Clinical trial results:
A Phase 2b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Rilematovir (JNJ-53718678) in Adult Outpatients with Respiratory Syncytial Virus (RSV) Infection who are at High Risk for RSV-related Disease Progression

Summary

EudraCT number	2020-005980-30
Trial protocol	SE DE ES IT PL HU BG
Global end of trial date	14 April 2022

Results information

Result version number	v1 (current)
This version publication date	14 April 2023
First version publication date	14 April 2023

Trial information

Trial identification

Sponsor protocol code	53718678RSV2008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04978337
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 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 evaluate efficacy of rilematovir compared to placebo with respect to the time to resolution of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) symptoms.

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	07 October 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 1
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Poland: 1
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	5
EEA total number of subjects	3

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	4

From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

5 randomised subjects received study treatment and were included in the analysis. Out of 5, 4 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	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subject received oral dose of placebo matching to rilematovir twice daily for 7 days.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo matching to rilematovir twice daily for 7 days.

Arm title	Rilematovir 250 mg bid

Arm description:

Subjects received oral dose of rilematovir 250 milligrams (mg) twice daily for 7 days.

Arm type	Experimental
Investigational medicinal product name	Rilematovir
Investigational medicinal product code	
Other name	JNJ-53718678
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received rilematovir 250 mg twice daily for 7 days.

Number of subjects in period 1	Placebo	Rilematovir 250 mg bid
Started	1	4
Completed	1	3
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subject received oral dose of placebo matching to rilematovir twice daily for 7 days.	
Reporting group title	Rilematovir 250 mg bid
Reporting group description:	
Subjects received oral dose of rilematovir 250 milligrams (mg) twice daily for 7 days.	

Reporting group values	Placebo	Rilematovir 250 mg bid	Total
Number of subjects	1	4	5
Age categorical Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	3	4
From 65-84 years	0	1	1
85 years and over	0	0	0
Age continuous			
Here,'99999' indicated that standard deviation could not be calculated as only one subject was available for analysis.			
Units: years			
arithmetic mean	55	51.8	
standard deviation	± 99999	± 2.9	-
Sex: Female, Male Units: Subjects			
Female	1	2	3
Male	0	2	2

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subject received oral dose of placebo matching to rilematovir twice daily for 7 days.	
Reporting group title	Rilematovir 250 mg bid
Reporting group description:	
Subjects received oral dose of rilematovir 250 milligrams (mg) twice daily for 7 days.	

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Baseline

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Baseline[1]

End point description:

RSV LRTD symptoms (cough, short of breath, wheezing, coughing up phlegm [sputum]) as assessed by RiiQ symptom scale score at baseline was reported. RiiQ symptom scale was a 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate, and 3=Severe. Higher scores indicated greater severity. The LRTD symptom score was calculated as the mean of the LRTD symptom scores. Intent-to-Treat infected (ITT-i) analysis set included subjects who were randomised and treated (at least 1 dose) and had RSV infection confirmed by central laboratory analysis. Subjects with confirmed severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection (positive test by central laboratory analysis) were excluded. Here, 'n' (number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Baseline

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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	1.25		
Subject 2 (n=0, 1)	99999	1.25		
Subject 3 (n=0, 1)	99999	1.25		
Subject 4 (n=0, 1)	99999	2.25		
Subject 5 (n=1, 0)	2.25	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 3

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 3[2]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 3 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher scores indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 3

Notes:

[2] - 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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: Scored on a scale				
number (not applicable)				
Subject 3 (n=0, 1)	99999	0.75		
Subject 5 (n=1, 0)	1.75	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 14

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 14[3]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 14 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher score indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central

RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 14

Notes:

[3] - 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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	1.25		
Subject 2 (n=0, 1)	99999	1		
Subject 3 (n=0, 1)	99999	0		
Subject 5 (n=1, 0)	0	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 8

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 8[4]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 8 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher scores indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 8

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistics was planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	1.25		
Subject 2 (n=0, 1)	99999	1.25		
Subject 3 (n=0, 1)	99999	0.75		
Subject 5 (n=1, 0)	0.5	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 21

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 21[5]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 21 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher score indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, ‘99999’ indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 21

Notes:

[5] - 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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	0		
Subject 2 (n=0, 1)	99999	1		
Subject 3 (n=0, 1)	99999	0		
Subject 5 (n=1, 0)	0	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 28

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 28[6]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 28 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher score indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 28

Notes:

[6] - 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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	0.5		
Subject 2 (n=0, 1)	99999	0.75		
Subject 3 (n=0, 1)	99999	0		
Subject 5 (n=1, 0)	0	99999		

Statistical analyses

No statistical analyses for this end point

Primary: Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD)

Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 35

End point title	Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease (LRTD) Symptoms as Assessed by Respiratory Infection Intensity and Impact Questionnaire (RiiQ) Symptom Scale Score at Day 35[7]

End point description:

RSV LRTD symptoms (cough,short of breath,wheezing,coughing up phlegm[sputum]) as assessed by RiiQ symptom scale score at Day 35 was reported. RiiQ symptom scale was 13-items questionnaire rated on 4-point scale. Each symptom and total score was ranged from 0-3 where 0=None,1=Mild,2=Moderate,3=Severe. Higher score indicated greater severity. LRTD symptom score was calculated as the mean of LRTD symptom scores. In this endpoint, only those individual subjects who had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis)were excluded.Here, 'N'(number of subjects analyzed) signifies number of subjects with available data for this endpoint and 'n'(number analysed) represent number of subjects evaluable for specified category. Here, '99999' indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Primary

End point timeframe:

Day 35

Notes:

[7] - 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 planned for this primary endpoint.

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Scores on a scale				
number (not applicable)				
Subject 1 (n=0, 1)	99999	0		
Subject 2 (n=0, 1)	99999	0		
Subject 3 (n=0, 1)	99999	0		
Subject 5 (n=1, 0)	0	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with New Antibiotic Use, or New Use or Increased Dose of Systemic or Inhaled Corticosteroids and Bronchodilator, or Home Oxygen Supplementation

End point title	Percentage of Subjects with New Antibiotic Use, or New Use or Increased Dose of Systemic or Inhaled Corticosteroids and Bronchodilator, or Home Oxygen Supplementation

End point description:

New antibiotic use, or new use or increased dose of systemic or inhaled corticosteroids and bronchodilators, or home oxygen supplementation were reported. ITT-i analysis set included all subjects who were randomised and treated (at least one dose) and had RSV infection confirmed by central laboratory analysis. Subjects with confirmed SARS-CoV-2 infection (positive test by central laboratory analysis) were excluded.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)				
New antibiotic use	0	25.0		
Systematic/inhaled corticosteroids,bronchodilators	0	25.0		
Home oxygen supplementation	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Post-Baseline RSV-related Complications

End point title	Percentage of Subjects with Post-Baseline RSV-related Complications

End point description:

RSV-related complications were reported. The RSV-related complications included pulmonary complications (primary viral pneumonia, bronchitis, respiratory failure, secondary bacterial pneumonia, and exacerbations of underlying chronic pulmonary diseases [such as chronic obstructive pulmonary disease {COPD} and asthma]) and extrapulmonary complications (cardiovascular and cerebrovascular disease events, congestive heart failure [CHF] or exacerbation of underlying CHF, acute exacerbation of chronic kidney disease, severe dehydration, decompensation of previously controlled diabetes mellitus, and other airway infections). Complications after first intake of study drug were considered for this endpoint. ITT-i analysis set included all subjects who were randomised and treated (at least one dose) and had RSV infection confirmed by central laboratory analysis. Subjects with confirmed SARS-CoV-2 infection (positive test by central laboratory analysis) were excluded.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Unscheduled Outpatient Clinic Visits, Emergency Room Visits or Hospitalization for Respiratory Infection

End point title	Percentage of Subjects with Unscheduled Outpatient Clinic Visits, Emergency Room Visits or Hospitalization for Respiratory Infection

End point description:

Unscheduled outpatient clinic visits, emergency room visits or hospitalization for respiratory infection were reported. ITT-i analysis set included all subjects who were randomised and treated (at least one dose) and had RSV infection confirmed by central laboratory analysis. Subjects with confirmed SARS-CoV-2 infection (positive test by central laboratory analysis) were excluded.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)				
Unscheduled outpatient clinic visits	0	25.0		
Emergency room visits	0	0		
Hospitalization for respiratory infection	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Abnormal Clinical Laboratory Findings

End point title	Percentage of Subjects with Treatment-emergent Abnormal Clinical Laboratory Findings

End point description:

Abnormal clinical laboratory findings were reported. Laboratory abnormalities were determined by division of microbiology and infectious diseases(DMID) toxicity as Grade 1:mild (transient or mild discomfort;no medical intervention/therapy required); Grade 2: moderate (mild-moderate limitation in activity-some assistance may be needed;no or minimal medical intervention/therapy required); Grade 3: severe(severe marked limitation in activity, some assistance usually required;medical intervention/therapy required, hospitalizations possible); Grade 4: life-threatening (extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalization care probable). A treatment emergent abnormality is any abnormality not present at baseline and occurring post first administration or worsening versus baseline post first administration. Safety analysis set included all subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)				
Decrease in hemoglobin (Grade 2) (n=1,4)	0	25		
Increase in glucose (Grade 2)(n=1,4)	0	25		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point title	Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse events (AEs) is any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. Any AE which occurred at or after the initial administration of study intervention through the end of the study (that is, Day 35) was considered treatment-emergent. Safety analysis set included all subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Meeting a Composite Endpoint of Either Developing RSV-Related Complications and/or Needing RSV-related Medical Attendance

End point title	Percentage of Subjects Meeting a Composite Endpoint of Either

	Developing RSV-Related Complications and/or Needing RSV-related Medical Attendance

End point description:

Percentage of subjects meeting a composite endpoint of either developing RSV-related complications (pulmonary and extra-pulmonary) and/or needing RSV-related medical attendance was derived. ITT-i analysis set included all subjects who were randomised and treated (at least one dose) and had RSV infection confirmed by central laboratory analysis. Subjects with confirmed SARS-CoV-2 infection (positive test by central laboratory analysis) were excluded.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)	0	25.0		

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 (Subtype: RSV A and RSV B) was measured over time by quantitative reverse transcription polymerase chain reaction (qRT-PCR) in nasal swab specimens collected at clinic visits and at home. Only those timepoints and RSV subtype (RSV A or RSV B) for which individual subjects had data were reported. ITT-i analysis set included randomised and treated subjects with central laboratory confirmed RSV infection. Subjects with confirmed SARS-CoV-2 infection(positive test by central laboratory analysis) were excluded. Here, 'N'(number of subject analysed) signifies number of subjects who were evaluable for this endpoint and 'n'(number analyzed) represents number of subjects evaluable at specified timepoints. Here, ‘99999’ indicate that data was not collected as subjects was randomised to other treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Days 3, 5, 8, 15, 21

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: log10 copies per millilitre (mL)				
number (not applicable)				
Subject 1: Baseline: RSV B (n= 0, 1)	99999	6.87		
Subject 1: Day 3: RSV B (n= 0, 1)	99999	5.84		
Subject 1: Day 8: RSV B (n= 0, 1)	99999	0		

Subject 1: Day 15: RSV B (n= 0, 1)	99999	0		
Subject 1: Day 21: RSV B (n= 0, 1)	99999	0		
Subject 2: Baseline RSV B (n= 0, 1)	99999	6.17		
Subject 2: Day 3: RSV B (n= 0, 1)	99999	6.71		
Subject 2: Day 5: RSV B (n= 0, 1)	99999	0		
Subject 2: Day 8: RSV B (n= 0, 1)	99999	0		
Subject 2: Day 15: RSV B (n= 0, 1)	99999	0		
Subject 2: Day 21: RSV B (n= 0, 1)	99999	0		
Subject 3: Baseline: RSV A (n= 0, 1)	99999	6.5		
Subject 3: Day 3: RSV A (n= 0, 1)	99999	6.4		
Subject 3: Day 5: RSV A (n= 0, 1)	99999	3.37		
Subject 3: Day 8: RSV A (n= 0, 1)	99999	2.9		
Subject 3: Day 15: RSV A (n= 0, 1)	99999	0		
Subject 3: Day 21: RSV A (n= 0, 1)	99999	0		
Subject 5: Baseline: RSV A (n=1, 0)	7.57	99999		
Subject 5: Day 3: RSV A (n=1, 0)	4.94	99999		
Subject 5: Day 5: RSV A (n=1, 0)	0	99999		
Subject 5: Day 8: RSV A (n=1, 0)	0	99999		
Subject 5: Day 15: RSV A (n=1, 0)	0	99999		
Subject 5: Day 21: RSV A (n=1, 0)	0	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Abnormal Vital Signs Findings

End point title	Percentage of Subjects with Treatment-emergent Abnormal Vital Signs Findings

End point description:

Abnormal vital parameters included pulse rate: abnormally low:<=45 bpm, abnormally high:>=120 bpm; Systolic Blood Pressure: abnormally low:<=90 millimeter of mercury (mmHg), Grade 1(mild):>140 mmHg to <160 mmHg, Grade 2(moderate): >=160 mmHg to <180 mmHg, Grade 3(severe):>=180 mmHg; Diastolic BP: abnormally low:<=50 mmHg, Grade 1:>90 mmHg to <100 mmHg, Grade 2:>=100 mmHg to <110 mmHg, Grade 3:>=110 mmHg; Respiratory rate: Grade 1(mild):17-20 breaths/minute, Grade 2(moderate):21-25 breaths/minute, Grade 3(severe):>25 breaths/minute, Grade 4(potentially life threatening):intubation; Oxygen saturation: abnormally low:<95%; Temperature: abnormally high:>38.0 degree celsius. A treatment emergent abnormality is any abnormality not present at baseline and occurring post first administration or worsening versus baseline post first administration. Safety analysis set included all subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Abnormalities in Electrocardiograms (ECGs)

End point title	Percentage of Subjects with Treatment-emergent Abnormalities in Electrocardiograms (ECGs)

End point description:

Various ECG variables assessed were heart rate: abnormally low (less than or equal to [<=] 45 beats per minute [bpm]), abnormally high (greater than or equal to [>=] 120 bpm); PR interval: abnormally high (>=210 milliseconds [msec]); QRS interval: abnormally high (>=120 msec); QTc: borderline prolonged: >450 msec and <=480 msec, prolonged: >480 msec and <=500 msec, pathologicaly prolonged: >500 msec. A treatment emergent abnormality is any abnormality not present at baseline and occurring post first administration or worsening versus baseline post first administration. Safety analysis set included all subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to Day 35

End point values	Placebo	Rilematovir 250 mg bid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Rilematovir

End point title	Plasma Concentration of Rilematovir [8]

End point description:

Plasma concentration of rilematovir was reported. This endpoint was planned to be analyzed for specified arm only. In this endpoint, only those timepoints for which individual subjects had data were reported. Pharmacokinetic (PK) analysis set included all subjects who were randomised and treated (at least one dose) and had RSV infection confirmed by central laboratory analysis. Here, 'N' (number of subject analysed) signifies number of subjects with available data for this endpoint .

End point type	Secondary

End point timeframe:

Day 1: 1 hour post dose, Day 3: pre-dose and 1 hour post dose, and Follow-up Day 8

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 arm only.

End point values	Rilematovir 250 mg bid			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Nanograms per millilitre (ng/mL)				
number (not applicable)				
Subject 1: Day 3 (Pre-dose)	658			
Subject 1: Day 3 (1 hour post dose)	682			
Subject 1: Follow-up-Day 8	9.63			
Subject 2: Day 3 (pre-dose)	15.9			
Subject 2: Day 3 (1 hour post dose)	465			
Subject 2: Follow-up-Day 8	494			
Subject 3: Day 1 (1 hour post dose)	257			
Subject 3: Day 3 (pre-dose)	2400			
Subject 3: Day 3 (1 hour post dose)	2960			
Subject 3: Follow-up-Day 8	3130			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Up to Day 35	
Adverse event reporting additional description:	
Safety analysis set included all subjects who took at least 1 dose of study intervention.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	Rilematovir 250 mg
Reporting group description:	
Subjects received oral dose of rilematovir 250 milligrams (mg) twice daily for 7 days.	
Reporting group title	Placebo
Reporting group description:	
Subjects received oral dose of placebo matching to rilematovir twice daily for 7 days.	

Serious adverse events	Rilematovir 250 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Rilematovir 250 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Data could not be reported as only 5 subjects enrolled in this study who did not experience any non-serious adverse events.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

As the study was terminated early, a low number of subjects were enrolled, hence some efficacy analyses were not performed per change in the planned analysis. Thereby, data were analysed for safety and selected efficacy parameters only.

Notes: