Day 1.	

Reporting group values	Nirsevimab	No Intervention	Total
Number of subjects	4038	4019	8057
Age categorical Units: Subjects			
Age Continuous Units: months			
arithmetic mean	4.53	4.48	
standard deviation	± 3.342	± 3.294	-
Sex: Female, Male Units: participants			
Female	1950	1912	3862
Male	2088	2107	4195
Race and Ethnicity Not Collected Units: Subjects			
Not collected	4038	4019	8057

End points

End points reporting groups

Reporting group title	Nirsevimab
Reporting group description:	
Participants received nirsevimab 50 milligrams (mg) (if weight <5 kilograms [kg]) or 100 mg (if weight ≥5 kg) as a single intramuscular (IM) injection on Day 1.	
Reporting group title	No Intervention
Reporting group description:	
Participants received no RSV preventive intervention on Day 1.	

Primary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through the Respiratory Syncytial Virus Season

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through the Respiratory Syncytial Virus Season
End point description:	
LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths per minute (/min); 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. RSV season was the period of increased RSV infection. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group.	
End point type	Primary
End point timeframe:	
From dosing/randomization (Day 1) up to approximately 7 months	

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants	11	64		

Statistical analyses

Statistical analysis title	Number of RSV LRTI hospitalization
Statistical analysis description:	
The 2-sided 95% confidence interval (CI) for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.	
Comparison groups	Nirsevimab v No Intervention

Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	84.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.493
upper limit	92.411

Secondary: Number of Participants With Very Severe Respiratory Syncytial Virus Lower Respiratory Tract Infection Through the Respiratory Syncytial Virus Season

End point title	Number of Participants With Very Severe Respiratory Syncytial Virus Lower Respiratory Tract Infection Through the Respiratory Syncytial Virus Season

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Very severe RSV LRTI was defined as RSV LRTI hospitalization with oxygen saturation <90% (at any time during hospitalization) and oxygen supplementation. Hospitalization was defined as the decision to admit to in-patient care by the treating physician. RSV season was the period of increased RSV infection. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) up to approximately 7 months

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants	5	21		

Statistical analyses

Statistical analysis title	Number of very severe RSV LRTI

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of very severe RSV LRTI in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention

Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0014
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	77.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.249
upper limit	93.432

Secondary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through the Respiratory Syncytial Virus Season in Each Country

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through the Respiratory Syncytial Virus Season in Each Country

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. RSV season was the period of increased RSV infection. Number of participants with RSV LRTI hospitalization through the RSV season in France, UK, and Germany is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) up to approximately 7 months

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
France (n=1090, 1087)	3	28		
United Kingdom (n=2052, 2039)	3	17		
Germany (n=896, 893)	5	19		

Statistical analyses

Statistical analysis title	France: Number of RSV LRTI hospitalization

Statistical analysis description:

The adjusted 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization. Adjustment based

on Bonferroni-Holm procedure.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	90.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.676
upper limit	98.813

Notes:

[1] - Adjusted p-value is reported.

Statistical analysis title	UK: Number of RSV LRTI hospitalization

Statistical analysis description:

The adjusted 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization. Adjustment based on Bonferroni-Holm procedure.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0036 [2]
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	83.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.589
upper limit	97.593

Notes:

[2] - Adjusted p-value is reported.

Statistical analysis title	Germany: Number of RSV LRTI hospitalization

Statistical analysis description:

The adjusted 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization. Adjustment based on Bonferroni-Holm procedure.

Comparison groups	Nirsevimab v No Intervention

Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0051 [3]
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	74.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.74
upper limit	92.595

Notes:

[3] - Adjusted p-value is reported.

Secondary: Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through the Respiratory Syncytial Virus Season

End point title	Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through the Respiratory Syncytial Virus Season

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. RSV season was the period of increased RSV infection. Number of participants with hospitalization for all-cause LRTI through the RSV season in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) up to approximately 7 months

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	48	106		
France (n=1090, 1087)	24	44		
United Kingdom (n=2052, 2039)	17	39		
Germany (n=896, 893)	7	23		

Statistical analyses

Statistical analysis title	Overall: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of all-cause LRTI hospitalizations in the nirsevimab group conditional on the total number

in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	57.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.36
upper limit	70.76

Statistical analysis title	Germany: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of all-cause LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0037
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	70.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.567
upper limit	89.396

Statistical analysis title	UK: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of all-cause LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0024
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	58.62

Confidence interval	
level	95 %
sides	2-sided
lower limit	25.115
upper limit	78.049

Statistical analysis title	France: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of all-cause LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0039
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	52.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.121
upper limit	72.36

Secondary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through 151 Days Post-dosing/Randomization

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through 151 Days Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with RSV LRTI hospitalization through 151 days post-dosing/randomization in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 151

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	12	67		
France (n=1090, 1087)	4	28		
United Kingdom (n=2052, 2039)	3	20		
Germany (n=896, 893)	5	19		

Statistical analyses

Statistical analysis title	Overall: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	82.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.271
upper limit	91.357

Statistical analysis title	Germany: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0055
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	74.36

Confidence interval	
level	95 %
sides	2-sided
lower limit	29.006
upper limit	92.518

Statistical analysis title	UK: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	85.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.084
upper limit	97.183

Statistical analysis title	France: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	86.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.283
upper limit	96.459

Secondary: Number of Participants With Very Severe Respiratory Syncytial Virus

Lower Respiratory Tract Infection Through 151 Days Post-dosing/Randomization

End point title	Number of Participants With Very Severe Respiratory Syncytial Virus Lower Respiratory Tract Infection Through 151 Days Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Very severe RSV LRTI was defined as RSV LRTI hospitalization with oxygen saturation <90% (at any time during hospitalization) and oxygen supplementation. Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with very severe RSV LRTI through 151 days post-dosing/randomization in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 151

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	6	24		
France (n=1090, 1087)	2	9		
United Kingdom (n=2052, 2039)	1	11		
Germany (n=896, 893)	3	4		

Statistical analyses

Statistical analysis title	Overall: Number of very severe RSV LRTI

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of very severe RSV LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0013
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	75.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.012
upper limit	91.747

Statistical analysis title	France: Number of very severe RSV LRTI

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of very severe RSV LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.062
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	78.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.823
upper limit	97.697

Statistical analysis title	UK: Number of very severe RSV LRTI

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of very severe RSV LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	91.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.156
upper limit	99.791

Statistical analysis title	Germany: Number of very severe RSV LRTI

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of very severe RSV LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-

dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9851
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	26.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-337.329
upper limit	89.162

Secondary: Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through 151 Days Post-dosing/Randomization

End point title	Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through 151 Days Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with hospitalization for all-cause LRTI through 151 days post-dosing/randomization in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 151

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	76	132		
France (n=1090, 1087)	32	48		
United Kingdom (n=2052, 2039)	35	58		
Germany (n=896, 893)	9	26		

Statistical analyses

Statistical analysis title	Overall: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	43.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.677
upper limit	58.057

Statistical analysis title	Germany: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0046
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	66.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.952
upper limit	86.137

Statistical analysis title	UK: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention

Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0177
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	40.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.211
upper limit	62.156

Statistical analysis title	France: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through Day 151 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0754
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	34.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.148
upper limit	59.648

Secondary: Number of Participants With Immediate Treatment-Emergent Adverse Events (TEAEs)

End point title	Number of Participants With Immediate Treatment-Emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. TEAEs were either events with the start date and time posterior to the start of the treatment period and up to the end of the treatment period or events with the start date and time prior to the start of the treatment period, whose severity was greater than 1 or missing and stop date is missing or not before the treatment period. Immediate events were recorded to capture medically relevant AEs which occurred within the first 30 minutes after immunization. The Safety Analysis Set (SafAS) consisted of all participants who received nirsevimab in the study and all randomized participants who were randomized to the no intervention group and did not receive nirsevimab inadvertently. As pre-specified in the protocol and SAP, results are presented by treatment group.

End point type	Secondary

End point timeframe:

Up to 30 minutes post-dosing/randomization on Day 1

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4016	4018		
Units: participants	27	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Non-Serious Treatment-Emergent Adverse Events

End point title	Number of Participants With Non-Serious Treatment-Emergent Adverse Events

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. TEAEs were either events with the start date and time posterior to the start of the treatment period and up to the end of the treatment period or events with the start date and time prior to the start of the treatment period, whose severity was greater than 1 or missing and stop date was missing or not before the treatment period. The SafAS consisted of all participants who received nirsevimab in the study and all randomized participants who were randomized to the no intervention group and did not receive nirsevimab inadvertently. As pre-specified in the protocol and SAP, results are presented by treatment group.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 31

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4016	4018		
Units: participants	1316	1265		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Serious Adverse Events (SAEs), Treatment-Emergent Adverse Events of Special Interest (AESIs) and Treatment-Emergent Medically Attended Adverse Events (MAAEs)

End point title	Number of Participants With Treatment-Emergent Serious

	Adverse Events (SAEs), Treatment-Emergent Adverse Events of Special Interest (AESIs) and Treatment-Emergent Medically Attended Adverse Events (MAAEs)

End point description:

AE:untoward medical occurrence in clinical study participant temporally associated with use of study intervention, whether or not related to it.TEAEs:events with start date/time posterior to start and up to end of treatment period(TP), or events with start date/time prior to start of TP, whose severity was>1/missing;stop date was missing/not before TP.SAE:AE at any dose resulting in death,persistent or significant disability/incapacity,required inpatient hospitalization/prolongation of existing hospitalization,was life-threatening or congenital anomaly/birth defect or medically important event.MAAE:new onset/worsening of condition that prompted participant or participant's parent/legally acceptable representative to seek unplanned medical advice at physician's office/Emergency Department.AESI:scientific,medical concern specific to Sponsor's study intervention/program for which ongoing monitoring and rapid communication by investigator to Sponsor was appropriate. SafAS.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 366

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4016	4018		
Units: participants				
Treatment-emergent SAEs	262	222		
Treatment-emergent AESIs	11	3		
Treatment-emergent MAAEs	3106	3100		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Related Serious Adverse Event (for United Kingdom Reconsented Participants)

End point title	Number of Participants With Treatment-Related Serious Adverse Event (for United Kingdom Reconsented Participants)

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. TEAEs were either events with start date and time posterior to start of treatment period (TP) and up to end of the TP or events with start date and time prior to start of TP, whose severity was >1 or missing and stop date is missing or not before TP. SAE: AE at any dose resulting in death, persistent or significant disability/incapacity, required inpatient hospitalization/prolongation of existing hospitalization, was life-threatening or congenital anomaly/birth defect or medically important event. A treatment-related TEAE was TEAE considered by the investigator as related or with unknown/missing relationship to treatment for participants who received nirsevimab on Day 1. Analysis was performed on the SafAS. As pre-specified in the protocol and SAP, results are presented by treatment group.

End point type	Secondary

End point timeframe:

From Day 366 to Day 731

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1140	1084		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through 181 Days Post-dosing/Randomization

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization Through 181 Days Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with RSV LRTI hospitalization through 181 days post-dosing/randomization in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 181

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	12	68		
France (n=1090, 1087)	4	28		
United Kingdom (n=2052, 2039)	3	21		
Germany (n=896, 893)	5	19		

Statistical analyses

Statistical analysis title	Overall: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations through Day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention

Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	82.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.826
upper limit	91.49

Statistical analysis title	UK: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations through Day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	85.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.85
upper limit	97.311

Statistical analysis title	Germany: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations through Day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0054
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	74.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	29.077
upper limit	92.525

Statistical analysis title	France: Number of RSV LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of RSV LRTI hospitalizations through Day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	86.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.34
upper limit	96.464

Secondary: Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through 181 Days Post-dosing/Randomization

End point title	Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection Through 181 Days Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with hospitalization for all-cause LRTI through 181 days post-dosing/randomization in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 181

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4038	4019		
Units: participants				
Overall (n=4038, 4019)	82	138		
France (n=1090, 1087)	34	49		
United Kingdom (n=2052, 2039)	38	62		
Germany (n=896, 893)	10	27		

Statistical analyses

Statistical analysis title	Overall:Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	41.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.073
upper limit	56.333

Statistical analysis title	Germany:Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0058
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	64.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	23.386
upper limit	84.478

Statistical analysis title	UK: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0164
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	39.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.449
upper limit	60.911

Statistical analysis title	France: Number of all-cause LRTI hospitalization

Statistical analysis description:

The 2-sided 95% CI for the efficacy was calculated by an exact method assuming a binomial distribution of the number of hospitalizations for all-cause LRTI through day 181 post-dosing/randomization in the nirsevimab group conditional on the total number in both groups accounting for the follow-up time post-dosing/randomization.

Comparison groups	Nirsevimab v No Intervention
Number of subjects included in analysis	8057
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1003
Method	Exact method using binomial distribution
Parameter estimate	Efficacy
Point estimate	32.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.188
upper limit	57.545

Secondary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization From Days 181 to 366 Post-dosing/Randomization

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization From Days 181 to 366 Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with RSV LRTI hospitalization from Days 181 to 366 post-dosing/randomization (with no RSV LRTI hospitalizations before Day 181) in France, UK, Germany, and overall is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Only participants with data collected are reported. Here, n=number of participants with data collected for each specified category.

End point type	Secondary

End point timeframe:

From Day 181 to Day 366

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4026	3951		
Units: participants				
Overall (n=4026, 3951)	31	28		
France (n=1086, 1059)	6	5		
United Kingdom (n=2049, 2018)	20	19		
Germany (n=891, 874)	5	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection From Days 181 to 366 Post-dosing/Randomization

End point title	Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection From Days 181 to 366 Post-dosing/Randomization

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with hospitalization for all-cause LRTI from Days 181 to 366 post-dosing/randomization (with no hospitalizations for all-cause LRTI before Day 181) is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Only participants with data collected are reported.

End point type	Secondary

End point timeframe:

From Day 181 to Day 366

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3956	3881		
Units: participants	68	55		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization From Days 366 to 731 Post-dosing/Randomization (for United Kingdom Reconsented Participants)

End point title	Number of Participants With Respiratory Syncytial Virus Lower Respiratory Tract Infection Hospitalization From Days 366 to 731 Post-dosing/Randomization (for United Kingdom Reconsented Participants)

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with RSV LRTI hospitalization from Days 366 to 731 post-dosing/randomization (with no RSV LRTI hospitalizations before Day 366) in UK reconsented participants is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Only participants with data collected are reported.

End point type	Secondary

End point timeframe:

From Day 366 to Day 731

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1132	1062		
Units: participants	7	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Hospitalization for All-Cause Lower Respiratory Tract Infection From Days 366 to 731 Post-dosing/Randomization (for United Kingdom Reconsented Participants)

End point title	Number of Participants With Hospitalization for All-Cause Lower

	Respiratory Tract Infection From Days 366 to 731 Post-dosing/Randomization (for United Kingdom Reconsented Participants)

End point description:

LRTI included the following common symptoms: clinical finding of rhonchi, rales, crackles, or wheeze; increased respiratory rate at rest (age: <2 months, ≥60 breaths/min; 2 to 6 months, ≥50 breaths/min; >6 months, ≥40 breaths/min), and hypoxemia (in room air: oxygen saturation <95%). Hospitalization was defined as the decision to admit to in-patient care by the treating physician. Number of participants with hospitalization for all-cause LRTI from Days 366 to 731 post-dosing/randomization (with no hospitalizations for all-cause LRTI before Day 366) in UK reconsented participants is presented. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Only participants with data collected are reported.

End point type	Secondary

End point timeframe:

From Day 366 to Day 731

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1096	1025		
Units: participants	18	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Recurrent Wheeze (for United Kingdom Reconsented Participants)

End point title	Number of Participants With Recurrent Wheeze (for United Kingdom Reconsented Participants)

End point description:

Wheeze was defined as a physician-diagnosed wheeze or asthma or related ear, nose and throat (ENT)/respiratory symptoms at an office visit or an illness for which the child was prescribed medication to treat an ENT/respiratory condition. Recurrent wheeze event was defined as 2 or more protocol-defined wheeze episodes throughout follow-up period. The All Randomized Set consisted of all participants randomly assigned to either the nirsevimab group or the no intervention group. Only participants with data collected are reported.

End point type	Secondary

End point timeframe:

From dosing/randomization (Day 1) to Day 731

End point values	Nirsevimab	No Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	928	888		
Units: participants	101	96		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and deaths: From dosing/randomization (Day 1) up to end of follow-up (Day 366 for France, Germany, UK non-reconsented participants and Day 731 for UK reconsented participants). Non-serious AEs: From dosing/randomization (Day 1) up to Day 31.

Adverse event reporting additional description:

Analysis was performed on the SafAS. As pre-specified in the protocol and SAP, results are presented by treatment group. Safety analysis was not planned exclusively for UK reconsented participants, and no separate safety data was collected for this subgroup.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	No intervention

Reporting group description:

Participants received no RSV preventive intervention on Day 1.

Reporting group title	Nirsevimab

Reporting group description:

Participants received nirsevimab 50 mg (if weight <5 kg) or 100 mg (if weight ≥5 kg) as a single IM injection on Day 1.

Serious adverse events	No intervention	Nirsevimab	
Total subjects affected by serious adverse events			
subjects affected / exposed	222 / 4018 (5.53%)	262 / 4016 (6.52%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myelomonocytic Leukaemia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Cyanosis			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kawasaki's Disease			

subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Hyperthermia			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crying			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocution			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	11 / 4018 (0.27%)	9 / 4016 (0.22%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			

Allergy To Vaccine			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alloimmunisation			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Hypersensitivity			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Allergy			
subjects affected / exposed	0 / 4018 (0.00%)	4 / 4016 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Milk Allergy			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic Reaction			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Breast Inflammation			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Testicular Torsion			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoea			
subjects affected / exposed	3 / 4018 (0.07%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	3 / 4018 (0.07%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	2 / 4018 (0.05%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choking			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Brief Resolved Unexplained Event			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	5 / 4018 (0.12%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal Respiratory Distress Syndrome			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive Sleep Apnoea Syndrome			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Depression			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Disorder			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinorrhoea			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar Hypertrophy			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Stereotypy			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breath Holding			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Coronavirus Test Positive			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human Rhinovirus Test Positive			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Decreased			
subjects affected / exposed	2 / 4018 (0.05%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 4018 (0.00%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 4018 (0.05%)	4 / 4016 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Accidental Exposure To Product			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle Fracture			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	5 / 4018 (0.12%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm Fracture			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body In Gastrointestinal Tract			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body Ingestion			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand Fracture			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head Injury			

subjects affected / exposed	1 / 4018 (0.02%)	5 / 4016 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull Fracture			
subjects affected / exposed	2 / 4018 (0.05%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Limb Fracture			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road Traffic Accident			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma Prolapse			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal Burn			
subjects affected / exposed	4 / 4018 (0.10%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity To Various Agents			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Haematoma			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Limb Fracture			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cataract Congenital			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous Malformation			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Septal Defect			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicuspid Aortic Valve			

subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Birth Mark			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choanal Stenosis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cleft Palate			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial Deformity			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital Megacolon			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coarctation Of The Aorta			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Factor Viii Deficiency			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypospadias			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kabuki Make-Up Syndrome			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Sequestration			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral Valves			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric Stenosis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngomalacia			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac Arrest			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			

subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered State Of Consciousness			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infantile Spasms			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertonia			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fontanelle Bulging			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile Convulsion			
subjects affected / exposed	10 / 4018 (0.25%)	10 / 4016 (0.25%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	2 / 4018 (0.05%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss Of Consciousness			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive To Stimuli			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonic Convulsion			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status Epilepticus			
subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure Like Phenomena			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	3 / 4018 (0.07%)	11 / 4016 (0.27%)	
occurrences causally related to treatment / all	0 / 3	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Petit Mal Epilepsy			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Hypersplenism			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune Thrombocytopenia			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Eye Movement Disorder			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye Disorder			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyclic Vomiting Syndrome			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic Hernia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 4018 (0.02%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea Haemorrhagic			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			

subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			
subjects affected / exposed	5 / 4018 (0.12%)	5 / 4016 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Disorder			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 4018 (0.05%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated Inguinal Hernia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flatulence			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Protein-Losing Gastroenteropathy			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Perforation			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	3 / 4018 (0.07%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia, Obstructive			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	4 / 4018 (0.10%)	6 / 4016 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis Allergic			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acne Infantile			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	3 / 4018 (0.07%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Petechiae			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema Multiforme			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal Impairment			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis Orbital			

subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Covid-19			
subjects affected / exposed	8 / 4018 (0.20%)	6 / 4016 (0.15%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bullous Impetigo			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta Haemolytic Streptococcal Infection			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus Infection			
subjects affected / exposed	2 / 4018 (0.05%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Neck			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis Bacterial			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus Infection			

subjects affected / exposed	2 / 4018 (0.05%)	6 / 4016 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup Infectious			
subjects affected / exposed	3 / 4018 (0.07%)	5 / 4016 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Infected			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermo-Hypodermitis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear Infection Viral			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema Herpeticum			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema Infected			

subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovirus Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Pyelonephritis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Infection			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	12 / 4018 (0.30%)	11 / 4016 (0.27%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Adenovirus			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Enteroviral			
subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impetigo			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Rotavirus			

subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Viral			
subjects affected / exposed	2 / 4018 (0.05%)	4 / 4016 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Infection			
subjects affected / exposed	4 / 4018 (0.10%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Viral Infection			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes Simplex			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Norovirus			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Mononucleosis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	6 / 4018 (0.15%)	8 / 4016 (0.20%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Discitis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	3 / 4018 (0.07%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Abscess			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph Node Abscess			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised Infection			

subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Enteroviral			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Neonatal			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis Viral			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Norovirus Infection			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis Bacterial			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis Media Acute			
subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral Candidiasis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital Cellulitis			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	9 / 4018 (0.22%)	10 / 4016 (0.25%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Acute			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Syncytial Virus Infection			

subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	3 / 4018 (0.07%)	4 / 4016 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus Infection			
subjects affected / exposed	3 / 4018 (0.07%)	3 / 4016 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Roseola			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus Infection			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Skin Infection			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal Infection			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal Sepsis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subglottic Laryngitis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected Covid-19			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis Bacterial			
subjects affected / exposed	0 / 4018 (0.00%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	9 / 4018 (0.22%)	10 / 4016 (0.25%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urachal Abscess			

subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	4 / 4018 (0.10%)	7 / 4016 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	2 / 4018 (0.05%)	7 / 4016 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Diarrhoea			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Infection			
subjects affected / exposed	7 / 4018 (0.17%)	11 / 4016 (0.27%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Pharyngitis			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Rash			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Rhinitis			

subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 4018 (0.10%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Feeding Disorder			
subjects affected / exposed	1 / 4018 (0.02%)	2 / 4016 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure To Thrive			
subjects affected / exposed	2 / 4018 (0.05%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 4018 (0.02%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Refusal			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			
subjects affected / exposed	2 / 4018 (0.05%)	0 / 4016 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 Diabetes Mellitus			

subjects affected / exposed	0 / 4018 (0.00%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight Gain Poor			
subjects affected / exposed	1 / 4018 (0.02%)	1 / 4016 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	No intervention	Nirsevimab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	279 / 4018 (6.94%)	324 / 4016 (8.07%)	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	279 / 4018 (6.94%)	324 / 4016 (8.07%)	
occurrences (all)	298	345	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 July 2023	The purpose of this amendment was to extend the follow-up of HARMONIE participants to 24 months as a result of a post-marketing commitment to the United States Food and Drug Administration to collect data for the evaluation of antibody-dependent enhancement of RSV disease in the second RSV season of neonates and infants who received nirsevimab prior to or during their first RSV season. The HARMONIE study design was updated with the addition of a 12-month follow-up period, including 2 phone calls at Day 546 and Day 731 post-dosing/randomization, in UK participants only. The 12-month extension period was also used as the opportunity to retrospectively collect information on wheeze at Day 366 and Day 731 post-dosing/randomization in UK reconsented participants only.
01 February 2024	The objectives of this amendment were to extend the time window for signing the addendum to the Inform Consent Form for UK's participants, to add routine immunization with Beyfortus® as reportable concomitant medications, to clarify the data collection during the 12-month extension period in case of wheeze (including any concomitant medications during wheezing episodes) for UK reconsented participants.
05 February 2024	The objective of this amendment was to clarify the definition of a wheezing episode.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported