



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	v1
This version publication date	31 December 2020
First version publication date	31 December 2020

Trial information

Trial identification

Sponsor protocol code	GS-US-540-5774
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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
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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
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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
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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
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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
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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]
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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
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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:

AEs: Part A: SAS included participants who were randomized into part A of the study and received at least 1 dose of study drug or completed Day 1 visit (SOC only group); Part B: Expanded RDV-Treated Analysis Set included participants who received at least 1 dose of study drug. All-cause mortality: Part A=All randomized Set; Part B=All Enrolled Set.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.1
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Reporting groups

Reporting group title	Part A: Remdesivir for 5 Days
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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
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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
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Reporting group description:

Participants received continued SOC therapy.

Reporting group title	Part B: Extension Treatment, Remdesivir for 10 Days
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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: • 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: • 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>