



## Clinical trial results:

### A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Clinical Outcomes, Antiviral Activity, Safety, Tolerability, Pharmacokinetics, and Pharmacokinetics/Pharmacodynamics of JNJ-53718678 in Adult and Adolescent Hematopoietic Stem Cell Transplant Recipients with Respiratory Syncytial Virus Infection of the Upper Respiratory Tract

#### Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2019-001551-39          |
| Trial protocol           | FR GB DE ES SE BE BG IT |
| Global end of trial date | 04 February 2022        |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 09 February 2023 |
| First version publication date | 09 February 2023 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | 53718678RSV2005 |
|-----------------------|-----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04056611 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Janssen Sciences Ireland UC   |
| Sponsor organisation address | Barnahely, Cork, Ringaskiddy, Ireland, P43 FA46                                       |
| Public contact               | Clinical Registry Group, Janssen Sciences Ireland UC,<br>ClinicalTrialsEU@its.jnj.com |
| Scientific contact           | Clinical Registry Group, Janssen Sciences Ireland UC,<br>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                       | 04 February 2022 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 04 February 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 the effect of JNJ-53718678 on the development of respiratory syncytial virus (RSV) lower respiratory tract infection (LRTI) in adult hematopoietic stem cell transplant recipients with RSV upper respiratory tract infection (URTI).

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                          | 26 December 2019 |
| 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 | France: 1 |
| Country: Number of subjects enrolled | Brazil: 1 |
| Country: Number of subjects enrolled | Israel: 1 |
| Worldwide total number of subjects   | 3         |
| EEA total number of subjects         | 1         |

Notes:

### Subjects enrolled per age group

|   |   |
|---|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days)                      | 0 |
| Infants and toddlers (28 days-23 months)  | 0 |
| Children (2-11 years)                     | 0 |
| Adolescents (12-17 years)                 | 0 |
| Adults (18-64 years)                      | 3 |
| From 65 to 84 years                       | 0 |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Randomised subjects received rilematovir treatment. The dose of rilematovir was dependent upon coadministration without/with cytochrome P450 3A4 inhibitors or with posaconazole.

### 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

|                  |              |
|------------------|--------------|
| <b>Arm title</b> | JNJ-53718678 |
|------------------|--------------|

Arm description:

Subjects with age of greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 75 years received rilematovir 125 milligrams (mg) twice daily (bid) for 21 days.

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

Dosage and administration details:

Subjects received JNJ-53718678 125 mg bid for 21 days.

|                                       |              |
|---------------------------------------|--------------|
| <b>Number of subjects in period 1</b> | JNJ-53718678 |
| Started                               | 3            |
| Completed                             | 2            |
| Not completed                         | 1            |
| Physician decision                    | 1            |

## Baseline characteristics

### Reporting groups

|                       |              |
|-----------------------|--------------|
| Reporting group title | JNJ-53718678 |
|-----------------------|--------------|

Reporting group description:

Subjects with age of greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 75 years received rilematovir 125 milligrams (mg) twice daily (bid) for 21 days.

| Reporting group values                             | JNJ-53718678 | Total |  |
|--|--------------|-------|--|
| Number of subjects                                 | 3            | 3     |  |
| Age categorical                                    |              |       |  |
| Units: Subjects                                    |              |       |  |
| In utero   | 0            | 0     |  |
| Preterm newborn infants (gestational age < 37 wks) | 0            | 0     |  |
| Newborns (0-27 days)                               | 0            | 0     |  |
| Infants and toddlers (28 days-23 months)           | 0            | 0     |  |
| Children (2-11 years)                              | 0            | 0     |  |
| Adolescents (12-17 years)                          | 0            | 0     |  |
| Adults (18-64 years)                               | 3            | 3     |  |
| From 65-84 years                                   | 0            | 0     |  |
| 85 years and over                                  | 0            | 0     |  |
| Age continuous                                     |              |       |  |
| Units: years                                       |              |       |  |
| arithmetic mean                                    | 47           |       |  |
| standard deviation                                 | $\pm 13.89$  | -     |  |
| Sex: Female, Male                                  |              |       |  |
| Units: subjects                                    |              |       |  |
| Female   | 1            | 1     |  |
| Male   | 2            | 2     |  |

## End points

### End points reporting groups

|  |              |
|--|--------------|
| Reporting group title  | JNJ-53718678 |
| Reporting group description:   |              |
| Subjects with age of greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 75 years received rilematovir 125 milligrams (mg) twice daily (bid) for 21 days. |              |

### Primary: Percentage of Subjects Who Developed Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Infection (LRTI)

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Developed Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Infection (LRTI) <sup>[1]</sup> |
|-----------------|--|

End point description:

RSV LRTI: defined as development of lower respiratory sign/symptom (eg, decrease in oxygen (O<sub>2</sub>) saturation/increase in supplemental O<sub>2</sub> to maintain O<sub>2</sub> saturation, wheezing, rhonchi, rales, dyspnea, tachypnea, worsening cough) & positive RSV test from lower respiratory tract (LRT) sample (eg, sputum [S], induced sputum [IS], bronchoalveolar lavage [BAL], lung biopsy [LB]/ autopsy specimen [AS]) within  $\pm 4$  days of new chest image finding, compared to baseline, consistent with LRTI; OR positive RSV test from LRT sample (eg, S, IS, BAL, LB/AS) only; OR positive RSV test from upper respiratory tract sample within  $\pm 4$  days of new chest image finding, compared to baseline, consistent with RSV LRTI determined by Endpoint Adjudication Committee. Efficacy analysis set: all subjects randomised, treated (had at least 1 dose) & had RSV infection confirmed by central laboratory analysis, excluding subjects infected with co-pathogen at baseline not identified during screening, analysed as randomised.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Day 28

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.

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Developed RSV-associated Lower Respiratory Tract Complication (LRTC)

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Who Developed RSV-associated Lower Respiratory Tract Complication (LRTC) |
|-----------------|---|

End point description:

Percentage of subjects who developed RSV-associated LRTC was assessed. RSV-associated LRTC: development of a lower respiratory sign or symptom (including decrease in oxygen saturation or increase in supplemental oxygen to maintain oxygen saturation, wheezing, rhonchi, rales, dyspnea, tachypnea, and worsening cough) and met one of following subcategories determined by Endpoint Adjudication Committee (EAC): a) RSV LRTI, b) secondary bacterial LRTI, c) secondary LRTI due to

unusual pathogens, d) secondary LRTC of unknown etiology (new chest image finding than baseline, consistent with LRTI, inflammatory process/ some other clinically significant pulmonary process which were absent within 4 days of new chest image finding). Efficacy analysis set: all subjects who were randomised, treated (took at least 1 dose), and had RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analyzed as randomised.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to Day 28         |           |

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is any untoward medical occurrence in a clinical study participant administered a medicinal (investigational or non investigational) product. An AE did not necessarily have a causal relationship with the intervention. Any AE which occurred post 1st dose administration of study drug up to the end of study (i.e., Day 49) was considered as treatment-emergent. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to Day 49         |           |

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Subjects             | 2               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects with Treatment-emergent Abnormal (Grade

### >=3) Clinical Laboratory Findings

|   |  |
|---|--|
| End point title   | Percentage of Subjects with Treatment-emergent Abnormal (Grade >=3) Clinical Laboratory Findings |
| End point description:<br>Percentage of subjects with greater than or equal to (>=) Grade 3 treatment-emergent clinical laboratory abnormalities (platelet count decreased, glucose increase) was assessed in this outcome measure. Treatment-emergent: any abnormality occurred post 1st dose of study drug up to end of study (i.e., Day 49). The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Up to Day 49  |  |

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       |                 |  |  |  |
| Platelet count decreased      | 33.33           |  |  |  |
| Glucose increase              | 33.33           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Clinically Significant Abnormalities in Electrocardiogram (ECG) Findings

|  |  |
|--|--|
| End point title  | Percentage of Subjects with Clinically Significant Abnormalities in Electrocardiogram (ECG) Findings |
| End point description:<br>Percentage of subjects with clinically significant abnormalities in ECG findings was assessed in this endpoint. Various ECG variables assessed were heart rate: abnormally low (<= 45 beats per minute [bpm]), abnormally high (>= 120 bpm); PR interval: abnormally high (>=210 milliseconds [msec]); QRS interval: abnormally high (>=120 msec), QT interval and corrected QT (QTcF; according to Fridericia's formula) interval (>450 msec, >480 msec, or >500 msec, increases from baseline >30 msec or >60 msec). The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Up to Day 49   |  |



|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       |                 |  |  |  |
| Heart rate                    | 0               |  |  |  |
| PR interval                   | 0               |  |  |  |
| QRS interval                  | 0               |  |  |  |
| QTcF                          | 0               |  |  |  |

## 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:

Percentage of subjects with abnormal vital signs findings was assessed. Abnormal vital parameters included pulse rate: abnormally low  $\leq 45$  bpm, abnormally high  $\geq 120$  bpm; SBP: abnormally low  $\leq 90$  Millimeter of mercury (mmHg), Grade 1 (mild):  $> 90$  mmHg -  $< 100$  mmHg, Grade 2 (moderate):  $\geq 100$  mmHg to  $< 110$  mmHg, Grade 3 (severe):  $\geq 110$  mmHg; DBP: abnormally low  $\leq 50$  mmHg, Grade 1:  $> 90$  mmHg to  $< 100$  mmHg, Grade 2:  $\geq 100$  mmHg to  $< 110$  mmHg, Grade 3:  $\geq 110$  mmHg; Respiratory rate-Grade 1 (mild): 17-20 breaths per minute (bpm), Grade 2 (moderate): 21-25 bpm, Grade 3 (severe):  $> 25$  bpm, Grade 4 (potentially life threatening): intubation; Temperature: abnormally high  $> 38.0$  degree celsius. Treatment-emergent: any abnormality occurred post 1st dose of study drug up to EOS (Day 49). Vital signs abnormalities reported for at least 1 subject were reported in this endpoint. The safety analysis set: all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       |                 |  |  |  |
| Respiratory rate: Grade 2     | 67.67           |  |  |  |
| DBP: Grade 1                  | 33.33           |  |  |  |

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) and/or Death Among Those Who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) and/or Death Among Those Who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment |
|-----------------|--|

**End point description:**

Percentage of subjects who progressed to respiratory failure (of any cause) requiring mechanical ventilation (invasive or noninvasive) and/or death among those who developed RSV LRTI or RSV-associated LRTC per the EAC's assessment was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. Here, '0' in the 'number of subjects analysed' field (N=0) signifies that no subjects were available for the analysis because none of the subjects developed RSV LRTI or RSV-associated LRTC per the EAC's assessment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

**End point timeframe:**

Up to Day 49

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|                               |                  |  |  |  |
|-------------------------------|------------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678     |  |  |  |
| Subject group type            | Reporting group  |  |  |  |
| Number of subjects analysed   | 0 <sup>[2]</sup> |  |  |  |
| Units: Percentage of subjects |                  |  |  |  |
| number (not applicable)       |                  |  |  |  |

**Notes:**

[2] - No subject was available for analysis as none of subject developed RSV LRTI or RSV-associated LRTC.

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) and/or Death (all-cause Mortality)**

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|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) and/or Death (all-cause Mortality) |
|-----------------|---|

**End point description:**

Percentage of subjects who progressed to respiratory failure (of any cause) requiring mechanical ventilation (invasive or noninvasive) and/or death (all-cause mortality) was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

**End point timeframe:**

Up to Day 49

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|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Progressed to Death (All-cause Mortality) Among Those Who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Progressed to Death (All-cause Mortality) Among Those Who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment |
|-----------------|---|

End point description:

Percentage of subjects who progressed to death (all-cause mortality) among those who developed RSV LRTI or RSV-associated LRTC per the EAC's assessment was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analyzed as randomised. Here, '0' in the 'number of subjects analysed' field (N=0) signifies that no subjects were available for the analysis because none of the subjects developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                  |  |  |  |
|-------------------------------|------------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678     |  |  |  |
| Subject group type            | Reporting group  |  |  |  |
| Number of subjects analysed   | 0 <sup>[3]</sup> |  |  |  |
| Units: Percentage of subjects |                  |  |  |  |
| number (not applicable)       |                  |  |  |  |

Notes:

[3] - No subject was available for analysis as none of subject developed RSV LRTI or RSV-associated LRTC.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Progressed to Death (All-cause Mortality)

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Who Progressed to Death (All-cause Mortality) |
|-----------------|--|

End point description:

Percentage of subjects who progressed to death (All-cause mortality) was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) Among Those who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) Among Those who Developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment |
|-----------------|---|

End point description:

Percentage of subjects who progressed to respiratory failure (of any cause) requiring mechanical ventilation (invasive or noninvasive) among those who developed RSV LRTI or RSV-associated LRTC per the EAC's assessment was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. Here, '0' in the 'number of subjects analysed' field (N=0) signifies that no subjects were available for the analysis because none of the subjects developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                  |  |  |  |
|-------------------------------|------------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678     |  |  |  |
| Subject group type            | Reporting group  |  |  |  |
| Number of subjects analysed   | 0 <sup>[4]</sup> |  |  |  |
| Units: Percentage of subjects |                  |  |  |  |
| number (not applicable)       |                  |  |  |  |

Notes:

[4] - No subject was available for analysis as none of subject developed RSV LRTI or RSV-associated LRTC.

## Statistical analyses

No statistical analyses for this end point

**Secondary: Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive)**

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects who Progressed to Respiratory Failure (of any Cause) Requiring Mechanical Ventilation (Invasive or Noninvasive) |
|-----------------|--|

End point description:

Percentage of subjects who progressed to respiratory failure (of any cause) requiring mechanical ventilation (invasive or noninvasive) was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of Supplemental Oxygen Free Days**

|                 |   |
|-----------------|---|
| End point title | Number of Supplemental Oxygen Free Days |
|-----------------|---|

End point description:

Number of supplemental oxygen free days was reported. The number of supplemental oxygen free days was the number of days the subjects did not receive/require supplemental oxygen during the first 28 days post treatment. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analyzed as randomised. Here, "n" (number analyzed)" is defined as number of subjects analysed for each specified category.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Through Day 28

|                             |                  |  |  |  |
|-----------------------------|------------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678     |  |  |  |
| Subject group type          | Reporting group  |  |  |  |
| Number of subjects analysed | 3 <sup>[5]</sup> |  |  |  |
| Units: Days                 |                  |  |  |  |
| Subject 1 (n=1)             | 25               |  |  |  |
| Subject 2 (n=1)             | 28               |  |  |  |
| Subject 3 (n=1)             | 28               |  |  |  |

Notes:

[5] - Planned analysis was not performed as study terminated prematurely due to low subject recruitment.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Treatment-emergent Oxygen Supplementation

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects with Treatment-emergent Oxygen Supplementation |
|-----------------|---|

End point description:

Percentage of subjects who required treatment-emergent oxygen supplementation (e.g., supplemental oxygen, noninvasive pressure ventilation, invasive mechanical ventilation [tracheal tube, laryngeal mask or tracheostomy]). Any AE which occurred post 1st dose administration of study drug up to the end of study (i.e., Day 49) were considered as treatment-emergent. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening and were analysed as randomised.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

## 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 over time was assessed by investigator. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint and 'n' (number analysed) represent number of subjects with available data for each specified timepoint. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Day 1), Days 15, 28, and 35

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 2               |  |  |  |
| Units: Breaths per minute   |                 |  |  |  |
| number (not applicable)     |                 |  |  |  |
| Subject 1: Baseline (n=1)   | 99999           |  |  |  |
| Subject 1: Day 15 (n=1)     | 20              |  |  |  |
| Subject 1: Day 28 (n=1)     | 20              |  |  |  |
| Subject 1: Day 35 (n=1)     | 20              |  |  |  |
| Subject 2: Baseline (n=1)   | 16              |  |  |  |
| Subject 2: Day 15 (n=1)     | 20              |  |  |  |
| Subject 2: Day 28 (n=1)     | 16              |  |  |  |
| Subject 2: Day 35 (n=1)     | 99999           |  |  |  |

## 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 over time was reported by investigator. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. Here, 'n' (number analysed) represent number of subjects with available data for each specified timepoints. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol. |                      |
| End point type  | Secondary            |
| End point timeframe:  |                      |
| Baseline (Day 1), Days 15, 28, and 35   |                      |

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Beats per minute     |                 |  |  |  |
| number (not applicable)     |                 |  |  |  |
| Subject 1: Baseline (n=1)   | 83              |  |  |  |
| Subject 1: Day 15 (n=1)     | 99999           |  |  |  |
| Subject 1: Day 28 (n=1)     | 99999           |  |  |  |
| Subject 1: Day 35 (n=1)     | 99999           |  |  |  |
| Subject 2: Baseline (n=1)   | 72              |  |  |  |
| Subject 2: Day 15 (n=1)     | 79              |  |  |  |
| Subject 2: Day 28 (n=1)     | 99999           |  |  |  |
| Subject 2: Day 35 (n=1)     | 70              |  |  |  |

|                           |       |  |  |  |
|---------------------------|-------|--|--|--|
| Subject 3: Baseline (n=1) | 70    |  |  |  |
| Subject 3: Day 15 (n=1)   | 73    |  |  |  |
| Subject 3: Day 28 (n=1)   | 78    |  |  |  |
| Subject 3: Day 35 (n=1)   | 99999 |  |  |  |

## 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 (SpO2) over time was reported by investigator. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. Here, 'n' (number analysed) represent number of subjects with available data for each specified timepoint. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Days 15, 28, and 35

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage (%) of Spo2 |                 |  |  |  |
| number (not applicable)       |                 |  |  |  |
| Subject 1: Baseline (n=1)     | 96              |  |  |  |
| Subject 1: Day 15 (n=1)       | 99999           |  |  |  |
| Subject 1: Day 28 (n=1)       | 99999           |  |  |  |
| Subject 1: Day 35 (n=1)       | 99999           |  |  |  |
| Subject 2: Baseline (n=1)     | 98              |  |  |  |
| Subject 2: Day 15 (n=1)       | 97              |  |  |  |
| Subject 2: Day 28 (n=1)       | 100             |  |  |  |
| Subject 2: Day 35 (n=1)       | 96              |  |  |  |
| Subject 3: Baseline (n=1)     | 96              |  |  |  |
| Subject 3: Day 15 (n=1)       | 97              |  |  |  |
| Subject 3: Day 28 (n=1)       | 95              |  |  |  |
| Subject 3: Day 35 (n=1)       | 99999           |  |  |  |

## 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 (in degrees celsius) over time was reported. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. Here, 'n' (number analysed) represent number of subjects with available data for each specified timepoint. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

**End point timeframe:**

Baseline, Days 15, 28, and 35

| End point values            | JNJ-53718678    |  |  |  |
|-----------------------------|-----------------|--|--|--|
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Degree Celsius       |                 |  |  |  |
| number (not applicable)     |                 |  |  |  |
| Subject 1: Baseline (n=1)   | 36.3            |  |  |  |
| Subject 1: Day 15 (n=1)     | 99999           |  |  |  |
| Subject 1: Day 28 (n=1)     | 99999           |  |  |  |
| Subject 1: Day 35 (n=1)     | 99999           |  |  |  |
| Subject 2: Baseline (n=1)   | 36.8            |  |  |  |
| Subject 2: Day 15 (n=1)     | 36.8            |  |  |  |
| Subject 2: Day 28 (n=1)     | 36.5            |  |  |  |
| Subject 2: Day 35 (n=1)     | 36.7            |  |  |  |
| Subject 3: Baseline (n=1)   | 35.9            |  |  |  |
| Subject 3: Day 15 (n=1)     | 36.1            |  |  |  |
| Subject 3: Day 28 (n=1)     | 36.2            |  |  |  |
| Subject 3: Day 35 (n=1)     | 99999           |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Percentage of Subjects Hospitalised (of Subjects Who Were not Hospitalised at Baseline)**

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Hospitalised (of Subjects Who Were not Hospitalised at Baseline) |
|-----------------|---|

**End point description:**

Percentage of subjects who were not hospitalised at baseline and required hospitalisation during the study was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

**End point timeframe:**

Up to Day 49

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 0               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who were Re-hospitalised

|  |   |
|--|---|
| End point title  | Percentage of Subjects Who were Re-hospitalised |
| End point description:   |   |
| Percentage of subjects who were re-hospitalised (of subjects who were hospitalised at baseline and discharged during the study and of subjects who were not hospitalised at baseline and required hospitalisation and were discharged during the study) were assessed in this endpoint. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. |   |
| End point type   | Secondary                                       |
| End point timeframe:   |   |
| Up to Day 49   |   |

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Percentage of subjects |                 |  |  |  |
| number (not applicable)       | 33.33           |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Hospital Stay

|   |                           |
|---|---------------------------|
| End point title   | Duration of Hospital Stay |
| End point description:  |                           |
| Duration (in days) of hospital stay was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed 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 49  |                           |

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 1               |  |  |  |
| Units: Days                 |                 |  |  |  |
| number (not applicable)     | 4               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Intensive Care Unit (ICU) Stay

|   |  |
|---|--|
| End point title   | Duration of Intensive Care Unit (ICU) Stay |
| End point description:  |  |
| Duration of ICU stay was reported. Duration (in hours) was defined as total number of hours a subjects was in ICU from first dose of study drug until study termination. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Up to Day 49  |  |

|                               |                 |  |  |  |
|-------------------------------|-----------------|--|--|--|
| <b>End point values</b>       | JNJ-53718678    |  |  |  |
| Subject group type            | Reporting group |  |  |  |
| Number of subjects analysed   | 3               |  |  |  |
| Units: Hours                  |                 |  |  |  |
| median (full range (min-max)) | 0 (0 to 0)      |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects with Grade 3 and Grade 4 Treatment-emergent Adverse Events (TEAEs) in the Infections and Infestations System Organ Class

|  |   |
|--|---|
| End point title  | Number of Subjects with Grade 3 and Grade 4 Treatment-emergent Adverse Events (TEAEs) in the Infections and Infestations System Organ Class |
| End point description:   |   |
| An AE is any untoward medical occurrence in a clinical study subject administered a medicinal (investigational or non investigational) product. An AE did not necessarily had a causal relationship with the intervention. Subjects with Grade 3 or Grade 4 AE were assessed in this endpoint. Any AE which occurred post 1st dose administration of study drug up to the end of study (i.e., Day 49) were |   |

considered as treatment-emergent. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to Day 49         |           |

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Subjects             | 1               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects with Respiratory Related AEs

|  |   |
|--|---|
| End point title  | Number of Subjects with Respiratory Related AEs |
| End point description:   |   |
| Number of subjects with respiratory related AEs (respiratory infections) was assessed. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. |   |
| End point type   | Secondary                                       |
| End point timeframe:   |   |
| Up to Day 49   |   |

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Subjects             | 0               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects with Thoracic-related AEs

|  |  |
|--|--|
| End point title  | Number of Subjects with Thoracic-related AEs |
| End point description:   |  |
| Number of subjects with thoracic-related AEs was assessed. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'. |  |
| End point type   | Secondary                                    |

End point timeframe:

Up to Day 49

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678    |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 3               |  |  |  |
| Units: Subjects             | 0               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects with Antibiotic Use Among Those Who Developed RSV LRTI or RSV-Associated LRTC per the EAC's Assessment

|                 |   |
|-----------------|---|
| End point title | Number of Subjects with Antibiotic Use Among Those Who Developed RSV LRTI or RSV-Associated LRTC per the EAC's Assessment |
|-----------------|---|

End point description:

Number of subjects with antibiotic use among those who developed RSV LRTI or RSV-associated LRTC per the EAC's assessment was assessed. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. Here, '0' in the 'number of subjects analysed' field (N=0) signifies that no subjects were available for the analysis because none of the subjects developed RSV LRTI or RSV-associated LRTC per the EAC's Assessment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 49

|                             |                  |  |  |  |
|-----------------------------|------------------|--|--|--|
| <b>End point values</b>     | JNJ-53718678     |  |  |  |
| Subject group type          | Reporting group  |  |  |  |
| Number of subjects analysed | 0 <sup>[6]</sup> |  |  |  |
| Units: Subjects             |                  |  |  |  |

Notes:

[6] - No subject was available for analysis as none of subject developed RSV LRTI or RSV-associated LRTC.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Plasma Concentration of JNJ-53718678

|                 |                                      |
|-----------------|--------------------------------------|
| End point title | Plasma Concentration of JNJ-53718678 |
|-----------------|--------------------------------------|

End point description:

Plasma Concentration of JNJ-53718678 was reported. PK analysis set included all subjects who received JNJ-53718678 and for whom at least one PK concentration was reported. Here, 'n' (number analyzed)

represents number of subjects with available data for each specified timepoints. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol.

|                         |           |
|-------------------------|-----------|
| End point type          | Secondary |
| End point timeframe:    |           |
| Days 1, 3, 8, 15 and 22 |           |

|   |                 |  |  |  |
|---|-----------------|--|--|--|
| <b>End point values</b>                 | JNJ-53718678    |  |  |  |
| Subject group type                      | Reporting group |  |  |  |
| Number of subjects analysed             | 3               |  |  |  |
| Units: nanograms per millilitre (ng/mL) |                 |  |  |  |
| number (not applicable)                 |                 |  |  |  |
| Subject 1: Day 1 (n=1)                  | 1380            |  |  |  |
| Subject 1: Day 3 (n=1)                  | 99999           |  |  |  |
| Subject 1: Day 8 (n=1)                  | 99999           |  |  |  |
| Subject 1: Day 15 (n=1)                 | 99999           |  |  |  |
| Subject 1: Day 22 (n=1)                 | 99999           |  |  |  |
| Subject 2: Day 1 (n=1)                  | 653             |  |  |  |
| Subject 2: Day 3 (n=1)                  | 99999           |  |  |  |
| Subject 2: Day 8 (n=1)                  | 1780            |  |  |  |
| Subject 2: Day 15 (n=1)                 | 1680            |  |  |  |
| Subject 2: Day 22 (n=1)                 | 802             |  |  |  |
| Subject 3: Day 1 (n=1)                  | 155             |  |  |  |
| Subject 3: Day 3 (n=1)                  | 1680            |  |  |  |
| Subject 3: Day 8 (n=1)                  | 2290            |  |  |  |
| Subject 3: Day 15 (n=1)                 | 2510            |  |  |  |
| Subject 3: Day 22 (n=1)                 | 812             |  |  |  |

## 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 (RSV B) load was measured over time by quantitative reverse transcription polymerase chain reaction in the nasal swab specimens collected at the clinic visits and at home. Efficacy analysis set included all subjects who were randomised, treated (took at least 1 dose), and had a RSV infection confirmed by central laboratory analysis, excluding subjects infected with a co-pathogen at baseline not identified during screening, analysed as randomised. Here, 'n' (number analysed) represent number of subjects with available data for each specified timepoints. Here, '99999' indicates that data was not collected for this time point because sample collection was not performed as prespecified in the protocol. |                          |
| End point type  | Secondary                |
| End point timeframe:  |                          |
| Baseline, Days 15, 28, and 35   |                          |

|   |                 |  |  |  |
|---|-----------------|--|--|--|
| <b>End point values</b>                 | JNJ-53718678    |  |  |  |
| Subject group type                      | Reporting group |  |  |  |
| Number of subjects analysed             | 3               |  |  |  |
| Units: log10 copies per millilitre (mL) |                 |  |  |  |
| number (not applicable)                 |                 |  |  |  |
| Subject 1: RSV B: Baseline (n=1)        | 3.85            |  |  |  |
| Subject 1: RSV B: Day 15 (n=1)          | 99999           |  |  |  |
| Subject 1: RSV B: Day 28 (n=1)          | 0               |  |  |  |
| Subject 1: RSV B: Day 35 (n=1)          | 99999           |  |  |  |
| Subject 2: RSV B: Baseline (n=1)        | 8.01            |  |  |  |
| Subject 2: RSV B: Day 15 (n=1)          | 5.95            |  |  |  |
| Subject 2: RSV B: Day 28 (n=1)          | 5.16            |  |  |  |
| Subject 2: RSV B: Day 35 (n=1)          | 5.63            |  |  |  |
| Subject 3: RSV B: Baseline (n=1)        | 8.73            |  |  |  |
| Subject 3: RSV B: Day 15 (n=1)          | 5.36            |  |  |  |
| Subject 3: RSV B: Day 28 (n=1)          | 0               |  |  |  |
| Subject 3: RSV B: Day 35 (n=1)          | 99999           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to Day 49

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who took at least 1 dose of study intervention and were analysed 'as treated'.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 24.1 |
|--------------------|------|

### Reporting groups

|                       |              |
|-----------------------|--------------|
| Reporting group title | JNJ-53718678 |
|-----------------------|--------------|

Reporting group description:

Subjects with age of greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 75 years received rilematovir 125 milligrams (mg) twice daily (bid) for 21 days.

| Serious adverse events                            | JNJ-53718678   |  |  |
|---|----------------|--|--|
| Total subjects affected by serious adverse events |                |  |  |
| subjects affected / exposed                       | 1 / 3 (33.33%) |  |  |
| number of deaths (all causes)                     | 0              |  |  |
| number of deaths resulting from adverse events    |                |  |  |
| Infections and infestations                       |                |  |  |
| Sepsis  |                |  |  |
| subjects affected / exposed                       | 1 / 3 (33.33%) |  |  |
| occurrences causally related to treatment / all   | 0 / 1          |  |  |
| deaths causally related to treatment / all        | 0 / 0          |  |  |

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

| Non-serious adverse events                            | JNJ-53718678   |  |  |
|---|----------------|--|--|
| Total subjects affected by non-serious adverse events |                |  |  |
| subjects affected / exposed                           | 2 / 3 (66.67%) |  |  |
| Vascular disorders                                    |                |  |  |
| Hot Flush   |                |  |  |
| subjects affected / exposed                           | 1 / 3 (33.33%) |  |  |
| occurrences (all)                                     | 1              |  |  |
| Nervous system disorders                              |                |  |  |



|  |                     |  |  |
|--|---------------------|--|--|
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)  | 1 / 3 (33.33%)<br>1 |  |  |
| Blood and lymphatic system disorders<br>Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 3 (33.33%)<br>1 |  |  |
| Infections and infestations<br>Cytomegalovirus Infection<br>Reactivation<br>subjects affected / exposed<br>occurrences (all) | 1 / 3 (33.33%)<br>1 |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment   |
|------------------|---|
| 21 June 2019     | The purpose of this amendment was to correct an inconsistency regarding the classification of Cytochrome P450 3A4 (CYP3A4) inhibitors and CYP3A4 inducers in the concomitant therapy section and to update the exclusion criteria to clarify that enrollment of subjects during the follow-up phase of another clinical study was allowed.  |
| 11 December 2019 | The purpose of this amendment was to ensure consistency between different sections, to clarify, and make minor corrections to different parts of the protocol. In addition, regulatory feedback from competent authorities was incorporated.  |
| 03 June 2020     | The purpose of this amendment was to implement a risk mitigation plan (including dose modifications) following an exposure (C <sub>max</sub> )-related important potential risk of QT interval prolongation identified in the thorough QT Study 53718678RSV1009 in healthy adult subjects.  |
| 10 July 2020     | The purpose of this amendment was to implement recommendations regarding cardiac safety and concomitant medications by Health Authorities.  |
| 03 August 2020   | The purpose of this amendment was to implement recommendations regarding cardiac safety and concomitant medications by Health Authorities.  |
| 07 May 2021      | The purpose of this amendment was to replace the oral suspension formulations of rilematovir and placebo by oral film-coated tablets, to specify the clinical management of laboratory-confirmed SARS-CoV-2 infection, diagnosed during the study and to add specifics on the administration of a locally approved (including emergency use-authorized) coronavirus disease 2019 (COVID-19) vaccine during the study. |

Notes:

### 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 due to low number of subjects enrolled, some efficacy analyses were not performed as per change in the planned analysis. Hence, data was collected and analyzed for safety and selected efficacy parameters only.

Notes: