



Clinical trial results:

A Phase 3 Randomized Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants with Moderate COVID-19 Compared to Standard of Care Treatment

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2020-000842-32 |
| Trial protocol | DE ES FR IT NL GB SE |
| Global end of trial date | 26 June 2020 |

Results information

| | |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Result version number | v2 (current) |
| This version publication date | 06 February 2021 |
| First version publication date | 31 December 2020 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Updated adverse events reporting description in the Adverse Events section. |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | GS-US-540-5774 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|----------------|
| ISRCTN number | ISRCTN85762140 |
| ClinicalTrials.gov id (NCT number) | NCT04292730 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--------------------------------------------------------------------------------------------|
| Sponsor organisation name | Gilead Sciences |
| Sponsor organisation address | 333 Lakeside Drive, Foster City, CA, United States, 94404 |
| Public contact | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com |
| Scientific contact | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.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? | Yes |

Notes:

Results analysis stage

| | |
|------------------------------------------------------|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 26 June 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 29 April 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 26 June 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the efficacy of 2 remdesivir (RDV) regimens compared to standard of care (SOC), with respect to clinical status assessed by a 7-point ordinal scale on Day 11.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment | 15 March 2020 |
| 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 | Korea, Republic of: 37 |
| Country: Number of subjects enrolled | Netherlands: 5 |
| Country: Number of subjects enrolled | Singapore: 32 |
| Country: Number of subjects enrolled | United States: 593 |
| Country: Number of subjects enrolled | Spain: 144 |
| Country: Number of subjects enrolled | Italy: 134 |
| Country: Number of subjects enrolled | United Kingdom: 64 |
| Country: Number of subjects enrolled | Germany: 36 |
| Country: Number of subjects enrolled | Hong Kong: 28 |
| Country: Number of subjects enrolled | Switzerland: 19 |
| Country: Number of subjects enrolled | France: 8 |
| Country: Number of subjects enrolled | Taiwan: 6 |
| Country: Number of subjects enrolled | Japan: 4 |
| Country: Number of subjects enrolled | Sweden: 3 |

| | |
|------------------------------------|------|
| Worldwide total number of subjects | 1113 |
| EEA total number of subjects | 394 |

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) | 5 |
| Adults (18-64 years) | 788 |
| From 65 to 84 years | 295 |
| 85 years and over | 25 |

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States, Europe, and Asia. The first participant was screened on 15 March 2020. The last study visit occurred on 26 June 2020.

Pre-assignment

Screening details:

1138 participants were screened.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Part A: Remdesivir (RDV) for 5 Days |

Arm description:

Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.

| | |
|----------------------------------------|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Remdesivir |
| Investigational medicinal product code | |
| Other name | GS-5734™, Veklury® |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-5.

| | |
|----------------------------------------|------------------|
| Investigational medicinal product name | Standard of care |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Not mentioned |

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

| | |
|------------------|--------------------------------|
| Arm title | Part A: Remdesivir for 10 Days |
|------------------|--------------------------------|

Arm description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

| | |
|----------------------------------------|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Remdesivir |
| Investigational medicinal product code | |
| Other name | GS-5734™, Veklury® |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-10.

| | |
|----------------------------------------|------------------|
| Investigational medicinal product name | Standard of care |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Not mentioned |

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

| | |
|------------------|---------------------|
| Arm title | Part A: SOC Therapy |
|------------------|---------------------|

Arm description:

Participants received continued SOC therapy.

| | |
|----------------------------------------|------------------|
| Arm type | Standard of care |
| Investigational medicinal product name | Standard of Care |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Not mentioned |

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

| | |
|------------------|-----------------------------------------------------|
| Arm title | Part B: Extension Treatment, Remdesivir for 10 Days |
|------------------|-----------------------------------------------------|

Arm description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

| | |
|----------------------------------------|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Remdesivir |
| Investigational medicinal product code | |
| Other name | GS-5734™, Veklury® |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-10.

| | |
|----------------------------------------|------------------|
| Investigational medicinal product name | Standard of care |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Not mentioned |

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

| Number of subjects in period 1^[1] | Part A: Remdesivir (RDV) for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy |
|-----------------------------------------------------|-------------------------------------|--------------------------------|---------------------|
| Started | 191 | 193 | 200 |
| Completed | 179 | 176 | 178 |
| Not completed | 12 | 17 | 22 |
| Death | 2 | 2 | 4 |
| Non-compliance with study drug | - | 1 | - |

| | | | |
|--------------------|---|----|----|
| Protocol Violation | - | - | 1 |
| Lost to follow-up | 8 | 12 | 12 |
| Withdrew consent | 2 | 2 | 5 |

| Number of subjects in period 1^[1] | Part B: Extension Treatment, Remdesivir for 10 Days |
|-----------------------------------------------------|-----------------------------------------------------|
| Started | 503 |
| Completed | 437 |
| Not completed | 66 |
| Death | 12 |
| Non-compliance with study drug | - |
| Protocol Violation | - |
| Lost to follow-up | 48 |
| Withdrew consent | 6 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 26 participants (8 from 'Remdesivir for 5 days' group, 4 from 'Remdesivir for 10 days' group, 14 from 'Extension treatment-Remdesivir for 10 days' group) who were randomized but did not receive the study drug are not included in the subject disposition table.

Baseline characteristics

Reporting groups

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Reporting group title | Part A: Remdesivir (RDV) for 5 Days |
| Reporting group description: | |
| Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5. | |
| Reporting group title | Part A: Remdesivir for 10 Days |
| Reporting group description: | |
| Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10. | |
| Reporting group title | Part A: SOC Therapy |
| Reporting group description: | |
| Participants received continued SOC therapy. | |
| Reporting group title | Part B: Extension Treatment, Remdesivir for 10 Days |
| Reporting group description: | |
| Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10. | |

| Reporting group values | Part A: Remdesivir (RDV) for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy |
|------------------------|-------------------------------------|--------------------------------|---------------------|
| Number of subjects | 191 | 193 | 200 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|-------------------------------------------------------------------------------------|--------|--------|--------|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 56 | 55 | 55 |
| standard deviation | ± 14.6 | ± 15.5 | ± 15.1 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 77 | 75 | 75 |
| Male | 114 | 118 | 125 |
| Race | | | |
| Not Permitted = local regulators did not allow collection of race information. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 2 | 0 | 1 |
| Asian | 34 | 31 | 37 |
| Black | 35 | 37 | 27 |
| Native Hawaiian or Pacific Islander | 1 | 1 | 1 |
| White | 109 | 107 | 112 |
| Not Permitted | 5 | 5 | 7 |
| Other | 5 | 12 | 15 |
| Ethnicity | | | |
| Not Permitted = local regulators did not allow collection of ethnicity information. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 25 | 42 | 34 |
| Not Hispanic or Latino | 162 | 144 | 152 |
| Not Permitted | 4 | 7 | 13 |
| Missing | 0 | 0 | 1 |

| Reporting group values | Part B: Extension Treatment, Remdesivir for 10 Days | Total | |
|------------------------------------|-----------------------------------------------------|-------|--|
| Number of subjects | 503 | 1087 | |
| Age categorical Units: Subjects | | | |

| | | | |
|-------------------------------------------------------------------------------------|--------------|-----|--|
| Age continuous Units: years arithmetic mean standard deviation | 55 ± 16.1 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 221 | 448 | |
| Male | 282 | 639 | |
| Race | | | |
| Not Permitted = local regulators did not allow collection of race information. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 3 | 6 | |
| Asian | 61 | 163 | |
| Black | 107 | 206 | |
| Native Hawaiian or Pacific Islander | 1 | 4 | |
| White | 260 | 588 | |
| Not Permitted | 21 | 38 | |
| Other | 50 | 82 | |
| Ethnicity | | | |
| Not Permitted = local regulators did not allow collection of ethnicity information. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 156 | 257 | |
| Not Hispanic or Latino | 325 | 783 | |
| Not Permitted | 22 | 46 | |
| Missing | 0 | 1 | |

End points

End points reporting groups

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Reporting group title | Part A: Remdesivir (RDV) for 5 Days |
| Reporting group description: Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5. | |
| Reporting group title | Part A: Remdesivir for 10 Days |
| Reporting group description: Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10. | |
| Reporting group title | Part A: SOC Therapy |
| Reporting group description: Participants received continued SOC therapy. | |
| Reporting group title | Part B: Extension Treatment, Remdesivir for 10 Days |
| Reporting group description: Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10. | |

Primary: Part A: Percentage of Participants in Each Clinical Status Category as Assessed by a 7-Point Ordinal Scale on Day 11

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Part A: Percentage of Participants in Each Clinical Status Category as Assessed by a 7-Point Ordinal Scale on Day 11 ^[1] |
| End point description: Clinical status was derived from death, hospital discharge, and ordinal scale as follows: 1 for all days on/after death date; 7 for all days on/after discharged alive date; last assessment for missing value. The scale is as follows: 1. Death; 2. Hospitalized, on invasive mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO); 3. Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4. Hospitalized, requiring low flow supplemental oxygen; 5. Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (coronavirus (COVID-19) related or otherwise); 6. Hospitalized, not requiring supplemental oxygen - no longer required ongoing medical care (other than per protocol remdesivir administration; 7. Not hospitalized. Full Analysis Set (FAS) included all participants who were randomized into Part A of the study and received at least 1 dose of study treatment (RDV groups) or had protocol Day 1 visit (SOC arm). | |
| End point type | Primary |
| End point timeframe: Day 11 | |

Notes:

[1] - 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 not analyzed for 'Part B: Extension Treatment, Remdesivir for 10 Days'.

| End point values | Part A: Remdesivir (RDV) for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy | |
|-----------------------------------|-------------------------------------|--------------------------------|---------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 191 | 193 | 200 | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Score: 1 | 0.0 | 1.0 | 2.0 | |
| Score: 2 | 0.0 | 0.5 | 2.0 | |
| Score: 3 | 2.6 | 0.0 | 3.5 | |

| | | | | |
|----------|------|------|------|--|
| Score: 4 | 3.7 | 6.2 | 5.5 | |
| Score: 5 | 19.9 | 22.8 | 23.0 | |
| Score: 6 | 3.7 | 4.7 | 4.0 | |
| Score: 7 | 70.2 | 64.8 | 60.0 | |

Statistical analyses

| | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Statistical analysis title | Part A: RDV for 5 Days vs Part A: SOC Therapy |
| Statistical analysis description: | |
| Primary analysis; The odds ratio represents the odds of improvement in the ordinal scale for a RDV group relative to the SOC group. | |
| Comparison groups | Part A: Remdesivir (RDV) for 5 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 391 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0174 ^[2] |
| Method | Proportional odds model |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.65 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.092 |
| upper limit | 2.483 |

Notes:

[2] - P-value was calculated using proportional odds model with treatment as the independent variable.

| | |
|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Statistical analysis title | Part A: RDV for 10 Days vs Part A: SOC Therapy |
| Statistical analysis description: | |
| Primary analysis; The odds ratio represents the odds of improvement in the ordinal scale for a RDV group relative to the SOC group. | |
| Comparison groups | Part A: Remdesivir for 10 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1826 ^[3] |
| Method | Proportional odds model |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.952 |

Notes:

[3] - P-value was calculated using proportional odds model with treatment as the independent variable.

| | |
|-----------------------------------|-----------------------------------------------|
| Statistical analysis title | Part A: RDV for 5 Days vs Part A: SOC Therapy |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Secondary analysis; The odds ratio represents the odds of improvement in the ordinal scale for a RDV group relative to the SOC group.

| | |
|-----------------------------------------|-----------------------------------------------------------|
| Comparison groups | Part A: Remdesivir (RDV) for 5 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 391 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0168 ^[4] |
| Method | Proportional odds model |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.65 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.095 |
| upper limit | 2.497 |

Notes:

[4] - P-value was calculated using proportional odds model with treatment as the independent variable and baseline clinical status as a nominal covariate.

| | |
|-----------------------------------|------------------------------------------------|
| Statistical analysis title | Part A: RDV for 10 Days vs Part A: SOC Therapy |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Secondary analysis; The odds ratio represents the odds of improvement in the ordinal scale for a RDV group relative to the SOC group.

| | |
|-----------------------------------------|------------------------------------------------------|
| Comparison groups | Part A: Remdesivir for 10 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2186 ^[5] |
| Method | Proportional odds model |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.29 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.862 |
| upper limit | 1.917 |

Notes:

[5] - P-value was calculated using proportional odds model with treatment as the independent variable and baseline clinical status as a nominal covariate.

Secondary: Part A: Percentage of Participants Who Experienced Treatment-Emergent Adverse Events (TEAEs)

| | |
|-----------------|-------------------------------------------------------------------------------------------------------------|
| End point title | Part A: Percentage of Participants Who Experienced Treatment-Emergent Adverse Events (TEAEs) ^[6] |
|-----------------|-------------------------------------------------------------------------------------------------------------|

End point description:

TEAEs were defined as the following: any AE with an onset date on or after the study treatment start date and no later than 30 days after permanent discontinuation of study treatment and/or any AE leading to premature discontinuation of study treatment. For participants randomized to the SOC group, all AEs reported on or after the protocol-specified Day 1 visit were considered as treatment emergent. Safety Analysis Set (SAS) included participants who were randomized into part A of the study and received at least 1 dose of study treatment or completed the Day 1 visit (SOC only group).

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

End point timeframe:

First dose date up to last dose date (maximum: 10 days) plus 30 days

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was not analyzed for 'Part B: Extension Treatment, Remdesivir for 10 Days'.

| End point values | Part A: Remdesivir (RDV) for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy | |
|-----------------------------------|----------------------------------------------|--------------------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 191 | 193 | 200 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 51.3 (44.0 to 58.6) | 58.5 (51.3 to 65.6) | 46.5 (39.4 to 53.7) | |

Statistical analyses

| | |
|-----------------------------------------|-----------------------------------------------------------|
| Statistical analysis title | Part A: RDV for 5 Days, Part A: SOC Therapy |
| Comparison groups | Part A: Remdesivir (RDV) for 5 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 391 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3633 ^[7] |
| Method | Fisher exact |
| Parameter estimate | Difference in the Percentages |
| Point estimate | 4.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.2 |
| upper limit | 14.7 |

Notes:

[7] - P-value was calculated from the Fisher exact test to compare each RDV group and the SOC group.

| | |
|-----------------------------------------|------------------------------------------------------|
| Statistical analysis title | Part A: RDV for 10 Days vs Part A: SOC Therapy |
| Comparison groups | Part A: Remdesivir for 10 Days v Part A: SOC Therapy |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0201 ^[8] |
| Method | Fisher exact |
| Parameter estimate | Difference in the Percentages |
| Point estimate | 12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.6 |
| upper limit | 21.8 |

Notes:

[8] - P-value was calculated from the Fisher exact test to compare each RDV group and the SOC group.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First dose date up to the last dose date (maximum: 10 days for Part A, 11 days for Part B) plus 30 days.

Adverse event reporting additional description:

Part A=Safety Analysis Set included participants who were randomized into part A of the study and received at least 1 dose of study treatment or completed the Day 1 visit (SOC only group); Part B=Expanded RDV-Treated Analysis Set included participants who were enrolled into part B of the study and received at least 1 dose of study drug.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 22.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------------------|
| Reporting group title | Part A: Remdesivir for 5 Days |
|-----------------------|-------------------------------|

Reporting group description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.

| | |
|-----------------------|--------------------------------|
| Reporting group title | Part A: Remdesivir for 10 Days |
|-----------------------|--------------------------------|

Reporting group description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

| | |
|-----------------------|---------------------|
| Reporting group title | Part A: SOC Therapy |
|-----------------------|---------------------|

Reporting group description:

Participants received continued SOC therapy.

| | |
|-----------------------|-----------------------------------------------------|
| Reporting group title | Part B: Extension Treatment, Remdesivir for 10 Days |
|-----------------------|-----------------------------------------------------|

Reporting group description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

| Serious adverse events | Part A: Remdesivir for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy |
|---------------------------------------------------------------------|-------------------------------|--------------------------------|---------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 191 (4.71%) | 10 / 193 (5.18%) | 18 / 200 (9.00%) |
| number of deaths (all causes) | 2 | 3 | 4 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cancer pain | | | |

| | | | |
|------------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemodynamic instability | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Shock | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Death | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 5 / 200 (2.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 2 / 193 (1.04%) | 2 / 200 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 2 / 200 (1.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung opacity | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Confusional state | | | |

| | | | |
|-------------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Heart rate decreased | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 2 / 200 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Cardiac failure acute | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Brain oedema | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysarthria | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| Anaemia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis acute | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal colic | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Corona virus infection | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis infective | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 191 (0.00%) | 1 / 193 (0.52%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary sepsis | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Empyema | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 191 (0.52%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |

| | | | |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Fluid overload | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 1 / 200 (0.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 191 (0.00%) | 0 / 193 (0.00%) | 0 / 200 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---------------------------------------------------------------------|-----------------------------------------------------|--|--|
| Serious adverse events | Part B: Extension Treatment, Remdesivir for 10 Days | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 40 / 503 (7.95%) | | |
| number of deaths (all causes) | 13 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 2 | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung neoplasm malignant | | | |

| | | | |
|------------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemodynamic instability | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Shock | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Death | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 2 | | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 2 | | |

| | | | |
|----------------------------------------------------------------------|-----------------|--|--|
| General physical health deterioration subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Impaired healing subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pyrexia subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure subjects affected / exposed | 4 / 503 (0.80%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 2 | | |
| Respiratory distress subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Dyspnoea subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoxia | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung opacity | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Confusional state | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Heart rate decreased | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Post procedural bile leak | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Brain oedema | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dysarthria | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intestinal perforation | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vomiting | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal failure | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Corona virus infection | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 503 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Arthritis infective | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bacteraemia | | | |

| | | | | |
|-------------------------------------------------|-----------------|--|--|--|
| subjects affected / exposed | 0 / 503 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Biliary sepsis | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Empyema | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neutropenic sepsis | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia bacterial | | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia viral | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Septic shock | | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Metabolism and nutrition disorders | | | |
| Fluid overload | | | |
| subjects affected / exposed | 0 / 503 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 503 (0.20%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Part A: Remdesivir for 5 Days | Part A: Remdesivir for 10 Days | Part A: SOC Therapy |
|-------------------------------------------------------|----------------------------------|-----------------------------------|---------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 41 / 191 (21.47%) | 42 / 193 (21.76%) | 30 / 200 (15.00%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 10 / 191 (5.24%) | 10 / 193 (5.18%) | 5 / 200 (2.50%) |
| occurrences (all) | 10 | 11 | 5 |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 19 / 191 (9.95%) | 18 / 193 (9.33%) | 6 / 200 (3.00%) |
| occurrences (all) | 19 | 18 | 6 |
| Diarrhoea | | | |
| subjects affected / exposed | 12 / 191 (6.28%) | 10 / 193 (5.18%) | 14 / 200 (7.00%) |
| occurrences (all) | 12 | 10 | 15 |
| Constipation | | | |
| subjects affected / exposed | 8 / 191 (4.19%) | 5 / 193 (2.59%) | 9 / 200 (4.50%) |
| occurrences (all) | 8 | 5 | 9 |
| Metabolism and nutrition disorders | | | |
| Hypokalaemia | | | |

| | | | |
|-----------------------------|------------------|------------------|-----------------|
| subjects affected / exposed | 10 / 191 (5.24%) | 13 / 193 (6.74%) | 4 / 200 (2.00%) |
| occurrences (all) | 10 | 13 | 4 |

| | | | |
|-------------------------------------------------------|-----------------------------------------------------|--|--|
| Non-serious adverse events | Part B: Extension Treatment, Remdesivir for 10 Days | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 113 / 503 (22.47%) | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 27 / 503 (5.37%) | | |
| occurrences (all) | 32 | | |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 41 / 503 (8.15%) | | |
| occurrences (all) | 42 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 28 / 503 (5.57%) | | |
| occurrences (all) | 29 | | |
| Constipation | | | |
| subjects affected / exposed | 26 / 503 (5.17%) | | |
| occurrences (all) | 26 | | |
| Metabolism and nutrition disorders | | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 23 / 503 (4.57%) | | |
| occurrences (all) | 23 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 15 March 2020 | Amendment 1: <ul style="list-style-type: none">• Revised primary endpoint to allow for more robust analysis• Expanded number of sites and participants globally to meet urgent needs• Divided enrollment into 2 parts: A and B• Included an Extension Treatment Group during enrollment to extend RDV therapy (Part B)• Provided further clarification to the inclusion and exclusion criteria• Included parameters for adolescent participants and adolescent dosing• Revised statistical methodology and analysis due to changes in endpoints and study design• Clarified requirements for oxygen supplementation. |
| 29 April 2020 | Amendment 2: <ul style="list-style-type: none">• Increased number of centers globally• Revised section on pediatric dosing with minor edits• Added language around discontinuation of study medication• Clarified exclusion criteria requirements• Clarified section on concomitant medications disallowed during study and revised concomitant medication assessment window• Added further guidance on pharmacokinetic (PK) assessments and sample collection timepoints• Added further guidance on virologic testing• Clarified assessment guidance for laboratory abnormalities• Revised sections on other endpoints of interest and planned analyses• Incorporated changes per the latest administrative amendment. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32821939>