Clinical trial results:
A Phase 2, Double-blind, Placebo-controlled Study to Evaluate the Antiviral Activity, Clinical Outcomes, Safety, Tolerability, and Pharmacokinetic/Pharmacodynamic Relationships of Different Doses of JNJ-53718678 in Children 28 Days and 3 Years of Age With Acute Respiratory Tract Infection Due to Respiratory Syncytial Virus Infection

Summary

EudraCT number	2016-003642-93
Trial protocol	GB BE ES HU SE FR DE PL BG Outside EU/EEA IT
Global end of trial date	18 April 2022

Results information

Result version number	v1
This version publication date	03 November 2022
First version publication date	03 November 2022

Trial information

Trial identification

Sponsor protocol code	53718678RSV2002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03656510
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001838-PIP01-15
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 April 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to establish antiviral activity of JNJ-53718678 as measured by respiratory syncytial virus (RSV) viral load in nasal swab samples by a quantitative reverse transcription polymerase chain reaction (qRT-PCR) assay in children greater than or equal to (>=) 28 days and less than or equal to (<=) 3 years of age with RSV disease.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 16
Country: Number of subjects enrolled	Bulgaria: 24
Country: Number of subjects enrolled	Brazil: 26
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Spain: 65
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	Hungary: 13
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Japan: 39
Country: Number of subjects enrolled	Korea, Republic of: 2
Country: Number of subjects enrolled	Mexico: 3
Country: Number of subjects enrolled	Malaysia: 12
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	Thailand: 10
Country: Number of subjects enrolled	Turkey: 4
Country: Number of subjects enrolled	Taiwan: 12
Country: Number of subjects enrolled	United States: 4

Country: Number of subjects enrolled	South Africa: 1
Worldwide total number of subjects	246
EEA total number of subjects	113

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	215
Children (2-11 years)	31
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: -

Pre-assignment

Screening details:

A total of 246 subjects were enrolled in the study and received JNJ-53718678 or placebo. Out of 246 subjects, 242 subjects completed the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Placebo

Arm description:

Subjects of age groups (age group 1: greater than or equal to [>=] 28 days to less than [<] 3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to less than or equal to [<=3] years), who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to JNJ-53718678 orally once daily for 7 days.

Arm title	Cohort 1: JNJ-53718678 Low Dose

Arm description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 1.7 milligrams per kilogram (mg/kg) for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	JNJ-53718678
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-53718678 low dose, orally once daily for 7 days.

Arm title	Cohort 1: JNJ-53718678 High Dose

Arm description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	JNJ-53718678
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-53718678 high dose, orally once daily for 7 days.

Arm title	Cohort 2: Placebo

Arm description:

As per the original dosing, outpatient of age groups (age group 1: >=28 days to <3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to <=3 years) were randomised to receive placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days. After Protocol amendment 4, subjects received placebo matching to JNJ-53718678 orally twice daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to JNJ-53718678 orally once daily for 7 days. After Protocol amendment 4, subjects were randomised to receive placebo matching to JNJ-53718678 orally twice daily for 7 days.

Arm title	Cohort 2: JNJ-53718678 Low Dose

Arm description:

As per the original dosing, outpatients were randomised to receive JNJ-53718678 1.7 mg/kg for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 0.85 mg/kg for age group 1, JNJ-53718678 1.0 mg/kg for age group 2, and JNJ-53718678 1.5 mg/kg for age group 3, orally twice daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	JNJ-53718678
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-53718678 low dose, orally once daily for 7 days. After protocol amendment 4, subjects received JNJ-53718678 low doses, orally twice daily for 7 days.

Arm title	Cohort 2: JNJ-53718678 High Dose

Arm description:

As per the original dosing, outpatient were randomised to receive JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 2.5 mg/kg for age group 1, JNJ-53718678 3.0 mg/kg for age group 2, and JNJ-53718678 4.5 mg/kg for age group 3, orally twice daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	JNJ-53718678
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-53718678 high dose, orally once daily for 7 days. After protocol amendment 4, subjects received JNJ-53718678 high doses, orally twice daily for 7 days.

Number of subjects in period 1	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose
Started	50	49	48
Completed	48	48	48
Not completed	2	1	0
Consent withdrawn by subject	1	1	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort 2: Placebo	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose
Started	34	34	31
Completed	33	34	31
Not completed	1	0	0
Consent withdrawn by subject	1	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1: Placebo
Reporting group description:	
Subjects of age groups (age group 1: greater than or equal to [>=] 28 days to less than [<] 3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to less than or equal to [<=3] years), who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days.	
Reporting group title	Cohort 1: JNJ-53718678 Low Dose
Reporting group description:	
Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 1.7 milligrams per kilogram (mg/kg) for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.	
Reporting group title	Cohort 1: JNJ-53718678 High Dose
Reporting group description:	
Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.	
Reporting group title	Cohort 2: Placebo
Reporting group description:	
As per the original dosing, outpatient of age groups (age group 1: >=28 days to <3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to <=3 years) were randomised to receive placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days. After Protocol amendment 4, subjects received placebo matching to JNJ-53718678 orally twice daily for 7 days.	
Reporting group title	Cohort 2: JNJ-53718678 Low Dose
Reporting group description:	
As per the original dosing, outpatients were randomised to receive JNJ-53718678 1.7 mg/kg for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 0.85 mg/kg for age group 1, JNJ-53718678 1.0 mg/kg for age group 2, and JNJ-53718678 1.5 mg/kg for age group 3, orally twice daily for 7 days.	
Reporting group title	Cohort 2: JNJ-53718678 High Dose
Reporting group description:	
As per the original dosing, outpatient were randomised to receive JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 2.5 mg/kg for age group 1, JNJ-53718678 3.0 mg/kg for age group 2, and JNJ-53718678 4.5 mg/kg for age group 3, orally twice daily for 7 days.	

Reporting group values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose
Number of subjects	50	49	48
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	47	45	45
Children (2-11 years)	3	4	3

Age continuous			
Units: months			
arithmetic mean	8.4	8.6	8.5
standard deviation	± 8.59	± 8.74	± 8.21
Sex: Female, Male			
Units: Subjects			
Female	23	20	23
Male	27	29	25

Reporting group values	Cohort 2: Placebo	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose
Number of subjects	34	34	31
Age categorical			
Units: Subjects			
Infants and toddlers (28 days-23 months)	27	26	25
Children (2-11 years)	7	8	6
Age continuous			
Units: months			
arithmetic mean	13.8	14.8	17.2
standard deviation	± 10.31	± 10.9	± 8.81
Sex: Female, Male			
Units: Subjects			
Female	13	8	14
Male	21	26	17

Reporting group values	Total		
Number of subjects	246		
Age categorical			
Units: Subjects			
Infants and toddlers (28 days-23 months)	215		
Children (2-11 years)	31		
Age continuous			
Units: months			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Subjects			
Female	101		
Male	145		

End points

End points reporting groups

Reporting group title	Cohort 1: Placebo

Reporting group description:

Subjects of age groups (age group 1: greater than or equal to [>=] 28 days to less than [<] 3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to less than or equal to [<=3] years), who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days.

Reporting group title	Cohort 1: JNJ-53718678 Low Dose

Reporting group description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 1.7 milligrams per kilogram (mg/kg) for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Reporting group title	Cohort 1: JNJ-53718678 High Dose

Reporting group description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Reporting group title	Cohort 2: Placebo

Reporting group description:

As per the original dosing, outpatient of age groups (age group 1: >=28 days to <3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to <=3 years) were randomised to receive placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days. After Protocol amendment 4, subjects received placebo matching to JNJ-53718678 orally twice daily for 7 days.

Reporting group title	Cohort 2: JNJ-53718678 Low Dose

Reporting group description:

As per the original dosing, outpatients were randomised to receive JNJ-53718678 1.7 mg/kg for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 0.85 mg/kg for age group 1, JNJ-53718678 1.0 mg/kg for age group 2, and JNJ-53718678 1.5 mg/kg for age group 3, orally twice daily for 7 days.

Reporting group title	Cohort 2: JNJ-53718678 High Dose

Reporting group description:

As per the original dosing, outpatient were randomised to receive JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 2.5 mg/kg for age group 1, JNJ-53718678 3.0 mg/kg for age group 2, and JNJ-53718678 4.5 mg/kg for age group 3, orally twice daily for 7 days.

Subject analysis set title	Cohorts 1 and 2: Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

As per the original dosing, subjects of age groups (age group 1: >=28 days to <3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to less than or equal to [<=3] years) were randomised to receive placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days in Cohorts 1 and 2. After protocol amendment 4, subjects in Cohort 2 were randomised to receive placebo matching to JNJ-53718678 orally twice daily for 7 days.

Subject analysis set title	Cohorts 1 and 2: JNJ-53718678 Low Dose
Subject analysis set type	Intention-to-treat

Subject analysis set description:

As per the original dosing, subjects were randomised to receive JNJ-53718678 1.7 mg/kg for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for

age group 3: >=6 months to <=3 years, orally once daily for 7 days in Cohorts 1 and 2. After protocol amendment 4, subjects in Cohort 2 were randomised to receive JNJ-53718678 0.85 mg/kg for age group 1, JNJ-53718678 1.0 mg/kg for age group 2, and JNJ-53718678 1.5 mg/kg for age group 3, orally twice daily for 7 days.

Subject analysis set title	Cohorts 1 and 2: JNJ-53718678 High Dose
Subject analysis set type	Intention-to-treat

Subject analysis set description:

As per the original dosing, subjects were randomised to receive JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days in Cohorts 1 and 2 . After protocol amendment 4, subjects in Cohort 2 were randomised to receive JNJ-53718678 2.5 mg/kg for age group 1, JNJ-53718678 3.0 mg/kg for age group 2, and JNJ-53718678 4.5 mg/kg for age group 3, orally twice daily for 7 days.

Primary: Respiratory Syncytial Virus (RSV) Viral Load Area Under Curve from Immediately Prior to First Dose of Study Drug Through Day 5 (AUC[Day5])

End point title	Respiratory Syncytial Virus (RSV) Viral Load Area Under Curve from Immediately Prior to First Dose of Study Drug Through Day 5 (AUC[Day5])[1]

End point description:

RSV viral load AUC from immediately prior to first dose of study drug through day 5 was determined. The RSV viral load was measured by quantitative reverse transcription polymerase chain reaction (qRT-PCR) assay in mid-turbinate nasal swab specimens. As planned, combined data for both the cohorts was collected, analysed and reported for this endpoint. Intent-To-Treat-infected (ITT-i) analysis set included all randomised subjects who received at least one dose of study drug and who had a centrally confirmed RSV RNA viral load of greater than or equal to (>=) 1 log10 copies/mL above the lower limit of quantification (LLOQ) of the RSV RT-qPCR assay at baseline. Analyses on the ITT-i set were performed as randomised.

End point type	Primary

End point timeframe:

Baseline through Day 5

Notes:

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

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: log10 copies*day per milliliter (mL)				
arithmetic mean (confidence interval 95%)	22.74 (21.677 to 23.800)	21.48 (20.402 to 22.566)	21.51 (20.374 to 22.650)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV Viral Load Over Time

End point title	RSV Viral Load Over Time

End point description:

RSV viral load actual values over time were measured by qRT-PCR in the nasal swab specimens collected at the clinic visits and at home. As planned, combined data for both the cohorts was collected,

analysed and reported for this endpoint. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14, and 21

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: log10 copies/mL				
arithmetic mean (standard deviation)				
Baseline (n=79, 80, 72)	6.913 (± 1.3449)	7.113 (± 1.3667)	7.004 (± 1.4709)	
Day 3 (n=77, 79, 71)	5.398 (± 1.5834)	5.432 (± 1.8952)	5.271 (± 1.7710)	
Day 5 (n=77, 77, 72)	4.146 (± 1.8508)	4.079 (± 1.8760)	3.883 (± 1.9815)	
Day 8 (n=78, 73,70)	2.604 (± 2.0857)	2.108 (± 1.8538)	2.078 (± 1.8319)	
Day 14 (n=73, 74, 67)	1.640 (± 1.9515)	1.636 (± 2.2221)	1.440 (± 1.8768)	
Day 21 (n=74, 78, 68)	1.150 (± 1.7752)	0.817 (± 1.5347)	0.810 (± 1.6699)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in RSV Viral Load Over Time

End point title	Change From Baseline in RSV Viral Load Over Time

End point description:

Change from baseline in RSV viral load over time was measured by qRT-PCR in the nasal swab specimens collected at the clinic visits and at home. As planned, combined data for both the cohorts was collected, analysed and reported for this endpoint. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline up to Days 3, 5, 8, 14, and 21

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: log10 copies/mL				
arithmetic mean (standard deviation)				
Day 3 (n=77, 79, 71)	-1.502 (± 1.3290)	-1.690 (± 1.6225)	1.694 (± 1.5134)	
Day 5 (n=77, 77, 72)	-2.754 (± 1.7699)	-3.049 (± 1.6493)	-3.121 (± 1.8453)	
Day 8 (n=78, 73, 70)	-4.308 (± 2.2435)	-5.017 (± 1.8563)	-4.948 (± 1.8428)	
Day 14 (n=73, 74, 67)	-5.292 (± 2.2968)	-5.471 (± 2.4289)	-5.578 (± 2.2707)	
Day 21 (n=74, 78, 68)	-5.801 (± 2.1652)	-6.302 (± 2.0439)	-6.268 (± 1.9394)	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV Viral Load AUC from Immediately Prior to First Dose of Study Drug (Baseline) Through Days 3, 8, and 14

End point title	RSV Viral Load AUC from Immediately Prior to First Dose of Study Drug (Baseline) Through Days 3, 8, and 14

End point description:

RSV viral load AUC from immediately prior to first dose of study drug (baseline) through Days 3, 8, and 14 was determined. Here,'99999' indicates that no subjects analyzed for this outcome measure at Day 14 due to the study termination. As planned, combined data for both the cohorts was analysed and reported for this endpoint. ITT-i analysis set included all randomized subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline through Days 3, 8, and 14

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: log10 copies*day/mL				
least squares mean (confidence interval 95%)				
Day 3 (n=79, 80, 72)	5.48 (5.129 to 5.834)	5.36 (5.009 to 5.717)	5.32 (4.949 to 5.695)	
Day 8 (n=79, 80, 72)	2.66 (2.307 to 3.011)	2.08 (1.716 to 2.444)	2.08 (1.701 to 2.450)	

Day 14 (n=0, 0, 0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Undetectable RSV Viral Load

End point title	Time to Undetectable RSV Viral Load

End point description:

Time to undetectable RSV viral load was defined as the time in hours from first dose of study drug to first post-baseline timepoint at which the virus is undetectable and after which no more detectable virus assessments. As planned, combined data for both the cohorts was analysed and reported for this endpoint. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: Hours				
median (confidence interval 95%)	467.0 (332.90 to 478.40)	428.3 (309.50 to 480.40)	330.7 (308.28 to 476.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Undetectable RSV Viral Load at Each Timepoint Throughout the Study

End point title	Percentage of Subjects with Undetectable RSV Viral Load at Each Timepoint Throughout the Study

End point description:

Percentage of subjects with undetectable RSV viral load at each timepoint throughout the study were reported. As planned, combined data for both the cohorts was analysed and reported for this endpoint. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analyzed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14 and 21

End point values	Cohorts 1 and 2: Placebo	Cohorts 1 and 2: JNJ-53718678 Low Dose	Cohorts 1 and 2: JNJ-53718678 High Dose	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	79	80	72	
Units: percentage of subjects				
number (not applicable)				
Baseline (n=79, 80, 72)	0	0	0	
Day 3 (n=77, 79, 71)	1.3	3.8	2.8	
Day 5 (n=77, 77, 72)	7.8	9.1	11.1	
Day 8 (n=78, 73, 70)	33.3	38.4	38.6	
Day 14 (n=73, 74, 67)	54.8	58.1	58.2	
Day 21 (n=74, 78, 68)	67.6	76.9	77.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Parent(s)/Caregiver(s) Pediatric RSV Electronic Severity and Outcomes Rating System (PRESORS) Scores

End point title	Change from Baseline in Parent(s)/Caregiver(s) Pediatric RSV Electronic Severity and Outcomes Rating System (PRESORS) Scores

End point description:

PRESORS is a questionnaire recording presence and severity of signs and symptoms of RSV disease (fever, cough, sputum, wheezing, difficulty breathing, nasal congestion, and feeding issues). PRESORS overall RSV symptoms summary parameter consisted of 12-items, each item score ranges from 0 to 3. A summary score was derived (mean of the item scores) which also ranges from 0 to 3. The higher the score, the worse the symptom. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline up to Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	44	32
Units: Units on a scale				
arithmetic mean (standard deviation)				

Day 3 (n=45, 40, 41, 25, 27, 26)	-0.51 (± 0.571)	-0.55 (± 0.618)	-0.70 (± 0.594)	-0.25 (± 0.576)
Day 5 (n=45, 41, 41, 28, 27, 26)	-0.91 (± 0.585)	-0.88 (± 0.542)	-1.11 (± 0.581)	-0.48 (± 576)
Day 8 (n=44, 41, 41, 28, 27, 26)	-1.15 (± 0.581)	-1.25 (± 0.537)	-1.39 (± 0.514)	-0.85 (± 0.526)
Day 14 (n=44, 39, 40, 28, 27, 26)	-1.40 (± 0.591)	-1.39 (± 0.582)	-1.59 (± 0.458)	-1.06 (± 0.529)
Day 21 (n=42, 40, 41, 28, 26, 26)	-1.41 (± 0.637)	-1.33 (± 0.559)	-1.56 (± 0.468)	-1.12 (± 0.529)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	28		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Day 3 (n=45, 40, 41, 25, 27, 26)	-0.15 (± 0.427)	-0.21 (± 0.537)		
Day 5 (n=45, 41, 41, 28, 27, 26)	-0.52 (± 0.558)	-0.58 (± 0.644)		
Day 8 (n=44, 41, 41, 28, 27, 26)	-0.83 (± 0.582)	-1.04 (± 0.628)		
Day 14 (n=44, 39, 40, 28, 27, 26)	-1.08 (± 0.568)	-1.24 (± 0.681)		
Day 21 (n=42, 40, 41, 28, 26, 26)	-1.15 (± 0.496)	-1.29 (± 0.596)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinician PRESORS Score

End point title	Change from Baseline in Clinician PRESORS Score

End point description:

Change from baseline in clinician (for concepts: activity level, sleep disturbance, breathing problems, retractions, tachypnea, feeding problem, cough, nasal secretions, wheezing, dehydration) PRESORS scores was reported. PRESORS is a questionnaire recording presence and severity of signs and symptoms of RSV disease and consisted of 10-items, each item score ranges from 0 to 3. Overall RSV symptoms summary parameter was derived (mean of the item scores) which also ranges from 0 to 3. The higher the score, the worse the symptom. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline up to Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	44	32
Units: Units on a scale				
arithmetic mean (standard deviation)				
Day 3 (n=43, 41, 42, 29, 29, 26)	-0.45 (± 0.441)	-0.45 (± 0.517)	-0.48 (± 0.469)	-0.25 (± 0.424)
Day 5 (n=42, 38, 41, 28, 28, 25)	-0.73 (± 0.582)	-0.71 (± 0.424)	-0.83 (± 0.483)	-0.38 (± 0.415)
Day 8 (n=41, 38, 38, 30, 29, 26)	-0.92 (± 0.461)	-1.04 (± 0.396)	-1.04 (± 0.449)	-0.71 (± 0.529)
Day 14 (n=40, 37, 34, 28, 27, 23)	-1.10 (± 0.466)	-1.11 (± 0.428)	-1.14 (± 0.369)	-0.81 (± 0.497)
Day 21 (n=45, 40, 33, 29, 28, 27)	-1.13 (± 0.424)	-1.12 (± 0.433)	-1.17 (± 0.336)	-0.87 (± 0.455)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	28		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Day 3 (n=43, 41, 42, 29, 29, 26)	-0.21 (± 0.378)	-0.29 (± 0.338)		
Day 5 (n=42, 38, 41, 28, 28, 25)	-0.37 (± 0.462)	-0.60 (± 0.516)		
Day 8 (n=41, 38, 38, 30, 29, 26)	-0.63 (± 0.423)	-0.85 (± 0.552)		
Day 14 (n=40, 37, 34, 28, 27, 23)	-0.77 (± 0.436)	-0.91 (± 0.541)		
Day 21 (n=45, 40, 33, 29, 28, 27)	-0.81 (± 0.411)	-0.93 (± 0.524)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Resolution of RSV Symptoms

End point title	Time to Resolution of RSV Symptoms

End point description:

Time to resolution from first dose of study drug until the first time of resolution of all RSV symptoms (breathing problems, retractions, tachypnea, breathing sounds, cough, tachycardia, nasal secretions, sleep disturbance, crying, illness behavior, feeding problems, and dehydration) were reported. Resolution occurs when all symptoms from the caregiver reported outcomes (ObsRO) are scored as none or mild (score of 0 or 1, respectively) for at least 24 hours. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	44	32
Units: Hours				
median (confidence interval 95%)	193.5 (161.80 to 243.80)	163.6 (108.70 to 198.70)	151.8 (114.70 to 223.70)	166.6 (141.50 to 207.20)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	28		
Units: Hours				
median (confidence interval 95%)	206.1 (159.20 to 232.80)	176.9 (148.30 to 264.20)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Improvement on Overall Health

End point title	Time to Improvement on Overall Health [2]

End point description:

Time to improvement based on general questions on overall health was reported. Time from first dose of study drug until first time status of improvement of RSV symptoms reported as "very much improved" or "much improved" based on response to question 'Would you say the child's RSV symptoms have improved, are about the same or are worse than when the child entered the study'. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	44	43	
Units: Hours				
median (confidence interval 95%)	189.6 (187.80 to 192.50)	190.2 (188.70 to 200.00)	189.1 (186.90 to 191.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects by Status of RSV Symptoms Based on PRESORS Caregiver (ObsRO) General Question Over Time

End point title	Percentage of Subjects by Status of RSV Symptoms Based on PRESORS Caregiver (ObsRO) General Question Over Time[3]

End point description:

Percentage of subjects by status of RSV symptoms based on PRESORS caregiver (ObsRO) general question over time were reported. PRESORS is a questionnaire recording presence and severity of signs and symptoms of RSV disease (fever, cough, sputum, wheezing, difficulty breathing, nasal congestion, and feeding issues). Status of RSV symptoms was assessed by a question (how would you rate the child's RSV symptoms now?) of PRESORS questionnnaire that range: 1) none, 2) very mild, 3) mild, 4) moderate, 5) severe, and 6) very severe. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14, and 21

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: percentage of subjects				
number (not applicable)				
Baseline: None (n=45,43,41)	0	0	0	
Baseline: Very mild (n=45,43,41)	0	0	2.4	
Baseline: Mild (n=45,43,41)	6.7	7.0	4.9	
Baseline: Moderate (n=45,43,41)	51.1	55.8	51.2	
Baseline: Severe (n=45,43,41)	37.8	27.9	41.5	
Baseline: Very severe (n=45,43,41)	4.4	9.3	0	
Day 3: None (n=47,43,44)	0	2.3	0	
Day 3: Very mild (n=47,43,44)	6.4	9.3	6.8	
Day 3: Mild (n=47,43,44)	23.4	18.6	36.4	
Day 3: Moderate (n=47,43,44)	46.8	48.8	43.2	
Day 3: Severe (n=47,43,44)	17.0	18.6	9.1	

Day 3: Very severe (n=47,43,44)	6.4	2.3	4.5	
Day 5: None (n=47,43,43)	2.1	0	7.0	
Day 5: Very mild (n=47,43,43)	23.4	23.3	16.3	
Day 5: Mild (n=47,43,43)	38.3	27.9	32.6	
Day 5: Moderate (n=47,43,43)	21.3	39.5	41.9	
Day 5: Severe (n=47,43,43)	10.6	9.3	2.3	
Day 5: Very severe (n=47,43,43)	4.3	0	0	
Day 8: None (n=46,43,42)	13.0	16.3	26.2	
Day 8: Very mild (n=46,43,42)	30.4	37.2	28.6	
Day 8: Mild (n=46,43,42)	34.8	23.3	28.6	
Day 8: Moderate (n=46,43,42)	17.4	23.3	16.7	
Day 8: Severe (n=46,43,42)	2.2	0	0	
Day 8: Very severe (n=46,43,42)	2.2	0	0	
Day 14: None (n=41,40,41)	48.8	55.0	58.5	
Day 14: Very mild (n=41,40,41)	36.6	30.0	26.8	
Day 14: Mild (n=41,40,41)	12.2	2.5	7.3	
Day 14: Moderate (n=41,40,41)	2.4	10.0	7.3	
Day 14: Severe (n=41,40,41)	0	2.5	0	
Day 14: Very severe (n=41,40,41)	0	0	0	
Day 21: None (n=27,37, 33)	66.7	67.6	57.6	
Day 21: Very mild (n=27,37, 33)	18.5	18.9	24.2	
Day 21: Mild (n=27,37, 33)	11.1	2.7	12.1	
Day 21: Moderate (n=27,37, 33)	3.7	8.1	6.1	
Day 21: Severe (n=27,37, 33)	0	2.7	0	
Day 21: Very severe (n=27,37, 33)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects by Health Status Assessment Based on PRESORS Caregiver (ObsRO) General Question Over Time

End point title	Percentage of Subjects by Health Status Assessment Based on PRESORS Caregiver (ObsRO) General Question Over Time[4]

End point description:

Percentage of subjects by health status assessment based on PRESORS caregiver (ObsRO) general question over time were reported. PRESORS is a questionnaire recording presence and severity of signs and symptoms of RSV disease (fever, cough, sputum, wheezing, difficulty breathing, nasal congestion, and feeding issues). Health status was assessed by a question (how is the child's health now) of PRESORS score that was categorized as : 1) excellent, 2) very good, 3) good, 4) fair, 5) poor, and 6) very poor. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14, and 21

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Percentage of subjects				
number (not applicable)				
Baseline: Excellent (n= 45, 44, 41)	0	2.3	0	
Baseline: Very good (n= 45, 44, 41)	0	4.7	0	
Baseline: Good (n= 45, 44, 41)	4.4	7.0	7.3	
Baseline: Fair (n= 45, 44, 41)	42.2	51.2	43.9	
Baseline: poor (n= 45, 44, 41)	48.9	30.2	48.8	
Baseline: Very poor (n= 45, 44, 41)	4.4	4.7	0	
Day 3: Excellent (n= 47, 44, 43)	0	0	0	
Day 3: Very good (n= 47, 44, 43)	8.5	9.3	2.3	
Day 3: Good (n= 47, 44, 43)	23.4	20.9	34.1	
Day 3: Fair (n= 47, 44, 43)	38.3	46.5	45.5	
Day 3: Poor (n= 47, 44, 43)	21.3	23.3	13.6	
Day 3: Very poor (n= 47, 44, 43)	8.5	0	4.5	
Day 5: Excellent (n= 47, 43, 43)	2.1	0	0	
Day 5: Very good (n= 47, 43, 43)	19.1	9.3	20.9	
Day 5: Good (n= 47, 43, 43)	23.4	41.9	37.2	
Day 5: Fair (n= 47, 43, 43)	36.2	39.5	34.9	
Day 5: Poor (n= 47, 43, 43)	12.8	9.3	7.0	
Day 5: Very poor (n= 47, 43, 43)	6.4	0	0	
Day 8: Excellent (n= 46, 43, 42)	13.0	9.3	16.7	
Day 8: Very Good (n= 46, 43, 42)	23.9	32.6	21.4	
Day 8: Good (n= 46, 43, 42)	32.6	32.6	38.1	
Day 8: Fair (n= 46, 43, 42)	23.9	25.6	21.4	
Day 8: Poor (n= 46, 43, 42)	4.3	0	2.4	
Day 8: Very poor (n= 46, 43, 42)	2.2	0	0	
Day 14: Excellent (n= 41, 40, 41)	24.4	42.5	43.9	
Day 14: Very good (n= 41, 40, 41)	43.9	47.5	36.6	
Day 14: Good (n= 41, 40, 41)	19.5	5.0	9.8	
Day 14: fair (n= 41, 40, 41)	9.8	5.0	7.3	
Day 14: Poor (n= 41, 40, 41)	2.4	0	2.4	
Day 14: Very poor (n= 41, 40, 41)	0	0	0	
Day 21: Excellent (n= 27,37, 33)	55.6	45.9	45.5	
Day 21: Very Good (n= 27,37, 33)	22.2	32.4	33.3	
Day 21: Good (n= 27,37, 33)	11.1	13.5	15.2	
Day 21: Fair (n= 27,37, 33)	11.1	5.4	6.1	
Day 21: Poor (n= 27,37, 33)	0	2.7	0	
Day 21: Very poor (n= 27,37, 33)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Worsening or Improvement Status of RSV Disease

End point title	Percentage of Subjects with Worsening or Improvement Status of RSV Disease[5]

End point description:

Percentage of subjects with worsening or improvement of RSV disease based on general questions on overall health was reported. Improvement was defined improvement of RSV symptoms reported as "very much improved, much improved, a little improved, about the same, a little worse, much worse, and very much worse" based on response to question 'Would you say the child's RSV symptoms have improved, are about the same or are worse than when the child entered the study'. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Days 14 and 21

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Percentage of subjects				
number (not applicable)				
Day 14: Very much improved (n=41, 40, 40)	58.5	57.5	67.5	
Day 14: Much improved (n=41, 40, 40)	34.1	40.0	30.0	
Day 14: A little improved (n=41, 40, 40)	7.3	2.5	2.5	
Day 14: About the same (n=41, 40, 40)	0	0	0	
Day 14: A little worse (n=41, 40, 40)	0	0	0	
Day 14: Much worse (n=41, 40, 40)	0	0	0	
Day 14: Very much worse (n=41, 40, 40)	0	0	0	
Day 21: Very much improved (n=27, 36, 32)	77.8	63.9	56.3	
Day 21: Much improved (n=27, 36, 32)	14.8	30.6	37.5	
Day 21: A little improved (n=27, 36, 32)	3.7	2.8	3.1	
Day 21: About the same (n=27, 36, 32)	3.7	2.8	3.1	
Day 21: A little worse (n=27, 36, 32)	0	0	0	
Day 21: Much worse (n=27, 36, 32)	0	0	0	
Day 21: Very much worse (n=27, 36, 32)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects by Return to Pre-RSV Disease Health Status Assessment Based on PRESORS Caregiver (ObsRO) General Question Over Time

End point title	Percentage of Subjects by Return to Pre-RSV Disease Health Status Assessment Based on PRESORS Caregiver (ObsRO) General Question Over Time[6]

End point description:

Percentage of subjects by return to pre-RSV disease health status assessment based on PRESORS caregiver (ObsRO) general question over time was assessed by a question (Has the child's health returned to normal [how it was before RSV?]) of PRESORS score that was categorized as: 1) No, and 2) Yes. PRESORS is a questionnaire recording presence and severity of signs and symptoms of RSV disease. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'n' (number analysed) represent number of subjects evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14, and 21

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: percentage of subjects				
number (not applicable)				
Baseline (n=11, 4,9)	0	0	0	
Day 3 (n=39, 35, 32)	15.4	8.6	28.1	
Day 5 (n=42, 37, 39)	23.8	16.2	25.6	
Day 8 (n= 40, 38, 34)	37.5	44.7	58.8	
Day 14 (n=29, 36, 32)	72.4	77.8	84.4	
Day 21 (n=27, 36, 32)	81.5	86.1	84.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Respiratory Rate Over Time

End point title	Respiratory Rate Over Time

End point description:

Respiratory rate was measured by the investigator over time. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analyzed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analyzed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Breaths/minute				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 34, 34, 31)	45.0 (± 10.60)	45.6 (± 11.82)	45.7 (± 10.85)	41.3 (± 13.66)
Day 3 (n=48, 48, 48, 33, 34, 31)	44.1 (± 11.44)	41.8 (± 10.13)	42.7 (± 10.04)	37.9 (± 10.16)
Day 5 (n=47, 45, 46, 33, 34, 31)	38.3 (± 9.36)	38.1 (± 9.57)	39.1 (± 8.81)	38.2 (± 13.37)
Day 8 (n=47, 44, 46, 32, 34, 31)	35.5 (± 7.90)	34.4 (± 7.87)	39.2 (± 9.45)	37.4 (± 11.70)
Day 14 (n=47, 45, 46, 30, 32, 29)	35.6 (± 7.13)	34.9 (± 8.89)	35.2 (± 7.45)	35.7 (± 9.27)
Day 21 (n=46, 48, 44, 31, 34, 31)	36.07 (± 10.21)	34.9 (± 8.96)	36.6 (± 7.43)	36.4 (± 9.61)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Breaths/minute				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 34, 34, 31)	41.3 (± 11.76)	37.0 (± 8.77)		
Day 3 (n=48, 48, 48, 33, 34, 31)	37.3 (± 9.54)	34.4 (± 9.19)		
Day 5 (n=47, 45, 46, 33, 34, 31)	38.1 (± 8.89)	35.4 (± 9.53)		
Day 8 (n=47, 44, 46, 32, 34, 31)	36.9 (± 9.75)	34.0 (± 10.54)		
Day 14 (n=47, 45, 46, 30, 32, 29)	35.6 (± 10.53)	32.6 (± 8.38)		
Day 21 (n=46, 48, 44, 31, 34, 31)	35.5 (± 9.65)	34.7 (± 11.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Respiratory Rate

End point title	Change from Baseline in Respiratory Rate

End point description:

Change from baseline in respiratory rate was derived based on the reported measurements of respiratory rate over time. The respiratory rate over time was reported by the investigator. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analyzed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analyzed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline to Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Breaths/minute				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 31)	-0.8 (± 10.88)	-3.5 (± 11.99)	-3.0 (± 12.43)	-3.7 (± 12.47)
Day 5 (n=47, 45, 46, 33, 34, 31)	-6.5 (± 9.41)	-7.1 (± 11.13)	-7.0 (± 11.94)	-3.4 (± 8.59)
Day 8 (n=47,44, 46, 32, 34, 31)	-9.4 (± 9.19)	-11.4 (± 12.96)	-6.3 (± 12.69)	-4.4 (± 11.56)
Day 14 (n=47, 45, 46, 30, 32, 29)	-9.3 (± 9.96)	-10.3 (± 12.59)	-10.2 (± 10.92)	-6.4 (± 3.13)
Day 21 (n=46, 48, 44, 31, 34, 31)	-8.4 (± 10.84)	-10.4 (± 13.01)	-9.8 (± 12.36)	-5.5 (± 14.15)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Breaths/minute				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 31)	-4.0 (± 9.54)	-2.6 (± 9.20)		
Day 5 (n=47, 45, 46, 33, 34, 31)	-3.3 (± 8.40)	-1.5 (± 9.62)		
Day 8 (n=47,44, 46, 32, 34, 31)	-4.4 (± 10.39)	-2.9 (± 10.54)		
Day 14 (n=47, 45, 46, 30, 32, 29)	-5.8 (± 12.82)	-4.0 (± 9.92)		
Day 21 (n=46, 48, 44, 31, 34, 31)	-5.8 (± 11.95)	-2.3 (± 13.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Heart Rate Over Time

End point title	Heart Rate Over Time

End point description:

Heart rate was measured by the investigator over time. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analyzed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analyzed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Beats/minute				
arithmetic mean (standard deviation)				
Baseline (n=50,49,48,34, 34, 31)	143.2 (± 17.40)	138.9 (± 17.57)	139.0 (± 18.57)	131.2 (± 24.28)
Day 3 (n=48, 48, 38, 33, 34, 31)	138.8 (± 16.82)	137.5 (± 18.25)	138.5 (± 17.06)	127.8 (± 20.99)
Day 5 (n=47, 46, 47, 33, 34, 31)	136.0 (± 15.81)	132.7 (± 18.28)	16.1 (± 19.68)	119.2 (± 14.75)
Day 8 (n=48, 44, 46, 32, 34, 31)	133.3 (± 17.59)	127.9 (± 18.13)	134.0 (± 19.14)	118.7 (± 20.25)
Day 14 (n=47, 45, 46, 30, 32, 29)	131.7 (± 19.81)	132.4 (± 19.33)	134.4 (± 20.70)	117.4 (± 18.17)
Day 21 (n=46, 48, 44, 31, 34, 31)	128.2 (± 20.27)	131.5 (± 15.74)	132.5 (± 19.14)	117.2 (± 22.56)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Beats/minute				
arithmetic mean (standard deviation)				
Baseline (n=50,49,48,34, 34, 31)	135.6 (± 19.35)	126.1 (± 22.55)		
Day 3 (n=48, 48, 38, 33, 34, 31)	128.3 (± 17.97)	118.8 (± 28.10)		
Day 5 (n=47, 46, 47, 33, 34, 31)	122.6 (± 19.85)	120.4 (± 23.31)		
Day 8 (n=48, 44, 46, 32, 34, 31)	120.0 (± 19.61)	118.9 (± 27.04)		
Day 14 (n=47, 45, 46, 30, 32, 29)	118.0 (± 19.17)	115.2 (± 18.82)		
Day 21 (n=46, 48, 44, 31, 34, 31)	125.3 (± 20.95)	115.2 (± 19.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Heart Rate

End point title	Change from Baseline in Heart Rate

End point description:

Change from baseline in heart rate was reported. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analyzed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analyzed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline to Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Beats/minute				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 31)	-4.9 (± 19.36)	-1.6 (± 19.82)	-0.6 (± 18.84)	-3.0 (± 24.71)
Day 5 (n=47, 46, 47, 33, 34, 31)	-7.9 (± 20.31)	-5.8 (± 22.94)	-2.9 (± 20.56)	-11.6 (± 18.55)
Day 8 (n=48,44, 46, 32, 34, 31)	-10.4 (± 18.45)	-12.2 (± 23.20)	-5.2 (± 22.02)	-12.7 (± 26.09)
Day 14 (n=47, 45, 46, 30, 32, 29)	-12.0 (± 21.79)	-6.5 (± 23.99)	-5.1 (± 22.44)	-14.4 (± 24.62)
Day 21 (n=46, 48, 44, 31, 34, 31)	-15.0 (± 23.80)	-7.7 (± 25.88)	-6.5 (± 19.52)	-14.0 (± 25.38)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Beats/minute				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 31)	-7.4 (± 16.83)	-7.3 (± 28.39)		
Day 5 (n=47, 46, 47, 33, 34, 31)	-13.0 (± 17.11)	-5.6 (± 28.53)		
Day 8 (n=48,44, 46, 32, 34, 31)	-15.6 (± 20.67)	-7.2 (± 35.90)		
Day 14 (n=47, 45, 46, 30, 32, 29)	-17.7 (± 17.69)	-10.1 (± 28.02)		
Day 21 (n=46, 48, 44, 31, 34, 31)	-10.4 (± 21.02)	-10.9 (± 28.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Body Temperature Over Time

End point title	Body Temperature Over Time

End point description:

Body temperature was reported over time (either investigator or caregiver measured). The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomized treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Degree celsius				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 34, 34, 31)	36.84 (± 0.635)	36.64 (± 0.468)	36.82 (± 0.623)	36.84 (± 0.613)
Day 3 (n=48, 48, 48, 34, 34, 31)	36.77 (± 0.464)	36.87 (± 0.524)	36.80 (± 0.601)	37.14 (± 0.725)
Day 5 (n=49, 48, 48, 33, 34, 31)	36.75 (± 0.407)	36.54 (± 0.557)	36.70 (± 0.408)	36.87 (± 0.567)
Day 8 (n=48, 47, 48, 33, 34, 31)	36.70 (± 0.416)	36.73 (± 0.513)	36.65 (± 0.441)	36.67 (± 0.369)
Day 14 (n=47, 45, 47, 33, 34, 31)	36.86 (± 0.315)	36.68 (± 0.440)	36.60 (± 0.396)	36.63 (± 0.357)
Day 21 (n=47, 48, 47, 33, 34, 31)	36.76 (± 0.577)	36.67 (± 0.407)	36.66 (± 0.573)	36.74 (± 0.615)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Degree celsius				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 34, 34, 31)	36.94 (± 0.845)	36.79 (± 0.785)		
Day 3 (n=48, 48, 48, 34, 34, 31)	37.20 (± 0.694)	36.98 (± 0.817)		
Day 5 (n=49, 48, 48, 33, 34, 31)	36.71 (± 0.348)	36.84 (± 0.718)		
Day 8 (n=48, 47, 48, 33, 34, 31)	36.76 (± 0.536)	36.74 (± 0.559)		
Day 14 (n=47, 45, 47, 33, 34, 31)	36.72 (± 0.364)	36.59 (± 0.377)		
Day 21 (n=47, 48, 47, 33, 34, 31)	36.64 (± 0.292)	36.62 (± 0.418)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Body Temperature

End point title	Change from Baseline in Body Temperature

End point description:

Change from baseline in body temperature (either investigator or caregiver measured) was assessed. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable for the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline to Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Degree celsius				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 30)	-0.08 (± 0.697)	0.23 (± 0.541)	-0.02 (± 0.629)	0.33 (± 0.768)
Day 5 (n=49, 48, 48, 33, 34, 30)	-0.10 (± 0.713)	-0.09 (± 0.532)	-0.12 (± 0.627)	0.07 (± 0.700)
Day 8 (n=48, 47, 48, 33, 34, 30)	-0.13 (± 0.659)	0.10 (± 0.600)	-0.17 (± 0.596)	-0.13 (± 0.588)
Day 14 (n=47, 45, 47, 33, 34, 30)	0.01 (± 0.594)	0.04 (± 0.528)	-0.21 (± 0.609)	-0.17 (± 0.687)
Day 21 (n=47, 48, 47, 33, 34, 30)	-0.09 (± 0.758)	0.03 (± 0.519)	-0.17 (± 0.724)	-0.06 (± 0.704)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Degree celsius				
arithmetic mean (standard deviation)				
Day 3 (n=48, 48, 48, 33, 34, 30)	0.26 (± 0.835)	0.21 (± 0.724)		
Day 5 (n=49, 48, 48, 33, 34, 30)	-0.22 (± 0.767)	-0.04 (± 0.627)		
Day 8 (n=48, 47, 48, 33, 34, 30)	-0.17 (± 1.016)	-0.11 (± 0.772)		
Day 14 (n=47, 45, 47, 33, 34, 30)	-0.21 (± 0.866)	-0.19 (± 0.843)		
Day 21 (n=47, 48, 47, 33, 34, 30)	-0.30 (± 0.826)	-0.18 (± 0.913)		

Statistical analyses

No statistical analyses for this end point

Secondary: Peripheral Capillary Oxygen Saturation (SpO2) Over Time

End point title	Peripheral Capillary Oxygen Saturation (SpO2) Over Time

End point description:

Peripheral capillary oxygen saturation was measured by the investigator over time. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 14 and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Percentage of SpO2				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 32, 32, 30)	97.3 (± 2.47)	96.5 (± 3.44)	96.6 (± 2.10)	96.8 (± 2.07)
Day 3 (n=47,48, 48, 31, 32, 29)	96.8 (± 2.46)	96.3 (± 2.72)	96.0 (± 2.43)	96.9 (± 1.77)
Day 5 (n=47,46, 47, 32, 32, 30)	97.3 (± 1.67)	96.8 (± 3.74)	96.7 (± 2.25)	96.9 (± 1.68)
Day 8 (n=46, 44, 46, 30, 32, 30)	97.3 (± 1.99)	97.3 (± 2.47)	97.5 (± 1.74)	97.8 (± 1.48)
Day 14 (n=44, 43, 45, 29, 29, 28)	98.1 (± 1.42)	98.3 (± 1.84)	98.1 (± 1.64)	98.6 (± 2.03)
Day 21 (n=45, 47, 43, 30, 32, 30)	98.4 (± 1.47)	98.2 (± 1.80)	98.0 (± 2.12)	98.5 (± 1.74)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Percentage of SpO2				
arithmetic mean (standard deviation)				
Baseline (n=50, 49, 48, 32, 32, 30)	96.7 (± 1.91)	95.9 (± 2.92)		
Day 3 (n=47,48, 48, 31, 32, 29)	96.3 (± 3.12)	96.5 (± 2.96)		
Day 5 (n=47,46, 47, 32, 32, 30)	97.1 (± 2.12)	97.1 (± 2.43)		
Day 8 (n=46, 44, 46, 30, 32, 30)	97.4 (± 2.69)	97.9 (± 1.83)		
Day 14 (n=44, 43, 45, 29, 29, 28)	98.6 (± 1.53)	98.4 (± 1.73)		
Day 21 (n=45, 47, 43, 30, 32, 30)	98.7 (± 1.36)	98.9 (± 1.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Peripheral Capillary Oxygen Saturation (SpO2)

End point title	Change from Baseline in Peripheral Capillary Oxygen Saturation (SpO2)

End point description:

Change from baseline in peripheral capillary oxygen saturation levels was derived based on reported values over time. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline to Days 3, 5, 8, 14, and 21

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Percentage of SpO2				
arithmetic mean (standard deviation)				
Day 3 (n=47, 48, 48, 31, 32, 29)	-0.5 (± 2.93)	-0.2 (± 3.09)	-0.6 (± 2.72)	0.2 (± 2.31)
Day 5 (n=47, 46, 47, 31, 32, 30)	0.0 (± 2.92)	0.4 (± 2.93)	0.1 (± 2.38)	0.1 (± 2.49)
Day 8 (n=46, 44, 46, 30, 32, 30)	0.1 (± 3.02)	0.9 (± 3.53)	0.8 (± 2.47)	0.9 (± 2.59)
Day 14 (n=44, 43, 45, 29, 29, 28)	1.0 (± 2.28)	1.7 (± 3.08)	1.4 (± 2.32)	2.0 (± 2.72)
Day 21 (n=45, 47, 43, 29, 32, 30)	1.1 (± 2.45)	1.7 (± 3.38)	1.3 (± 2.40)	1.8 (± 2.57)

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Percentage of SpO2				
arithmetic mean (standard deviation)				
Day 3 (n=47, 48, 48, 31, 32, 29)	-0.4 (± 2.45)	0.7 (± 1.63)		
Day 5 (n=47, 46, 47, 31, 32, 30)	0.4 (± 2.41)	1.2 (± 2.54)		
Day 8 (n=46, 44, 46, 30, 32, 30)	0.8 (± 2.86)	2.0 (± 3.36)		
Day 14 (n=44, 43, 45, 29, 29, 28)	1.8 (± 2.05)	2.6 (± 3.06)		
Day 21 (n=45, 47, 43, 29, 32, 30)	2.0 (± 2.12)	3.0 (± 2.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Require (re)Hospitalization During Treatment and Follow-up

End point title	Percentage of Subjects who Require (re)Hospitalization During Treatment and Follow-up

End point description:

Percentage of subjects who require (re)hospitalization during treatment and follow-up was assessed. Percentage of subjects requiring re-hospitalization following the initial hospital discharge was assessed in Cohort 1 subjects (hospitalized cohort) whilst percentage of subjects requiring hospitalization after

first dose of study drug was assessed in Cohort 2 subjects (outpatient cohort). ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	47	44	32
Units: percentage of subjects				
number (not applicable)	6.4	4.3	2.3	6.3

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	28		
Units: percentage of subjects				
number (not applicable)	6.1	14.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Time to Return to Age-adjusted Normal Values for Vital Signs

End point title	Cohort 1: Time to Return to Age-adjusted Normal Values for Vital Signs [7]

End point description:

Time to return to age-adjusted normal values from first dose of study drug based on the reported vital signs (respiratory rate, heart rate, SpO2 >=92%, and SpO2 >=95%) values were assessed . ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 28

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Hours				
median (confidence interval 95%)				
Respiratory Rate (n=47, 47, 44)	13.6 (0.001 to 70.10)	20.0 (0.001 to 43.50)	30.2 (0.001 to 84.50)	
Heart Rate (n=47, 47, 44)	37.3 (0.001 to 51.50)	17.0 (0.001 to 67.50)	10.2 (0.001 to 160.50)	
SpO2 >=92% on Room Air (n=47, 47, 44)	65.4 (30.30 to 95.10)	86.6 (45.30 to 119.20)	68.9 (42.40 to 105.50)	
SpO2 >=95% on Room Air (n=47, 47, 44)	71.3 (47.70 to 99.30)	87.0 (47.80 to 120.00)	92.5 (48.50 to 141.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Time to Discharge From Hospital

End point title	Cohort 1: Time to Discharge From Hospital[8]

End point description:

Time to discharge from hospital was derived from the reported discharge date/time and from first dose date/time. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 28

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Hours				
median (confidence interval 95%)	96.2 (88.80 to 118.00)	95.3 (67.20 to 140.30)	96.2 (72.10 to 144.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Required Admission to the Intensive Care Unit (ICU)

End point title	Cohort 1: Percentage of Subjects who Required Admission to

	the Intensive Care Unit (ICU) [9]

End point description:

Percentage of subjects who required admission to the ICU were reported. This endpoint is applicable for those subjects that were not in ICU before first dose of study drug. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	42	44	39	
Units: Percentage of subjects				
number (not applicable)	2.4	4.5	2.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Duration of ICU Stay

End point title	Cohort 1: Duration of ICU Stay[10]

End point description:

Duration of ICU stay was derived based on the reported admission/discharge date/times for ICU. Duration defined as total number of hours a subject was in ICU from first dose of study drug until study termination. ITT-i analysis set included all randomised subjects who were admitted to ICU and received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	5	6	
Units: Hours				
arithmetic mean (standard deviation)	238.22 (± 70.570)	206.94 (± 204.940)	127.72 (± 89.389)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Time to Clinical Stability Evaluated by the Investigator

End point title	Cohort 1: Time to Clinical Stability Evaluated by the Investigator[11]

End point description:

Time to clinical stability was derived based on the vitals signs assessments and supplementation end dates as collected. Time to clinical stability is defined as time from initiation of study treatment until time at which following criteria are met: Time to return to age-adjusted normal value for otherwise healthy and pre-RSV infection status for subjects with risk factor for severe RSV disease, no more oxygen supplementation or otherwise healthy subjects and with risk factor for severe RSV disease and no more IV/nasogastric tube feeding/hydration in otherwise healthy subjects or return to pre-RSV status of IV/nasogastric tube feeding/hydration in subjects with risk factor for severe RSV disease for Cohort 1 only. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Hours				
median (confidence interval 95%)				
SpO2 >=92% on Room Air(n=47,47,44)	95.8 (63.50 to 165.80)	123.3 (82.00 to 169.10)	176.5 (77.80 to 309.50)	
SpO2 >=95% on Room Air(n=47,47,44)	95.8 (71.20 to 165.90)	134.8 (82.00 to 311.50)	180.5 (85.70 to 315.40)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Required Supplemental Oxygen

End point title	Cohort 1: Percentage of Subjects who Required Supplemental Oxygen [12]

End point description:

Percentage of subjects who required supplemental oxygen after first dose of study drug was reported. This parameter is only for subjects that did not require oxygen supplementation before first dose of study drug. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	12	7	
Units: Percentage of subjects				
number (not applicable)	21.4	25.0	28.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Duration of Supplemental Oxygen

End point title	Cohort 1: Duration of Supplemental Oxygen [13]

End point description:

Duration of supplemental oxygen was assessed. Duration is defined as total number of hours a subject used supplemental oxygen from first dose of study drug until study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	38	38	
Units: Hours				
median (full range (min-max))	74.25 (1.0 to 337.3)	74.60 (0.2 to 573.5)	68.05 (1.2 to 348.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Required Non-invasive Mechanical Ventilation Support

End point title	Cohort 1: Percentage of Subjects who Required Non-invasive Mechanical Ventilation Support[14]

End point description:

Percentage of subjects who required non-invasive mechanical ventilation support (example: continuous positive airway pressure) after first dose of study drug was reported. This parameter is only for subjects that did not require non-invasive mechanical ventilation support before first dose of study drug (no score was assigned otherwise). ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	44	38	
Units: Percentage of subjects				
number (not applicable)	2.2	6.8	2.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Required Invasive Mechanical Ventilation Support

End point title	Cohort 1: Percentage of Subjects who Required Invasive Mechanical Ventilation Support[15]

End point description:

Percentage of subjects who required invasive mechanical ventilation support (example: endotracheal-mechanical ventilation) after first dose of study drug was reported. This parameter is only for subjects that did not require invasive mechanical ventilation support before first dose of study drug. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR

assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Percentage of subjects				
number (not applicable)	4.3	2.1	2.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Required Non-invasive Non-mechanical Ventilation Support

End point title	Cohort 1: Percentage of Subjects who Required Non-invasive Non-mechanical Ventilation Support[16]

End point description:

Percentage of subjects who required non-invasive non-mechanical ventilation support after first dose of study drug was reported. This parameter is only for subjects that did not require non-invasive non-mechanical ventilation support before first dose of study drug. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	14	11	
Units: Percentage of subjects				
number (not applicable)	31.3	35.7	45.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Duration of Non-invasive Ventilation Support

End point title	Cohort 1: Duration of Non-invasive Ventilation Support [17]

End point description:

Duration of non-invasive ventilation support was not analysed individually due to low number of subjects in some categories hence combined data for 'duration of non-invasive ventilation support' is reported in above endpoint "DURATION OF SUPPLEMENTAL OXYGEN". ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[18]	0[19]	0[20]	
Units: Hours				
median (full range (min-max))	(to)	(to)	(to)	

Notes:

[18] - This endpoint was not feasible to analyze individually due to low number of subjects.

[19] - This endpoint was not feasible to analyze individually due to low number of subjects.

[20] - This endpoint was not feasible to analyze individually due to low number of subjects.

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Duration of Invasive Ventilation Support

End point title	Cohort 1: Duration of Invasive Ventilation Support [21]

End point description:

Duration of invasive ventilation support was not analysed individually due to low number of subjects in some categories hence combined data for 'duration of invasive ventilation support' is reported in above outcome measure "duration of supplemental oxygen". ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[22]	0[23]	0[24]	
Units: Hours				
median (full range (min-max))	(to)	(to)	(to)	

Notes:

[22] - This endpoint was not analyzed individually due to low number of subjects.

[23] - This endpoint was not analyzed individually due to low number of subjects.

[24] - This endpoint was not analyzed individually due to low number of subjects.

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Time to End of Supplemental Oxygen up to 72 Hours From First Hospital Discharge

End point title	Cohort 1: Time to End of Supplemental Oxygen up to 72 Hours From First Hospital Discharge[25]

End point description:

Time to end of supplemental oxygen up to 72 hours from first hospital discharge was assessed. Time to end of supplemental oxygen is defined as time (hours) from first dose of study drug to last end date/time of any oxygen supplementation received, but within 72 hours following first hospital discharge. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised.

End point type	Secondary

End point timeframe:

Up to 72 hours from first hospital discharge

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	47	44	
Units: Hours				
median (confidence interval 95%)	58.1 (22.90 to 75.90)	57.9 (35.30 to 85.50)	63.0 (31.80 to 92.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Percentage of Subjects who Needed Hydration and/or Feeding by Intravenous (IV) Administration or Nasogastric Tube

End point title	Cohort 1: Percentage of Subjects who Needed Hydration and/or Feeding by Intravenous (IV) Administration or Nasogastric Tube[26]

End point description:

Percentage of subjects who needed hydration and/or feeding by IV Administration or nasogastric tube after the first dose of study drug was reported. This parameter is only for subjects who didn’t require supplemental feeding/hydration before first dose of study drug. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 28

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	32	26	
Units: percentage of subjects				
number (not applicable)	6.3	15.6	19.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Adverse Events

End point title	Percentage of Subjects with Adverse Events

End point description:

Percentage of subjects with adverse events was reported. An AE is any untoward medical occurrence in clinical study subjects administered a medicinal (investigational or non-investigational) product. An adverse event does not necessarily have a causal relationship with the intervention. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Percentage of subjects				
number (not applicable)	58.0	59.2	64.6	47.1

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Percentage of subjects				
number (not applicable)	58.8	41.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormal Laboratory Findings

End point title	Percentage of Subjects with Abnormal Laboratory Findings

End point description:

Percentage of subjects with abnormal laboratory findings (chemistry and hematology) worst toxicity grade were reported based on Division of Microbiology and Infectious Diseases (DMID) toxicity grading scale. DMID toxicity grades ranges from 1 to 4. Grade 1=mild: transient or mild discomfort (<48 hours); no medical intervention/therapy required. Grade 2 = moderate: no or minimal medical intervention/therapy required. Grade 3 = severe: medical intervention/therapy required, hospitalizations possible. Grade 4 = life-threatening or death. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints. Here, 99999 indicates no subjects identified as complying with the grade-level pre-defined criterion.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: percentage of subjects				
number (not applicable)				
Chemistry: ALT: Grade 1 (n=22, 27, 22, 32, 28, 29)	13.6	0	0	0
Chemistry: ALT: Grade 2 (n=22, 27, 22, 0, 0, 0)	0	0	4.5	99999
Chemistry: ALT: Grade 3 (n=22, 27, 22, 0, 0, 0)	4.5	0	0	99999
Chemistry: AST: Grade 1 (n=22, 25, 22, 31, 29, 30)	0	0	4.5	0
Chemistry: AST: Grade 3 (n=22, 25, 22, 0, 0, 0)	4.5	0	0	99999
Chemistry:Hyperbilirubinemia:G-2(n=37,37,34,0,0,0)	2.7	0	0	99999

Chemistry:Hyperglycemia:G-1(n=22,26,23,32,29,30)	13.6	0	4.3	6.3
Chemistry:Hyperkalemia:G-1(n=22,27,23,32,29,30)	59.1	22.2	39.1	21.9
Chemistry:Hyperkalemia:G-2(n=22,27,23,32,29,30)	0	0	4.3	3.1
Chemistry:Hyperkalemia:G-4(n=22, 27,23,0,0,0)	0	0	8.7	99999
Chemistry:Hypernatremia:G-2(n=22, 27,23,32,29,30)	4.5	3.7	0	3.1
Chemistry:Hypernatremia:G-3(n=22, 27,23,0,0,0)	4.5	0	0	99999
Chemistry:Hyperuricemia:G-1(n=22,27,23,0,0,0)	0	0	4.3	99999
Chemistry:Hypoglycemia:G-1(n=22,26,23,32,29,30)	4.5	0	4.3	6.3
Chemistry:Hypomagnesemia:G-1(n=22,27,23,32,29,30)	0	3.7	4.3	3.1
Chemistry:Hypomagnesemia:G-2(n=22,27,23,0,0,0)	0	0	4.3	99999
Chemistry:Hypomagnesemia:G-3(n=22,27,23,0,0,0)	0	0	4.3	99999
Chemistry:Hyponatremia:G-2(n=22, 27,23,32,29,30)	4.5	3.7	0	0
Hematology:ANC: G-1(n=37,35,36,33,33,28)	13.5	11.4	2.8	3.0
Hematology: ANC: G-3 (n=37,35,36,0,0,0)	0	2.9	0	99999
Hematology: APTT: Grade 1(n=9,10,15,1,3,3)	11.1	0	0	0
Hematology: Hemoglobin: Grade 1(n=38,36,35,0,0,0)	7.9	5.6	2.9	99999
Hematology: Hemoglobin: Grade 2(n=38,36,35,0,0,0)	2.6	2.8	0	99999
Hematology:Prothrombin Time:G-1(n=38,36,35,0,0,0)	0	10.0	0	99999
Hematology:Prothrombin Time:G-3(n=38,36,35,0,0,0)	11.1	0	6.7	99999
Chemistry:Hyperglycemia:G-2(n=0,0,0,32,29,30)	99999	99999	99999	0

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: percentage of subjects				
number (not applicable)				
Chemistry: ALT: Grade 1 (n=22, 27, 22, 32, 28, 29)	3.6	3.4		
Chemistry: ALT: Grade 2 (n=22, 27, 22, 0, 0, 0)	99999	99999		
Chemistry: ALT: Grade 3 (n=22, 27, 22, 0, 0, 0)	99999	99999		
Chemistry: AST: Grade 1 (n=22, 25, 22, 31, 29, 30)	0	3.3		
Chemistry: AST: Grade 3 (n=22, 25, 22, 0, 0, 0)	99999	99999		

Chemistry:Hyperbilirubinemia:G-2(n=37,37,34,0,0,0)	99999	99999		
Chemistry:Hyperglycemia:G-1(n=22,26,23,32,29,30)	3.4	10.0		
Chemistry:Hyperkalemia:G-1(n=22,27,23,32,29,30)	55.2	36.7		
Chemistry:Hyperkalemia:G-2(n=22,27,23,32,29,30)	3.4	3.3		
Chemistry:Hyperkalemia:G-4(n=22,27,23,0,0,0)	99999	99999		
Chemistry:Hypernatremia:G-2(n=22,27,23,32,29,30)	3.4	3.3		
Chemistry:Hypernatremia:G-3(n=22,27,23,0,0,0)	99999	99999		
Chemistry:Hyperuricemia:G-1(n=22,27,23,0,0,0)	99999	99999		
Chemistry:Hypoglycemia:G-1(n=22,26,23,32,29,30)	3.4	0		
Chemistry:Hypomagnesemia:G-1(n=22,27,23,32,29,30)	0	0		
Chemistry:Hypomagnesemia:G-2(n=22,27,23,0,0,0)	99999	99999		
Chemistry:Hypomagnesemia:G-3(n=22,27,23,0,0,0)	99999	99999		
Chemistry:Hyponatremia:G-2(n=22,27,23,32,29,30)	0	10.0		
Hematology:ANC: G-1(n=37,35,36,33,33,28)	9.1	0		
Hematology: ANC: G-3 (n=37,35,36,0,0,0)	99999	99999		
Hematology: APTT: Grade 1(n=9,10,15,1,3,3)	0	33.3		
Hematology: Hemoglobin: Grade 1(n=38,36,35,0,0,0)	99999	99999		
Hematology: Hemoglobin: Grade 2(n=38,36,35,0,0,0)	99999	99999		
Hematology:Prothrombin Time:G-1(n=38,36,35,0,0,0)	99999	99999		
Hematology:Prothrombin Time:G-3(n=38,36,35,0,0,0)	99999	99999		
Chemistry:Hyperglycemia:G-2(n=0,0,0,32,29,30)	0	3.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Abnormal Electrocardiograms (ECGs) Findings

End point title	Percentage of Subjects With Abnormal Electrocardiograms (ECGs) Findings

End point description:

Percentage of subjects with abnormal ECG (PR interval, RR interval, QT interval, QRS duration) findings was reported. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable at the specified categories (per ECG parameters).

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: percentage of subjects				
number (not applicable)				
QRS Duration: Abnormally High(n=49,48,48,33,33,31)	4.1	4.2	4.2	6.1
RR Interval: Abnormally Low(n=49,48,48,33,33,31)	12.2	8.3	12.5	21.2
PR Interval: Abnormally Low(n=49,48,48,33,33,31)	0	2.1	2.1	0
QT Interval: Abnormally Low(n=49,48,48,33,33,31)	2.0	4.2	2.1	3.0

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: percentage of subjects				
number (not applicable)				
QRS Duration: Abnormally High(n=49,48,48,33,33,31)	6.1	9.7		
RR Interval: Abnormally Low(n=49,48,48,33,33,31)	15.2	9.7		
PR Interval: Abnormally Low(n=49,48,48,33,33,31)	3.0	0		
QT Interval: Abnormally Low(n=49,48,48,33,33,31)	9.1	3.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Categorized Change from Baseline in ECG Parameters (QT/ QTc)

End point title	Percentage of Subjects with Categorized Change from Baseline in ECG Parameters (QT/ QTc)

End point description:

Percentage of subjects with categorized change from Baseline in ECG parameters (QT/ QTc interval) was assessed. Parameters for abnormal ECG findings were QT interval corrected for heart rate (QTc) according to Bazett's formula (QTcB) Interval ([450 milliseconds {ms}, 480 ms], [480 ms, 500 ms], and [more than 500 ms]), QTc according to Fridericia's formula (QTcF) Interval ([450 ms, 480 ms], [480 ms, 500 ms], and [more than 500 ms]), change from baseline for QTcB Interval ([30; 60] ms, and

greater than [>] 60 ms), and for QTcF Interval ([30; 60] ms, and >60 ms). The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable per ECG parameter.

End point type	Secondary

End point timeframe:

Baseline to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: Percentage of subjects				
number (not applicable)				
QT Interval:Normal QTc change(n=48,48,48,33,33,29)	66.7	70.8	68.8	66.7
QT Interval:Borderline QTc (n=48,48,48,33,33,29)	29.2	25.0	27.1	27.3
QT Interval:AbnormallyhighQTc(n=48,48,4	4.2	4.2	4.2	6.1
QTcB Interval:Normal QTc(n=48,48,48,33,33,29)	83.8	87.5	93.8	90.9
QTcB Interval:Borderline QTc(n=48,48,48,33,33,29)	14.6	12.5	6.3	9.1
QTcB: Abnormally high QTc(n=48,48,48,33,33,29)	2.1	0	0	0
QTcF Interval:Normal QTc(n=48,48,48,33,33,29)	81.3	83.3	83.3	90.9
QTcF Interval:Borderline QTc(n=48,48,48,33,33,29)	16.7	16.7	16.7	9.1
QTcF: Abnormally high QTc(n=48,48,48,33,33,29)	2.1	0	0	0

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: Percentage of subjects				
number (not applicable)				
QT Interval:Normal QTc change(n=48,48,48,33,33,29)	57.6	58.6		
QT Interval:Borderline QTc (n=48,48,48,33,33,29)	33.3	37.9		
QT Interval:AbnormallyhighQTc(n=48,48,4	9.1	3.4		
QTcB Interval:Normal QTc(n=48,48,48,33,33,29)	90.9	93.1		
QTcB Interval:Borderline QTc(n=48,48,48,33,33,29)	9.1	6.9		
QTcB: Abnormally high QTc(n=48,48,48,33,33,29)	0	0		

QTcF Interval:Normal QTc(n=48,48,48,33,33,29)	78.8	86.3		
QTcF Interval:Borderline QTc(n=48,48,48,33,33,29)	21.2	13.8		
QTcF: Abnormally high QTc(n=48,48,48,33,33,29)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vital Signs Abnormalities

End point title	Percentage of Subjects With Vital Signs Abnormalities

End point description:

Percentage of subjects with vital signs (systolic blood pressure [SBP], diastolic blood pressure [DBP], pulse rate, respiratory rate [RR], body temperature and SpO2) abnormalities (abnormally low [ABL] and abnormally high [ABH]) were reported. The Safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned. Here, 'n' (number analysed) represents number of subjects evaluable per vital signs parameter. Here, 99999 indicates no subjects identified as complying with the grade-level pre-defined criterion.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	48	34
Units: percentage of subjects				
number (not applicable)				
SBP:AbnormallyLow(n=49,48,48,33,34,31)	2.0	2.1	8.3	12.1
SBP:AbnormallyHigh(n=49,48,48,33,34,31)	42.9	45.8	35.4	18.2
DBP:AbnormallyLow(n=49,48,48,33,34,31)	8.2	18.8	25.0	15.2
DBP:AbnormallyHigh(n=49,48,48,33,34,31)	28.6	35.4	27.1	9.1
Pulse rate: Abnormally High(n=49,48,48,33,34,31)	30.6	27.1	27.1	12.1
Pulse rate: Abnormally Low(n=49,48,48,33,34,31)	0.0	2.1	0	6.1
RR:Abnormally High(n=49,48,48,34,34,31)	4.1	12.5	18.8	3.1
RR:Abnormally Low(n=49,48,48,0,0,0)	12.2	10.4	0.0	99999
Temperature: Abnormally High(n=49,48,48,34,34,31)	30.6	41.7	22.9	50.0
SpO2:Abnormally Low(n=49,48,48,32,32,30)	8.2	12.5	6.3	3.1

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	31		
Units: percentage of subjects				
number (not applicable)				
SBP:AbnormallyLow(n=49,48,48,33,34,31)	8.8	9.7		
SBP:AbnormallyHigh(n=49,48,48,33,34,31)	17.6	12.9		
DBP:AbnormallyLow(n=49,48,48,33,34,31)	2.9	0		
DBP:AbnormallyHigh(n=49,48,48,33,34,31)	17.6	6.5		
Pulse rate: Abnormally High(n=49,48,48,33,34,31)	20.6	16.1		
Pulse rate: Abnormally Low(n=49,48,48,33,34,31)	5.9	16.1		
RR:Abnormally High(n=49,48,48,34,34,31)	2.9	6.5		
RR:Abnormally Low(n=49,48,48,0,0,0)	99999	99999		
Temperature: Abnormally High(n=49,48,48,34,34,31)	52.9	54.8		
SpO2:Abnormally Low(n=49,48,48,32,32,30)	9.4	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve From Timepoint 0 Hours Until 24 Hours Post Dose (AUC[0-24 hours])

End point title	Area Under the Plasma Concentration-Time Curve From Timepoint 0 Hours Until 24 Hours Post Dose (AUC[0-24 hours])[27]

End point description:

AUC (0-24) is defined as area under the plasma concentration-time curve from timepoint 0 hours until 24 hours post dose. This endpoint was not analysed for Cohort 2 due to premature study termination. Pharmacokinetic (PK) analysis set included all subjects who received JNJ-53718678 and for whom at least one PK concentration was reported. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

0 to 24 hours post dose on Days 1 and 7

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	32		
Units: nanograms*hours per millilitre (ng*h/mL)				
arithmetic mean (standard deviation)				
>=28 days and <3 months: Day 1 (n=6,7)	6690 (± 1950)	20600 (± 3990)		
>=28 days and <3 months: Day 7 (n=6,7)	11400 (± 3930)	36000 (± 8140)		
>=3 months and <6 months: Day 1 (n=6,4)	5340 (± 2670)	23600 (± 12500)		
>=3 months and <6 months: Day 7 (n=6,4)	7370 (± 4270)	35000 (± 20100)		
>=6 months and <=3 years: Day 1 (n=11,17)	6910 (± 2900)	25000 (± 11600)		
>=6 months and <=3 years: Day 7 (n=11,17)	8160 (± 3950)	31000 (± 16300)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Plasma Concentration (Cmax) of JNJ-53718678

End point title	Maximum Plasma Concentration (Cmax) of JNJ-53718678[28]

End point description:

Cmax is the maximum plasma concentration of JNJ-53718678 estimated by population PK model. This endpoint was not analysed for Cohort 2 due to premature study termination. PK analysis set included all subjects who received JNJ-53718678 and for whom at least one PK concentration was reported. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Days 1 and 7

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	32		
Units: nanograms per millilitre (ng/mL)				
arithmetic mean (standard deviation)				
>=28 days and <3 months: Day 1 (n=6, 7)	531 (± 193)	1590 (± 345)		
>=28 days and <3 months: Day 7 (n=6, 7)	843 (± 255)	2550 (± 550)		
>=3 months and <6 months: Day 1 (n=6, 4)	497 (± 256)	2070 (± 1200)		

>=3 months and <6 months: Day 7 (n=6, 4)	691 (± 306)	2920 (± 1500)		
>=6 months and <=3 years: Day 1 (n=12, 18)	846 (± 268)	2720 (± 1040)		
>=6 months and <=3 years: Day 7 (n=11, 17)	1030 (± 310)	3560 (± 1330)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Plasma Concentration (Ctrough) of JNJ-53718678

End point title	Trough Plasma Concentration (Ctrough) of JNJ-53718678[29]

End point description:

Ctrough is the trough plasma concentration of JNJ-53718678 estimated by population PK model. This endpoint was not analysed for Cohort 2 due to premature study termination. PK analysis set included all subjects who received JNJ-53718678 and for whom at least one PK concentration was reported. Here, 'n' (number analysed) represents number of subjects evaluable at the specified timepoints.

End point type	Secondary

End point timeframe:

Days 1 and 7

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	32		
Units: ng/mL				
arithmetic mean (standard deviation)				
>=28 days and <3 months: Day 1 (n=6, 7)	64 (± 31.3)	167 (± 147)		
>=28 days and <3 months: Day 7 (n=6, 7)	267 (± 111)	885 (± 239)		
>=3 months and <6 months: Day 1 (n=6, 4)	55.5 (± 33.5)	204 (± 58.5)		
>=3 months and <6 months: Day 7 (n=6, 4)	126 (± 103)	702 (± 487)		
>=6 months and <=3 years: Day 1 (n=11, 17)	59.9 (± 43)	227 (± 149)		
>=6 months and <=3 years: Day 7 (n=11, 17)	89 (± 73.6)	386 (± 331)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Medical Resource Utilization (MRU)

End point title	Percentage of Subjects With Medical Resource Utilization (MRU)

End point description:

Percentage of subjects with MRU (any medical care encounters) were reported. MRU was assessed by the number, frequency and type of medical care encounters, including for RSV infection or RSV-related complications, based on investigator assessment. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	36	37	32
Units: percentage of subjects				
number (not applicable)	23.7	13.9	21.6	9.4

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	28		
Units: percentage of subjects				
number (not applicable)	15.2	25.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Acceptability and Palatability of the JNJ-53718678 Formulation as Assessed by Parent(s)/Caregiver(s)

End point title	Percentage of Subjects with Acceptability and Palatability of the JNJ-53718678 Formulation as Assessed by Parent(s)/Caregiver(s)

End point description:

Percentage of subjects with acceptability and palatability of the JNJ-53718678 formulation were assessed through a questionnaire asking about the child's reaction when given the medicine, completed by parent(s)/caregiver(s) after last dosing. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 8

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	32	37	24
Units: percentage of subjects				
number (not applicable)	67.6	84.4	73.0	70.8

End point values	Cohort 2: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: percentage of subjects				
number (not applicable)	90.5	85.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Emerging Variations in the Viral Genome Potentially Associated with Resistance to JNJ-53718678

End point title	Number of Subjects with Emerging Variations in the Viral Genome Potentially Associated with Resistance to JNJ-53718678[30]

End point description:

Number of subjects with F gene sequencing data available and with emerging genetic variations post-baseline as compared to baseline, considering 24 RSV F protein positions of interest (positions 127, 137, 138, 140, 141, 143, 144, 323, 338, 339, 392, 394, 396, 397, 398, 399, 400, 401, 474, 486, 487, 488, 489, and 517) was reported. This endpoint was not analysed for Cohort 2 due to premature study termination. ITT-i analysis set included all randomised subjects who received at least one dose of study drug and who had centrally confirmed RSV RNA viral load of >=1 log10 copies/mL above the LLOQ of the RSV RT-qPCR assay at baseline. Analyses on ITT-i set were performed as randomised. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 21

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analyzed for specified arms only.

End point values	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	40	
Units: Subjects	0	0	2	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Day 28

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least 1 dose of study agent, and were analysed as treated, regardless of the randomised treatment group assigned.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.124.1

Reporting groups

Reporting group title	Cohort 1: Placebo

Reporting group description:

Subjects of age groups (age group 1: greater than or equal to [>=] 28 days to less than [<] 3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to less than or equal to [<=3] years), who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days.

Reporting group title	Cohort 1: JNJ-53718678 Low Dose

Reporting group description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 1.7 milligrams per kilogram (mg/kg) for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Reporting group title	Cohort 2: JNJ-53718678 High Dose

Reporting group description:

As per the original dosing, outpatient subjects were randomised to receive JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 2.5 mg/kg for age group 1, JNJ-53718678 3.0 mg/kg for age group 2, and JNJ-53718678 4.5 mg/kg for age group 3, orally twice daily for 7 days.

Reporting group title	Cohort 2: Placebo

Reporting group description:

As per the original dosing, outpatient subjects of age groups (age group 1: >=28 days to <3 months, age group 2: >=3 months to <6 months, and age group 3: >=6 months to <=3 years) were randomised to receive placebo matching to JNJ-53718678 (high volume placebo or low volume placebo to match the calculated volume of the JNJ-53718678 for the high dose or low dose, respectively) orally once daily for 7 days. After Protocol amendment 4, subjects were randomised to receive placebo matching to JNJ-53718678 orally twice daily for 7 days.

Reporting group title	Cohort 2: JNJ-53718678 Low Dose

Reporting group description:

As per the original dosing, outpatients subjects were randomised to receive JNJ-53718678 1.7 mg/kg for age group 1: >=28 days to <3 months; 2 mg/kg for age group 2: >=3 months to <6 months; and 3 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days. After protocol amendment 4, subjects were randomised to receive JNJ-53718678 0.85 mg/kg for age group 1, JNJ-53718678 1.0 mg/kg for age group 2, and JNJ-53718678 1.5 mg/kg for age group 3, orally twice daily for 7 days.

Reporting group title	Cohort 1: JNJ-53718678 High Dose

Reporting group description:

Subjects who were hospitalized or expected to be hospitalized within 24 hours after presentation to the hospital received JNJ-53718678 5 mg/kg for age group 1: >=28 days to <3 months; 6 mg/kg for age group 2: >=3 months to <6 months; and 9 mg/kg for age group 3: >=6 months to <=3 years, orally once daily for 7 days.

Serious adverse events	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 50 (8.00%)	5 / 49 (10.20%)	3 / 31 (9.68%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	2 / 50 (4.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus Infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Feeding Disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2: Placebo	Cohort 2: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	2 / 48 (4.17%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			

subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus Infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Feeding Disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Cohort 1: Placebo	Cohort 1: JNJ-53718678 Low Dose	Cohort 2: JNJ-53718678 High Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 50 (56.00%)	29 / 49 (59.18%)	13 / 31 (41.94%)
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hyperaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Face Oedema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hyperthermia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Oedema Peripheral			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	2 / 50 (4.00%)	3 / 49 (6.12%)	1 / 31 (3.23%)
occurrences (all)	2	3	1
Respiratory, thoracic and mediastinal			

disorders			
Asthma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Atelectasis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Bronchial Obstruction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bronchial Secretion Retention			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Bronchospasm			
subjects affected / exposed	2 / 50 (4.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Catarrh			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Cough			
subjects affected / exposed	2 / 50 (4.00%)	1 / 49 (2.04%)	1 / 31 (3.23%)
occurrences (all)	2	1	1
Dysphonia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Lung Consolidation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasal Discomfort			

subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Respiratory Depth Increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Respiratory Distress			
subjects affected / exposed	2 / 50 (4.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Congestion			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			

subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Platelet Count Increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Transaminases Increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod Sting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Head Injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin Wound			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Radial Head Dislocation			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 50 (0.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Eosinophilia			

subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Lymphocytosis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Lymphadenopathy			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Thrombocytosis			
subjects affected / exposed	2 / 50 (4.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Eye disorders			
Eye Discharge			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Anorectal Discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Anal Erythema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Faeces Soft			

subjects affected / exposed	3 / 50 (6.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	4	0	0
Diarrhoea			
subjects affected / exposed	1 / 50 (2.00%)	2 / 49 (4.08%)	4 / 31 (12.90%)
occurrences (all)	1	2	4
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Noninfective Gingivitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Post-Tussive Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 50 (2.00%)	3 / 49 (6.12%)	0 / 31 (0.00%)
occurrences (all)	1	3	0
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Asteatosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dermatitis Atopic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dermatitis Diaper			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Eczema			

subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Miliaria			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	3 / 50 (6.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	3	1	0
Rash Erythematous			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Rash Macular			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Rash Papular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Skin Lesion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Polyuria			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Oliguria			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Musculoskeletal Stiffness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	2 / 50 (4.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Candida Nappy Rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Exanthema Subitum			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 50 (0.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Influenza			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Localised Infection			

subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection Bacterial			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	2 / 50 (4.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	2	2	0
Nasopharyngitis			
subjects affected / exposed	1 / 50 (2.00%)	2 / 49 (4.08%)	1 / 31 (3.23%)
occurrences (all)	1	2	1
Otitis Media			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Parainfluenzae Virus Infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Otitis Media Acute			
subjects affected / exposed	1 / 50 (2.00%)	2 / 49 (4.08%)	1 / 31 (3.23%)
occurrences (all)	1	2	1
Pneumonia			
subjects affected / exposed	2 / 50 (4.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	2	0	1
Pneumonia Bacterial			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Rhinovirus Infection			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 50 (8.00%)	3 / 49 (6.12%)	1 / 31 (3.23%)
occurrences (all)	4	3	1
Urinary Tract Infection			
subjects affected / exposed	0 / 50 (0.00%)	2 / 49 (4.08%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Viral Infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Viral Rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Metabolic Alkalosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Zinc Deficiency			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 31 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Cohort 2: Placebo	Cohort 2: JNJ-53718678 Low Dose	Cohort 1: JNJ-53718678 High Dose

Total subjects affected by non-serious adverse events subjects affected / exposed	14 / 34 (41.18%)	20 / 34 (58.82%)	30 / 48 (62.50%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hyperaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Face Oedema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	3 / 48 (6.25%)
occurrences (all)	0	1	3
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Bronchial Obstruction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Bronchial Secretion Retention			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Catarrh			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Lung Consolidation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Nasal Discomfort			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory Depth Increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory Distress			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Sinus Disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Upper Respiratory Tract Congestion			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Blood Creatinine Increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Blood Potassium Increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oxygen Saturation Decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Platelet Count Increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Transaminases Increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod Sting			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Head Injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Skin Wound			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Radial Head Dislocation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Eosinophilia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Lymphadenopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Thrombocytosis			

subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	3 / 48 (6.25%)
occurrences (all)	0	2	3
Eye disorders			
Eye Discharge			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Anorectal Discomfort			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Anal Erythema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Faeces Soft			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	3
Diarrhoea			
subjects affected / exposed	5 / 34 (14.71%)	3 / 34 (8.82%)	5 / 48 (10.42%)
occurrences (all)	5	3	5
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Noninfective Gingivitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Post-Tussive Vomiting			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Vomiting			

subjects affected / exposed	4 / 34 (11.76%)	1 / 34 (2.94%)	3 / 48 (6.25%)
occurrences (all)	4	1	3
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Asteatosis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Dermatitis Atopic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Dermatitis Diaper			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	3 / 48 (6.25%)
occurrences (all)	0	1	3
Eczema			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	3 / 48 (6.25%)
occurrences (all)	0	2	3
Rash Erythematous			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rash Macular			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Urticaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Skin Lesion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Polyuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Candida Nappy Rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Ear Infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Exanthema Subitum			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Fungal Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Localised Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Lower Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	6 / 48 (12.50%)
occurrences (all)	0	2	6
Otitis Media			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Otitis Media Acute			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Pneumonia Bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Respiratory Tract Infection Viral			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Rhinovirus Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Urinary Tract Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Viral Infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Viral Rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Metabolic Alkalosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Zinc Deficiency			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 May 2019	The purpose of this amendment was to increase the sample size of Cohort 1 (hospitalized cohort) from 24 to 48 subjects per treatment arm to increase the precision on the estimates for the clinical course related endpoints in this cohort.
05 July 2019	The purpose of this amendment was to clarify how the required balance within the symptom onset randomization strata (symptom onset less than or equal to (<=) 3 days and greater than (>) 3 days to <=5 days) for each of the interim analyses as well as for the final analysis will be achieved while allowing some flexibility in view of respiratory syncytial virus (RSV) seasonality and reducing the recruitment impact of a (temporary) pause in enrollment in one of the strata.
20 December 2019	The purpose of this amendment was to allow unblinding of the central sponsor team and selected local sponsor representatives from Japan to the data included in the second interim analysis and to allow unblinding of the sponsor, including the study team, and selected local sponsor representatives from Japan to all interim analyses planned after the second interim analysis.
26 May 2020	The purpose of this amendment was to implement a risk mitigation plan following identification of an exposure (Cmax)-related important potential risk of QT interval prolongation identified in the throughout QT (TQT) Study 53718678RSV1009 in healthy adult subjects. Given that Cohort 1 enrollment has completed and no more Cohort 1 subjects were ongoing in the study.
10 July 2020	The purpose of this amendment was to implement recommendations from Health Authorities (HA). Given that Cohort 1 enrollment had completed and no more Cohort 1 subjects were ongoing in the study, the changes were only applicable for the newly to be recruited Cohort 2 subjects.
01 December 2020	The purpose of this amendment was to maximize enrollment of subjects with at least moderate RSV disease severity, where potentially greater treatment benefit was achieved.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported