



Clinical trial results:

A Master Protocol Assessing the Safety, Tolerability, and Efficacy of Anti-Spike (S) SARS-CoV-2 Monoclonal Antibodies for the Treatment of Hospitalized Patients with COVID-19

Summary

EudraCT number	2020-002537-15
Trial protocol	RO
Global end of trial date	22 October 2021

Results information

Result version number	v1 (current)
This version publication date	06 November 2022
First version publication date	06 November 2022

Trial information

Trial identification

Sponsor protocol code	R10933-10987-COV-2066
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Regeneron Pharmaceuticals, Inc
Sponsor organisation address	777 Old Saw Mill River Rd., Tarrytown, United States, 10591
Public contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 8447346643, clinicaltrials@regeneron.com
Scientific contact	Clinical Trial Management, Regeneron Pharmaceuticals, Inc, 001 8447346643, clinicaltrials@regeneron.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 October 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	22 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives are:

Pooled Phase 3 (Cohort 1) and Phase 2 (Cohort 1A)

- To evaluate the virologic efficacy of REGN10933+REGN10987 compared to placebo in reducing viral load of SARS-CoV-2
- To evaluate the clinical efficacy of REGN10933+REGN10987 compared to placebo, as measured by death or mechanical ventilation

Phase 1/2 (Cohort 1)

- To exclude futility of REGN10933+REGN10987 compared to placebo, as measured by death or mechanical ventilation
- To evaluate the safety and tolerability of REGN10933+REGN10987 compared to placebo

Protection of trial subjects:

It is the responsibility of both the sponsor and the investigator(s) to ensure that this clinical study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the ICH guidelines for GCP and applicable regulatory requirements

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 June 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	Brazil: 65
Country: Number of subjects enrolled	Chile: 6
Country: Number of subjects enrolled	Mexico: 102
Country: Number of subjects enrolled	Moldova, Republic of: 87
Country: Number of subjects enrolled	Romania: 16
Country: Number of subjects enrolled	United States: 1927
Worldwide total number of subjects	2203
EEA total number of subjects	16

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1233
From 65 to 84 years	799
85 years and over	171

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 2324 participants were screened and 2203 participants randomized and treated, 49 participants were randomized but not treated, and 72 discontinued at the screening phase. Reasons for discontinuation at screening phase: 54 - Screen Failure, 10 - Subject Decision, 1- Sponsor Request, 7- Other.

Period 1

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

Arms

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

Arm description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 1 (Cohort 1).

Arm type	Placebo
Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

single dose of placebo matching to R10933+R10987 intravenously on Day 1

Arm title	Phase 1: Cohort 1 (R10933+R10987 2400 mg IV)
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Arm description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 1 (Cohort 1).

Arm type	Experimental
Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

single dose of 2400 mg IV R10933+R10987 intravenously on Day 1

Arm title	Phase 1: Cohort 1 (R10933+R10987 8000 mg IV)
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Arm description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 1 (Cohort 1).

Arm type	Experimental
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Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1 (Placebo)
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1)	
Arm type	Placebo
Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1 (R10933+R10987 2400 mg
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 2 (Cohort 1)	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 2400 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1 (R10933+R10987 8000 mg IV)
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1)	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 3: Cohort 1 (Placebo)
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1)	
Arm type	Placebo

Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Arm title	Phase 3: Cohort 1 (R10933+R10987 2400 mg)
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 3 (Cohort 1)	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 2400 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 3: Cohort 1 (R10933+R10987 8000 mg IV)
Arm description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1)	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1A (Placebo)
Arm description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1A).	
Arm type	Placebo
Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1A (R10933+R10987 2400 mg IV)
Arm description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1A).	
Arm type	Experimental

Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 2400 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 1A (R10933+R10987 8000 mg IV)
Arm description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1A).	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 2 (Placebo)
Arm description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 2).	
Arm type	Placebo
Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 2 (R10933+R10987 2400 mg IV)
Arm description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 2400 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 2 (R10933+R10987 8000 mg IV)
Arm description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Arm type	Experimental

Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 3 (Placebo)
Arm description: Participants on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 3).	
Arm type	Placebo
Investigational medicinal product name	Placebo matching to R10933+R10987
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 3 (R10933+R10987 2400 mg IV)
Arm description: Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 2400 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 2400 mg IV R10933+R10987 intravenously on Day 1	
Arm title	Phase 2: Cohort 3 (R10933+R10987 8000 mg IV)
Arm description: Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Arm type	Experimental
Investigational medicinal product name	R10933+R10987 8000 mg IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: single dose of 8000 mg IV R10933+R10987 intravenously on Day 1	

Number of subjects in period 1	Phase 1: Cohort 1 (Placebo)	Phase 1: Cohort 1 (R10933+R10987 2400 mg IV)	Phase 1: Cohort 1 (R10933+R10987 8000 mg IV)
Started	18	18	20
Completed	13	12	16
Not completed	5	6	4
Adverse event, serious fatal	2	-	1
Participant Decision	1	2	2
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	2	4	1
Sponsor Request	-	-	-

Number of subjects in period 1	Phase 2: Cohort 1 (Placebo)	Phase 2: Cohort 1 (R10933+R10987 2400 mg)	Phase 2: Cohort 1 (R10933+R10987 8000 mg IV)
Started	204	206	205
Completed	146	153	148
Not completed	58	53	57
Adverse event, serious fatal	27	25	21
Participant Decision	12	18	22
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	19	10	14
Sponsor Request	-	-	-

Number of subjects in period 1	Phase 3: Cohort 1 (Placebo)	Phase 3: Cohort 1 (R10933+R10987 2400 mg)	Phase 3: Cohort 1 (R10933+R10987 8000 mg IV)
Started	247	246	246
Completed	186	195	189
Not completed	61	51	57
Adverse event, serious fatal	42	23	37
Participant Decision	13	13	10
Physician decision	-	-	-
Adverse event, non-fatal	-	1	-
Lost to follow-up	5	14	10
Sponsor Request	1	-	-

Number of subjects in period 1	Phase 2: Cohort 1A (Placebo)	Phase 2: Cohort 1A (R10933+R10987 2400 mg IV)	Phase 2: Cohort 1A (R10933+R10987 8000 mg IV)
Started	198	202	197
Completed	157	165	166
Not completed	41	37	31
Adverse event, serious fatal	14	8	7
Participant Decision	15	16	17

Physician decision	1	-	-
Adverse event, non-fatal	-	1	1
Lost to follow-up	11	12	6
Sponsor Request	-	-	-

Number of subjects in period 1	Phase 2: Cohort 2 (Placebo)	Phase 2: Cohort 2 (R10933+R10987 2400 mg IV)	Phase 2: Cohort 2 (R10933+R10987 8000 mg IV)
Started	51	56	54
Completed	33	28	31
Not completed	18	28	23
Adverse event, serious fatal	13	25	19
Participant Decision	2	1	2
Physician decision	1	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	2	2	2
Sponsor Request	-	-	-

Number of subjects in period 1	Phase 2: Cohort 3 (Placebo)	Phase 2: Cohort 3 (R10933+R10987 2400 mg IV)	Phase 2: Cohort 3 (R10933+R10987 8000 mg IV)
Started	12	12	11
Completed	5	4	7
Not completed	7	8	4
Adverse event, serious fatal	7	8	4
Participant Decision	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Sponsor Request	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Phase 1: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 1: Cohort 1 (R10933+R10987 2400 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 1: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 2: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1 (R10933+R10987 2400 mg
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (R10933+R10987 2400 mg)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1A (Placebo)
Reporting group description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1A).	
Reporting group title	Phase 2: Cohort 1A (R10933+R10987 2400 mg IV)
Reporting group description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1A).	
Reporting group title	Phase 2: Cohort 1A (R10933+R10987 8000 mg IV)

Reporting group description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1A).

Reporting group title	Phase 2: Cohort 2 (Placebo)
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Reporting group description:

Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 2).

Reporting group title	Phase 2: Cohort 2 (R10933+R10987 2400 mg IV)
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Reporting group description:

Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).

Reporting group title	Phase 2: Cohort 2 (R10933+R10987 8000 mg IV)
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Reporting group description:

Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).

Reporting group title	Phase 2: Cohort 3 (Placebo)
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Reporting group description:

Participants on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 3).

Reporting group title	Phase 2: Cohort 3 (R10933+R10987 2400 mg IV)
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Reporting group description:

Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).

Reporting group title	Phase 2: Cohort 3 (R10933+R10987 8000 mg IV)
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Reporting group description:

Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).

Reporting group values	Phase 1: Cohort 1 (Placebo)	Phase 1: Cohort 1 (R10933+R10987 2400 mg IV)	Phase 1: Cohort 1 (R10933+R10987 8000 mg IV)
Number of subjects	18	18	20
Age Categorical Units: participants			
Age: 18- <40 years	1	1	2
Age: 40- <65 years	9	8	10
Age: >=65 years	8	9	8
Sex: Female, Male Units: participants			
Female	8	8	10
Male	10	10	10
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	12	7	10
Not Hispanic or Latino	6	11	10
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	2	8

White	12	11	11
More than one race	0	0	0
Unknown or Not Reported	3	3	1

Reporting group values	Phase 2: Cohort 1 (Placebo)	Phase 2: Cohort 1 (R10933+R10987 2400 mg)	Phase 2: Cohort 1 (R10933+R10987 8000 mg IV)
Number of subjects	204	206	205
Age Categorical Units: participants			
Age: 18- <40 years	26	16	17
Age: 40- <65 years	82	99	96
Age: >=65 years	96	91	92
Sex: Female, Male Units: participants			
Female	90	98	98
Male	114	108	107
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	49	50	52
Not Hispanic or Latino	144	148	146
Unknown or Not Reported	11	8	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	1	2
Asian	6	7	6
Native Hawaiian or Other Pacific Islander	2	1	1
Black or African American	34	21	33
White	136	146	134
More than one race	0	0	0
Unknown or Not Reported	25	30	29

Reporting group values	Phase 3: Cohort 1 (Placebo)	Phase 3: Cohort 1 (R10933+R10987 2400 mg)	Phase 3: Cohort 1 (R10933+R10987 8000 mg IV)
Number of subjects	247	246	246
Age Categorical Units: participants			
Age: 18- <40 years	29	28	14
Age: 40- <65 years	105	119	127
Age: >=65 years	113	99	105
Sex: Female, Male Units: participants			
Female	113	112	115
Male	134	134	131
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	92	94	82
Not Hispanic or Latino	146	140	155
Unknown or Not Reported	9	12	9
Race (NIH/OMB) Units: Subjects			

American Indian or Alaska Native	9	9	13
Asian	6	10	9
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	26	32	25
White	159	151	158
More than one race	0	0	0
Unknown or Not Reported	47	43	40

Reporting group values	Phase 2: Cohort 1A (Placebo)	Phase 2: Cohort 1A (R10933+R10987 2400 mg IV)	Phase 2: Cohort 1A (R10933+R10987 8000 mg IV)
Number of subjects	198	202	197
Age Categorical Units: participants			
Age: 18- <40 years	22	20	20
Age: 40- <65 years	82	101	91
Age: >=65 years	94	81	86
Sex: Female, Male Units: participants			
Female	91	87	89
Male	107	115	108
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	38	53	40
Not Hispanic or Latino	148	138	143
Unknown or Not Reported	12	11	14
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	11	8	6
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	27	32	25
White	111	116	131
More than one race	0	0	0
Unknown or Not Reported	49	46	34

Reporting group values	Phase 2: Cohort 2 (Placebo)	Phase 2: Cohort 2 (R10933+R10987 2400 mg IV)	Phase 2: Cohort 2 (R10933+R10987 8000 mg IV)
Number of subjects	51	56	54
Age Categorical Units: participants			
Age: 18- <40 years	4	4	6
Age: 40- <65 years	30	23	24
Age: >=65 years	17	29	24
Sex: Female, Male Units: participants			
Female	17	20	20
Male	34	36	34

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	13	22	18
Not Hispanic or Latino	35	33	30
Unknown or Not Reported	3	1	6
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	2	2	1
Native Hawaiian or Other Pacific Islander	1	1	0
Black or African American	7	6	9
White	33	39	36
More than one race	0	0	0
Unknown or Not Reported	7	8	8

Reporting group values	Phase 2: Cohort 3 (Placebo)	Phase 2: Cohort 3 (R10933+R10987 2400 mg IV)	Phase 2: Cohort 3 (R10933+R10987 8000 mg IV)
Number of subjects	12	12	11
Age Categorical			
Units: participants			
Age: 18- <40 years	0	1	1
Age: 40- <65 years	6	4	5
Age: ≥65 years	6	7	5
Sex: Female, Male			
Units: participants			
Female	8	4	2
Male	4	8	9
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	6	5	4
Not Hispanic or Latino	6	7	7
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	1	1	3
White	8	9	5
More than one race	0	0	0
Unknown or Not Reported	1	1	3

Reporting group values	Total		
Number of subjects	2203		
Age Categorical			
Units: participants			
Age: 18- <40 years	212		
Age: 40- <65 years	1021		
Age: ≥65 years	970		

Sex: Female, Male			
Units: participants			
Female	990		
Male	1213		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	647		
Not Hispanic or Latino	1453		
Unknown or Not Reported	103		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	36		
Asian	78		
Native Hawaiian or Other Pacific Islander	10		
Black or African American	295		
White	1406		
More than one race	0		
Unknown or Not Reported	378		

End points

End points reporting groups

Reporting group title	Phase 1: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 1: Cohort 1 (R10933+R10987 2400 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 1: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 1 (Cohort 1).	
Reporting group title	Phase 2: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1 (R10933+R10987 2400 mg)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (Placebo)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (R10933+R10987 2400 mg)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 3: Cohort 1 (R10933+R10987 8000 mg IV)
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 2: Cohort 1A (Placebo)
Reporting group description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1A).	
Reporting group title	Phase 2: Cohort 1A (R10933+R10987 2400 mg IV)
Reporting group description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1A).	

Reporting group title	Phase 2: Cohort 1A (R10933+R10987 8000 mg IV)
Reporting group description:	
Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1A).	
Reporting group title	Phase 2: Cohort 2 (Placebo)
Reporting group description:	
Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2: Cohort 2 (R10933+R10987 2400 mg IV)
Reporting group description:	
Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2: Cohort 2 (R10933+R10987 8000 mg IV)
Reporting group description:	
Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2: Cohort 3 (Placebo)
Reporting group description:	
Participants on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 3).	
Reporting group title	Phase 2: Cohort 3 (R10933+R10987 2400 mg IV)
Reporting group description:	
Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Reporting group title	Phase 2: Cohort 3 (R10933+R10987 8000 mg IV)
Reporting group description:	
Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Subject analysis set title	Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1)	
Subject analysis set title	Ph.3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1.	
Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).	
Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).	
Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other	

similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3

(Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Phase 3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received

single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1

Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1

Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of matching placebo intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 3 (Cohort 1) and participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Pooled Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single dose of placebo matching to R10933+R10987 intravenously on Day 1

Subject analysis set title	Pooled R10933+R10987 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of R10933+R10987 2400 mg intravenously on Day 1

Subject analysis set title	Pooled R10933+R10987 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of R10933+R10987 8000 mg intravenously on Day 1.

Subject analysis set title	Pooled Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1

Subject analysis set title	Pooled R10933+R10987 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of R10933+R10987 8000 mg intravenously on Day 1

Subject analysis set title	Phase 3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 Cohort 1: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 Cohort 1A: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A

Subject analysis set title	Phase 2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 Cohort 1: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A

Subject analysis set title	Phase 2 Cohort 1A: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1

Subject analysis set title	Phase 3 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1

Subject analysis set title	Phase 3 Cohort 1: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 Cohort 1A: Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 Cohort 1A: 8000 mg IV
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Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A	
Subject analysis set title	Phase 3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 3 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 3 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 Cohort 1A: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A	
Subject analysis set title	Phase 2: Cohort 1A Combined R10933+R10987
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 (2400 mg or 8000 mg) intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 3 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 3 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1	
Subject analysis set title	Phase 3 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.	

Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV) Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A	
Subject analysis set title	Phase 2 Cohort 1A: Combined
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 Cohort 1A: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 Cohort 1A: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A	
Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.	
Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol
Subject analysis set description: Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of	

R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 3 (Cohort 1): Combined R10933+R10987 IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Cohort 1A

Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
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Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg or 8000 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Cohort 1A.	
Subject analysis set title	Pooled (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1	
Subject analysis set title	Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg and 8000 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (2400 mg) intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 (8000 mg) intravenously on Day 1	
Subject analysis set title	Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of 2400mg or 8000 mg R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled(Ph1C1 and Ph2C1): R10933+R10987(2400mg IV)

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similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1).

Subject analysis set title	Phase 2 (Cohort 2): R10933+R10987 2400mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).

Subject analysis set title	Phase 2 (Cohort 2): R10933+R10987 8000mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).

Subject analysis set title	Phase 2 (Cohort 3): R10933+R10987 2400mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).

Subject analysis set title	Phase 2 (Cohort 3): R10933+R10987 8000mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 2400mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 3 (Cohort 1).

Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 8000mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1).

Subject analysis set title	Phase 1 [Cohort 1]: R10983+10987 2400mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 1 (Cohort 1).

Subject analysis set title	Phase 1 [Cohort 1]: R10983+10987 8000mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 1 (Cohort 1)

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 2400mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Phase 2 (Cohort 1A): R10933+R10987 8000mg IV
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with COVID-19 symptoms but not requiring supplemental oxygen received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1A).

Subject analysis set title	Phase 2 (Cohort 1): R10933+R10987 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 1).	
Subject analysis set title	Phase 2 (Cohort 1): R10933+R10987 8000mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1).	
Subject analysis set title	Phase 2 (Cohort 2): R10933+R10987 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Subject analysis set title	Phase 2 (Cohort 2): R10933+R10987 8000mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Subject analysis set title	Phase 2 (Cohort 3): R10933+R10987 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Subject analysis set title	Phase 2 (Cohort 3): R10933+R10987 8000mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 3 (Cohort 1).	
Subject analysis set title	Phase 3 (Cohort 1): R10933+R10987 8000mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1).	
Subject analysis set title	Pooled Placebo
Subject analysis set type	Per protocol
Subject analysis set description: Participants received single dose of placebo matching to R10933+R10987 intravenously on Day 1	
Subject analysis set title	Pooled R10933+R10987 2400mg IV
Subject analysis set type	Per protocol
Subject analysis set description: Participants received a single 2400mg intravenous dose of R10933+R10987	
Subject analysis set title	Pooled REGN10933+REGN10987 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 8000 mg intravenous dose of R10933+R10987

Subject analysis set title	Pooled Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single intravenous dose of placebo matching R10933+R10987

Subject analysis set title	Pooled R10933+R10987 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 2400mg dose of R10933+R10987 intravenously on Day 1

Subject analysis set title	Pooled REGN10933+REGN10987 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 8000 mg dose of R10933+R10987 intravenously on Day 1

Subject analysis set title	Pooled (Phase 2/3) Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received single dose of placebo matching to R10933+R10987 intravenously on Day 1

Subject analysis set title	Pooled (Phase 2/3) R10933+R10987 2400mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 2400mg intravenous dose of R10933+R10987

Subject analysis set title	Pooled (Phase 2/3) REGN10933+REGN10987 8000mg IV
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 8000 mg intravenous dose of R10933+R10987

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Time-weighted Average (TWA) Change in Viral Load in Nasopharyngeal (NP) Samples Based on Seronegative mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Time-weighted Average (TWA) Change in Viral Load in Nasopharyngeal (NP) Samples Based on Seronegative mFAS
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End point description:

Time-weighted average daily change from Day 1 to Day 7 in viral load (log₁₀ copies/mL), as measured by reverse transcription quantitative polymerase chain reaction (RT-qPCR) in nasopharyngeal (NP) swab samples.

End point type	Primary
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End point timeframe:

Day 1 to Day 7

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	150	160	310
Units: log ₁₀ copies/milliliter (mL)				
least squares mean (standard error)	-1.03 (± 0.10)	-1.28 (± 0.09)	-1.34 (± 0.09)	-1.31 (± 0.06)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo
Number of subjects included in analysis	281
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0663 ^[1]
Method	ANCOVA
Parameter estimate	Least Square (LS) Mean Difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	0.02

Notes:

[1] - P-value for change from baseline on log scale for each treatment group was based on the Analysis of covariance (ANCOVA) model with treatment group.

Statistical analysis title	Placebo vs. Combined
Statistical analysis description:	
To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.	
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	441
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0172 ^[2]
Method	ANCOVA
Parameter estimate	Least Square (LS) Mean Difference
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	-0.05

Notes:

[2] - P-value for change from baseline on log scale for each treatment group was based on the Analysis of covariance (ANCOVA) model with treatment group.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV

Number of subjects included in analysis	291
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0204 ^[3]
Method	ANCOVA
Parameter estimate	Least Square (LS) Mean Difference
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	0.05

Notes:

[3] - P-value for change from baseline on log scale for each treatment group was based on the Analysis of covariance (ANCOVA) model with treatment group.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants who Died or Went on Mechanical Ventilation From Day 6 Through Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants who Died or Went on Mechanical Ventilation From Day 6 Through Day 29 Based on High Viral Load mFAS
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End point description:

Percentage of participants who died or went on mechanical ventilation from Day 6 through Day 29 based on high viral load mFAS were reported.

End point type	Primary
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End point timeframe:

Day 6 to Day 29

End point values	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	211	220	225	445
Units: Percentage of Participants				
number (confidence interval 95%)	13.3 (9.0 to 18.6)	7.3 (4.2 to 11.5)	12.4 (8.4 to 17.5)	9.9 (7.3 to 13.0)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV

Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0431 [4]
Method	Cochran-Mantel-Haenszel

Notes:

[4] - P-value was derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
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Statistical analysis description:

To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.

Comparison groups	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	656
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2048 [5]
Method	Cochran-Mantel-Haenszel

Notes:

[5] - P-value was derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	436
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7975 [6]
Method	Cochran-Mantel-Haenszel

Notes:

[6] - P-value was derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 6 through Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 6 through Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who died or went on mechanical ventilation from Day 6 through Day 29 based on seronegative mFAS were reported.

End point type	Primary
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End point timeframe:

Day 6 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	147	162	179	341
Units: Percentage of Participants				
number (confidence interval 95%)	15.0 (9.6 to 21.8)	4.9 (2.2 to 9.5)	10.6 (6.5 to 16.1)	7.9 (5.3 to 11.3)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1+ Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	309
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0039 ^[7]
Method	Cochran-Mantel-Haenszel

Notes:

[7] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
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Statistical analysis description:

To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.

Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	488
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0195 ^[8]
Method	Cochran-Mantel-Haenszel

Notes:

[8] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	326
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2415 ^[9]
Method	Cochran-Mantel-Haenszel

Notes:

[9] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value was based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 6 Through Day 29 Based on overall mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 6 Through Day 29 Based on overall mFAS
End point description: Percentage of participants who died or went on mechanical ventilation from Day 6 through Day 29 based on overall FAS were reported.	
End point type	Primary
End point timeframe: Day 6 to Day 29	

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Phase 3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	367	387	383	770
Units: Percentage of Participants				
number (confidence interval 95%)	10.6 (7.7 to 14.2)	5.4 (3.4 to 8.2)	10.7 (7.8 to 14.2)	8.1 (6.2 to 10.2)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Phase 3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	754
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0085 ^[10]
Method	Cochran-Mantel-Haenszel

Notes:

[10] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Statistical analysis description: To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.	
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined

Number of subjects included in analysis	1137
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1486 ^[11]
Method	Cochran-Mantel-Haenszel

Notes:

[11] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	750
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9902 ^[12]
Method	Cochran-Mantel-Haenszel

Notes:

[12] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on High Viral Load mFAS
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End point description:

Percentage of participants who died or went on mechanical ventilation from Day 1 through Day 29 based on high viral load mFAS were reported.

End point type	Primary
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End point timeframe:

Day 1 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Percentage of Participants				
number (confidence interval 95%)	18.8 (13.9 to 24.4)	10.0 (6.4 to 14.6)	14.4 (10.2 to 19.5)	12.2 (9.4 to 15.5)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3

	Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0092 ^[13]
Method	Cochran-Mantel-Haenszel

Notes:

[13] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
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Statistical analysis description:

To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.

Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0249 ^[14]
Method	Cochran-Mantel-Haenszel

Notes:

[14] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.221 ^[15]
Method	Cochran-Mantel-Haenszel

Notes:

[15] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who died or went on mechanical ventilation from Day 1 through Day 29 based on seronegative mFAS were reported.

End point type	Primary
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End point timeframe:

Day 1 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Percentage of Participants				
number (confidence interval 95%)	19.4 (13.6 to 26.4)	8.1 (4.5 to 13.3)	12.2 (7.9 to 17.8)	10.3 (7.3 to 13.9)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0045 ^[16]
Method	Cochran-Mantel-Haenszel

Notes:

[16] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Statistical analysis description:	
To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.	
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0061 ^[17]
Method	Cochran-Mantel-Haenszel

Notes:

[17] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0714 ^[18]
Method	Cochran-Mantel-Haenszel

Notes:

[18] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < 5$ or $n(1-p) < 5$ in any treatment group, p-value was based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on Overall mFAS

End point title	Pooled Analysis (Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]): Percentage of Participants Who Died or Went on Mechanical Ventilation From Day 1 Through Day 29 Based on Overall mFAS
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End point description:

Percentage of participants who died or went on mechanical ventilation from Day 1 through Day 29 based on overall mFAS were reported.

End point type	Primary
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End point timeframe:

Day 1 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	393	406	398	804
Units: Percentage of Participants				
number (confidence interval 95%)	14.8 (11.4 to 18.7)	7.9 (5.5 to 10.9)	12.6 (9.5 to 16.2)	10.2 (8.2 to 12.5)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Phase 2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0023 ^[19]
Method	Cochran-Mantel-Haenszel

Notes:

[19] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
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Statistical analysis description:

To control alpha at a strict 0.05 level, this endpoint was tested hierarchically, with the virologic endpoint tested first. All hierarchical testing was done using the combined dose group.

Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
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Number of subjects included in analysis	1197
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0212 ^[20]
Method	Cochran-Mantel-Haenszel

Notes:

[20] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	791
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3544 ^[21]
Method	Cochran-Mantel-Haenszel

Notes:

[21] - P-value was derived CMH test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value was based on Fisher Exact Test.

Primary: Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Number of Participants with Treatment-Emergent Serious Adverse Events

End point title	Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Number of Participants with Treatment-Emergent Serious Adverse Events ^[22]
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End point description:

Treatment-emergent adverse events are defined as those that are not present at baseline or represent the exacerbation of a pre-existing condition during the observation period.

End point type	Primary
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End point timeframe:

Up to Day 169

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	222	224	225	449
Units: Participants	54	45	47	92

Statistical analyses

No statistical analyses for this end point

Primary: Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Number of Participants with Grade ≥ 2 Infusion Related Reactions up to Day 4

End point title	Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]):
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End point description:

Infusion-related reactions are defined as any relevant adverse event that occurs during the infusion or up to day 4. The severity of adverse events (including test findings classified as adverse events) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE).

End point type Primary

End point timeframe:

Up to Day 4

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	222	224	225	449
Units: Participants	3	2	6	8

Statistical analyses

No statistical analyses for this end point

Primary: Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Cumulative Incidence of Death or Mechanical Ventilation Based on Seronegative mFAS

End point title Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Cumulative Incidence of Death or Mechanical Ventilation Based on Seronegative mFAS^[24]

End point description:

Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type Primary

End point timeframe:

Up to Day 29

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint is only applicable to participants in specified phases/cohorts

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	46	41	87
Units: Cumulative Incidence Percentage				
number (confidence interval 80%)	23.0 (16.9 to 30.9)	15.1 (10.5 to 21.4)	20.3 (14.7 to 27.8)	17.6 (13.8 to 22.3)

Statistical analyses

No statistical analyses for this end point

Primary: Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Number of Participants with Grade ≥ 2 Hypersensitivity Reactions Up to Day 29

End point title	Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Number of Participants with Grade ≥ 2 Hypersensitivity Reactions Up to Day 29 ^[25]
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End point description:

Hypersensitivity reactions are defined as any relevant adverse event that occurs during the infusion or up to study day 29. The severity of adverse events (including test findings classified as adverse events) were graded according to NCI-CTCAE.

End point type	Primary
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End point timeframe:

Up to Day 29

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	222	224	225	449
Units: Participants	1	2	2	4

Statistical analyses

No statistical analyses for this end point

Primary: Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Cumulative Incidence of Death or Mechanical Ventilation Based on High Viral Load mFAS

End point title	Pooled Analysis (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Cumulative Incidence of Death or Mechanical Ventilation Based on High Viral Load mFAS ^[26]
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End point description:

Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Primary
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End point timeframe:

Up to Day 29

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses for this end point

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	50	53	58	111
Units: Cumulative Incidence Percentage				
number (confidence interval 80%)	20.7 (15.7 to 26.9)	18.9 (14.3 to 24.8)	11.6 (8.0 to 16.8)	15.3 (12.2 to 19.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on High Viral Load mFAS
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End point description:

Percentage of participants who went on mechanical ventilation by Day 29 based on High Viral Load mFAS in pooled analysis phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Percentage of Participants				
number (confidence interval 95%)	11.4 (7.6 to 16.2)	6.1 (3.4 to 10.0)	8.5 (5.3 to 12.8)	7.3 (5.1 to 10.0)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV

Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0575 ^[27]
Method	Cochran-Mantel-Haenszel

Notes:

[27] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0849 ^[28]
Method	Cochran-Mantel-Haenszel

Notes:

[28] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3133 ^[29]
Method	Cochran-Mantel-Haenszel

Notes:

[29] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who went on mechanical ventilation at Day 29 based on Seronegative mFAS in pooled analysis phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Percentage of Participants				
number (confidence interval 95%)	10.0 (5.8 to 15.7)	5.8 (2.8 to 10.4)	7.4 (4.1 to 12.2)	6.7 (4.3 to 9.8)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2167 ^[30]
Method	Cochran-Mantel-Haenszel

Notes:

[30] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2206 ^[31]
Method	Cochran-Mantel-Haenszel

Notes:

[31] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4123 ^[32]
Method	Cochran-Mantel-Haenszel

Notes:

[32] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 Through Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 Through Day 29 Based on High Viral Load mFAS
End point description:	Percentage of participants who died from Day 6 through Day 29 based on high viral load mFAS were reported.
End point type	Secondary
End point timeframe:	Day 6 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	222	226	228	454
Units: Percentage of Participants				
number (confidence interval 95%)	13.1 (8.9 to 18.2)	7.1 (4.1 to 11.2)	10.1 (6.5 to 14.8)	8.6 (6.2 to 11.6)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	448
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0383 ^[33]
Method	Cochran-Mantel-Haenszel

Notes:

[33] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	676
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0766 ^[34]
Method	Cochran-Mantel-Haenszel

Notes:

[34] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV

Number of subjects included in analysis	450
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3296 ^[35]
Method	Cochran-Mantel-Haenszel

Notes:

[35] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 Through Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 Through Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who died from Day 6 through Day 29 Based on seronegative mFAS in pooled analysis phase 3 (cohort 1) and phase 2 (cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Day 6 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	153	167	181	348
Units: Percentage of Participants				
number (confidence interval 95%)	13.7 (8.7 to 20.2)	4.8 (2.1 to 9.2)	7.2 (3.9 to 12.0)	6.0 (3.8 to 9.1)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 ^[36]
Method	Cochran-Mantel-Haenszel

Notes:

[36] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined

Number of subjects included in analysis	501
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0051 ^[37]
Method	Cochran-Mantel-Haenszel

Notes:

[37] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If np < =5 or n(1-p) <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	334
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0507 ^[38]
Method	Cochran-Mantel-Haenszel

Notes:

[38] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If np < =5 or n(1-p) <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on High Viral Load mFAS
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End point description:

Percentage of participants who died from Day 1 through Day 29 based on High Viral Load mFAS in pooled analysis phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Day 1 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Percentage of participants				
number (confidence interval 95%)	14.4 (10.1 to 19.6)	7.4 (4.3 to 11.5)	11.0 (7.3 to 15.7)	9.2 (6.7 to 12.2)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV

Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0174 ^[39]
Method	Cochran-Mantel-Haenszel

Notes:

[39] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0454 ^[40]
Method	Cochran-Mantel-Haenszel

Notes:

[40] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.29 ^[41]
Method	Cochran-Mantel-Haenszel

Notes:

[41] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who died from Day 1 through Day 29 based on seronegative mFAS in pooled analysis phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Day 1 to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Percentage of Participants				
number (confidence interval 95%)	15.0 (9.9 to 21.5)	5.2 (2.4 to 9.7)	8.0 (4.5 to 12.8)	6.7 (4.3 to 9.8)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.004 ^[42]
Method	Cochran-Mantel-Haenszel

Notes:

[42] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0032 ^[43]
Method	Cochran-Mantel-Haenszel

Notes:

[43] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0413 ^[44]
Method	Cochran-Mantel-Haenszel

Notes:

[44] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on High Viral Load mFAS
End point description:	Percentage of participants who were discharged by Day 29 based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported.
End point type	Secondary
End point timeframe:	by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Percentage of Participants				
number (confidence interval 95%)	80.3 (74.6 to 85.3)	89.2 (84.4 to 92.9)	86.9 (81.9 to 90.9)	88.0 (84.7 to 90.8)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0105 ^[45]
Method	Cochran-Mantel-Haenszel

Notes:

[45] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0622 ^[46]
Method	Cochran-Mantel-Haenszel

Notes:

[46] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined

Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0088 [47]
Method	Cochran-Mantel-Haenszel

Notes:

[47] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants who Were Discharged by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants who Were Discharged by Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who were discharged by Day 29 based on seronegative mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Percentage of Participants				
number (confidence interval 95%)	81.3 (74.3 to 87.0)	90.1 (84.6 to 94.1)	89.9 (84.7 to 93.8)	90.0 (86.4 to 92.9)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0275 [48]
Method	Cochran-Mantel-Haenszel

Notes:

[48] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined

Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0072 ^[49]
Method	Cochran-Mantel-Haenszel

Notes:

[49] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0223 ^[50]
Method	Cochran-Mantel-Haenszel

Notes:

[50] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital Over Time Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital Over Time Based on High Viral Load mFAS
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End point description:

Percentage of participants who died or were readmitted to hospital over time based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported. Readmission to hospital was based on investigator report.

End point type	Secondary
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End point timeframe:

Up to Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Percentage of Participants				
number (confidence interval 95%)	21.0 (15.9 to 26.8)	15.2 (10.8 to 20.4)	17.4 (12.8 to 22.8)	16.3 (13.0 to 19.9)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3

	Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1032 ^[51]
Method	Cochran-Mantel-Haenszel

Notes:

[51] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1314 ^[52]
Method	Cochran-Mantel-Haenszel

Notes:

[52] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.335 ^[53]
Method	Cochran-Mantel-Haenszel

Notes:

[53] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital by Day 29 Based on Seronegative mFAS
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End point description:

Percentage of participants who died or were readmitted to hospital at Day 29 based on seronegative mFAS in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Readmission to hospital was based on investigator report.

End point type	Secondary
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End point timeframe:

by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Percentage of Participants				
number (confidence interval 95%)	24.4 (17.9 to 31.8)	11.6 (7.2 to 17.4)	12.8 (8.4 to 18.4)	12.2 (9.0 to 16.1)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.00024 ^[54]
Method	Cochran-Mantel-Haenszel

Notes:

[54] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005 ^[55]
Method	Cochran-Mantel-Haenszel

Notes:

[55] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0054 ^[56]
Method	Cochran-Mantel-Haenszel

Notes:

[56] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death (ie, Overall Survival) by Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death (ie, Overall Survival) by Day 29 Based on High Viral Load mFAS
End point description: Overall Survival was defined as time interval from randomization to death. Percentage of participants with cumulative incidence of death (ie, overall survival) at Day 29 from randomization based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.	
End point type	Secondary
End point timeframe: by Day 29	

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	181	201	190	391
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	14.9 (10.8 to 20.3)	7.7 (4.8 to 12.1)	11.7 (8.1 to 16.7)	9.7 (7.3 to 12.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death (ie, Overall Survival) by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death (ie, Overall Survival) by Day 29 Based on Seronegative mFAS
End point description: Overall Survival was defined as time interval from randomization to death. Percentage of participants with cumulative incidence of death (ie, overall survival) at Day 29 from randomization based on seronegative mFAS in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.	
End point type	Secondary
End point timeframe: by Day 29	

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	121	148	308
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	8.4 (5.1 to	15.8 (10.9 to	5.6 (3.0 to	7.0 (4.8 to

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on High Viral Load mFAS
End point description:	Number of participants with cumulative incidence of mechanical ventilation by Day 29 based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.
End point type	Secondary
End point timeframe:	by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	170	194	183	377
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	11.8 (8.2 to 16.8)	6.3 (3.7 to 10.3)	9.1 (6.0 to 13.8)	7.7 (5.5 to 10.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on Seronegative mFAS
End point description:	Percentage of participants with cumulative incidence of mechanical ventilation by Day 29 based on seronegative mFAS in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.
End point type	Secondary

End point timeframe:
by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	114	143	152	295
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	10.6 (6.6 to 16.8)	6.0 (3.3 to 11.0)	7.9 (4.8 to 13.0)	7.0 (4.8 to 10.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on High Viral Load mFAS
End point description:	Percentage of participants with cumulative incidence of death or mechanical ventilation by Day 29 based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.
End point type	Secondary
End point timeframe:	by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	170	194	183	377
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	19.1 (14.6 to 24.9)	10.2 (6.9 to 15.0)	15.0 (11.0 to 20.4)	12.7 (9.9 to 16.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on Seronegative mFAS
End point description:	Percentage of participants with cumulative incidence of death or mechanical ventilation by Day 29 based on seronegative mFAS in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.
End point type	Secondary
End point timeframe:	by Day 29

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	114	143	152	295
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	20.1 (14.6 to 27.3)	8.4 (5.1 to 13.8)	12.7 (8.7 to 18.6)	10.7 (7.9 to 14.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on High Viral Load mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on High Viral Load mFAS
End point description:	Time to discharge from hospital based on High Viral Load mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) was reported.
End point type	Secondary
End point timeframe:	Up to Day 56

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	229	231	236	467
Units: Days				
median (confidence interval 95%)	5.0 (4.0 to 6.0)	4.0 (4.0 to 5.0)	4.0 (3.0 to 5.0)	4.0 (4.0 to 5.0)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0533 ^[57]
Method	Logrank

Notes:

[57] - P-value based on stratified log-rank test with the type of background standard-of-care and baseline serostatus as stratification factors.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	696
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0229 ^[58]
Method	Logrank

Notes:

[58] - P-value based on stratified log-rank test with the type of background standard-of-care and baseline serostatus as stratification factors.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	465
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0411 ^[59]
Method	Logrank

Notes:

[59] - P-value based on stratified log-rank test with the type of background standard-of-care and baseline serostatus as stratification factors.

Secondary: Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on Seronegative mFAS

End point title	Pooled Analysis Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on Seronegative mFAS
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End point description:

Time to discharge from hospital based on Seronegative mFAS in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

Up to Day 56

End point values	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	160	172	188	360
Units: Days				
median (confidence interval 95%)	4.5 (4.0 to 6.0)	4.0 (3.0 to 5.0)	4.0 (3.0 to 4.0)	4.0 (3.0 to 4.0)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 2400mg IV
Number of subjects included in analysis	332
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0218
Method	Stratified Log Rank Test

Statistical analysis title	Placebo vs. Combined
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Combined
Number of subjects included in analysis	520
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0067
Method	Stratified Log Rank Test

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: Placebo v Pooled Ph.3 Cohort 1 + Ph.2 Cohort 1A: 8000mg IV
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0156
Method	Stratified Log Rank Test

Secondary: Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Treatment-Emergent Serious Adverse Events

End point title	Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Treatment-Emergent Serious Adverse Events
End point description:	
End point type	Secondary
End point timeframe:	
Up to Day 169	

End point values	Pooled Placebo	Pooled R10933+R10987 2400 mg IV	Pooled R10933+R10987 8000 mg IV	Pooled Combined R10933+R10987 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	730	740	733	1473
Units: Participants	203	177	181	358

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Grade ≥ 2 Hypersensitivity Reactions Up to Day 29

End point title	Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Grade ≥ 2 Hypersensitivity Reactions Up to Day 29
End point description:	
End point type	Secondary
End point timeframe:	
Up to Day 29	

End point values	Pooled Placebo	Pooled R10933+R10987 2400 mg IV	Pooled R10933+R10987 8000 mg IV	Pooled Combined R10933+R10987 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	730	740	733	1473
Units: Participants	2	5	7	12

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Grade ≥ 2 Infusion Related Reactions up to Day 4

End point title	Pooled Analysis (Phases 1/2/3 [Cohort 1] and Phase 2 [Cohorts 1A/2/3]): Number of Participants with Grade ≥ 2 Infusion Related Reactions up to Day 4
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End point description:

End point type	Secondary
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End point timeframe:

Up to Day 4

End point values	Pooled Placebo	Pooled R10933+R10987 2400 mg IV	Pooled R10933+R10987 8000 mg IV	Pooled Combined R10933+R10987 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	730	740	733	1473
Units: Participants	6	11	15	26

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on Seronegative mFAS ^[60]
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End point description:

Percentage of participants who went on mechanical ventilation in phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

by Day 29

Notes:

[60] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Percentage of Participants				
number (confidence interval 95%)	17.1 (9.2 to 28.0)	4.4 (1.2 to 11.0)	8.8 (3.6 to 17.2)	17.1 (9.7 to 27.0)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: Percentage of Participants				
number (confidence interval 95%)	13.0 (8.2 to 19.1)	3.3 (0.7 to 9.2)	0.0 (0.0 to 0.0)	1.5 (0.3 to 4.4)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2162 ^[61]
Method	Cochran-Mantel-Haenszel

Notes:

[61] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs, Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2103 ^[62]
Method	Cochran-Mantel-Haenszel

Notes:

[62] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7189 ^[63]
Method	Cochran-Mantel-Haenszel

Notes:

[63] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	placebo vs. 8000mg IV
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Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0429 ^[64]
Method	Cochran-Mantel-Haenszel

Notes:

[64] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8783 ^[65]
Method	Cochran-Mantel-Haenszel

Notes:

[65] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5583 ^[66]
Method	Cochran-Mantel-Haenszel

Notes:

[66] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 through Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 6 through Day 29 Based on Seronegative mFAS ^[67]
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End point description:

Percentage of participants who died from Day 6 through Day 29 in phase 3 (cohort 1) and phase 2 (cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Day 6 to Day 29

Notes:

[67] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	67	86	79	80
Units: Percentage of Participants				
number (confidence interval 95%)	19.4 (10.8 to 30.9)	9.3 (4.1 to 17.5)	6.3 (2.1 to 14.2)	10.0 (4.4 to 13.6)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	159	88	101	189
Units: Percentage of Participants				
number (confidence interval 95%)	8.2 (4.4 to 13.6)	3.4 (0.7 to 9.6)	5.0 (1.6 to 11.2)	4.2 (1.8 to 8.2)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0223 [68]
Method	Cochran-Mantel-Haenszel

Notes:

[68] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1256 [69]
Method	Cochran-Mantel-Haenszel

Notes:

[69] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined

Number of subjects included in analysis	226
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.023 ^[70]
Method	Cochran-Mantel-Haenszel

Notes:

[70] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	174
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1298 ^[71]
Method	Cochran-Mantel-Haenszel

Notes:

[71] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2642 ^[72]
Method	Cochran-Mantel-Haenszel

Notes:

[72] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.097 ^[73]
Method	Cochran-Mantel-Haenszel

Notes:

[73] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died From Day 1 Through Day 29 Based on Seronegative mFAS ^[74]
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End point description:

Percentage of participants who died from Day 1 through Day 29 in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Day 1 to Day 29

Notes:

[74] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Percentage of Participants				
number (confidence interval 95%)	22.9 (13.7 to 34.4)	8.9 (3.9 to 16.8)	7.5 (2.8 to 15.6)	11.0 (5.1 to 19.8)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: Percentage of Participants				
number (confidence interval 95%)	9.3 (5.3 to 14.8)	3.3 (0.7 to 9.2)	5.7 (2.1 to 11.9)	4.5 (2.1 to 8.5)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0147 ^[75]
Method	Cochran-Mantel-Haenszel

Notes:

[75] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0669 ^[76]
Method	Cochran-Mantel-Haenszel

Notes:

[76] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0094 ^[77]
Method	Cochran-Mantel-Haenszel

Notes:

[77] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1306 ^[78]
Method	Cochran-Mantel-Haenszel

Notes:

[78] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3576 ^[79]
Method	Cochran-Mantel-Haenszel

Notes:

[79] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1476 ^[80]
Method	Cochran-Mantel-Haenszel

Notes:

[80] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on Seronegative mFAS ^[81]
End point description:	Percentage of participants who were discharged in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) by Day 29 were reported.
End point type	Secondary
End point timeframe:	by Day 29
Notes:	<p>[81] - 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.</p> <p>Justification: This endpoint is only applicable to participants in specified phases/cohorts</p>

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Percentage of Participants				
number (confidence interval 95%)	70.0 (57.9 to 80.4)	90.0 (81.9 to 95.3)	85.0 (75.3 to 92.0)	84.1 (74.4 to 91.3)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: Percentage of Participants				
number (confidence interval 95%)	84.6 (78.1 to 89.8)	94.6 (87.8 to 98.2)	94.3 (88.1 to 97.9)	94.4 (90.3 to 97.2)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0481 ^[82]
Method	Cochran-Mantel-Haenszel

Notes:

[82] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0535 ^[83]
Method	Cochran-Mantel-Haenszel

Notes:

[83] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.251 ^[84]
Method	Cochran-Mantel-Haenszel

Notes:

[84] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2784 ^[85]
Method	Cochran-Mantel-Haenszel

Notes:

[85] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1702 ^[86]
Method	Cochran-Mantel-Haenszel

Notes:

[86] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined

Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0199 ^[87]
Method	Cochran-Mantel-Haenszel

Notes:

[87] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital by Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital by Day 29 Based on Seronegative mFAS ^[88]
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End point description:

Percentage of participants who died or were readmitted to hospital in phase 3 (Cohort 1) and phase 2 (Cohort 1A) by Day 29 were reported. Readmission to hospital was based on investigator report.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[88] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Percentage of Participants				
number (confidence interval 95%)	27.1 (17.2 to 39.1)	22.2 (14.1 to 32.2)	13.8 (7.1 to 23.3)	14.6 (7.8 to 24.2)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: Percentage of Participants				
number (confidence interval 95%)	14.2 (9.2 to 20.5)	9.8 (4.6 to 17.8)	11.3 (6.0 to 18.9)	10.6 (6.7 to 15.8)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV

Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.05 ^[89]
Method	Cochran-Mantel-Haenszel

Notes:

[89] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0663 ^[90]
Method	Cochran-Mantel-Haenszel

Notes:

[90] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0229 ^[91]
Method	Cochran-Mantel-Haenszel

Notes:

[91] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0208 ^[92]
Method	Cochran-Mantel-Haenszel

Notes:

[92] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV

Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0388 ^[93]
Method	Cochran-Mantel-Haenszel

Notes:

[93] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0092 ^[94]
Method	Cochran-Mantel-Haenszel

Notes:

[94] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death up to Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death up to Day 29 Based on Seronegative mFAS ^[95]
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End point description:

Percentage of participants with cumulative incidence of death in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) up to Day 29 from randomization were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[95] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	51	70	70	70
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	23.6 (15.1 to 35.6)	9.6 (4.9 to 18.3)	7.8 (3.6 to 16.5)	11.4 (6.1 to 20.7)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2: Cohort 1A Combined R10933+R109 87
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	140	78	90	168
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	9.6 (5.9 to 15.4)	3.6 (1.2 to 10.9)	5.9 (2.7 to 12.8)	4.8 (2.6 to 9.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation by Day 29 Based on Seronegative mFAS ^[96]
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End point description:

Percentage of participants with cumulative incidence of mechanical ventilation in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) by Day 29 were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
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End point timeframe:

by Day 29

Notes:

[96] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 2 Cohort 1A: 8000 mg IV	Phase 3 Cohort 1: 2400 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	46	68	90	66
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	18.2 (10.8 to 30.0)	4.7 (1.8 to 12.1)	0.0 (0.0 to 0.0)	8.9 (4.4 to 17.8)

End point values	Phase 3 Cohort 1: 8000 mg IV	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	128	77	167
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	17.6 (10.8 to 27.9)	13.4 (8.9 to 19.8)	3.5 (1.1 to 10.5)	1.7 (0.5 to 5.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation by Day 29 Based on Seronegative mFAS ^[97]
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End point description:

Percentage of participants with cumulative incidence of death or mechanical ventilation in Phase 3 (Cohort 1) and Phase 2 (Cohort 1A) by Day 29 were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
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End point timeframe:

by Day 29

Notes:

[97] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 2 Cohort 1A: 8000 mg IV	Phase 3 Cohort 1: 2400 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	46	68	90	66
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	30.4 (21.0 to 42.7)	11.8 (6.5 to 20.8)	5.9 (2.7 to 12.8)	12.7 (7.0 to 22.3)

End point values	Phase 3 Cohort 1: 8000 mg IV	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	128	77	167
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	21.2 (13.8 to 31.9)	17.0 (12.0 to 23.8)	4.7 (1.8 to 12.1)	5.4 (2.9 to 9.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on Seronegative mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge From Hospital Based on Seronegative mFAS ^[98]
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End point description:

Time to discharge from hospital up to Day 56 was reported.

End point type	Secondary
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End point timeframe:

Up to Day 56

Notes:

[98] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Days				
median (confidence interval 95%)	8.5 (5.0 to 15.0)	4.0 (3.0 to 4.0)	5.0 (4.0 to 7.0)	6.0 (4.0 to 9.0)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	198	86	99
Units: Days				
median (confidence interval 95%)	6.0 (4.0 to 7.0)	3.0 (2.0 to 4.0)	3.0 (2.0 to 4.0)	3.0 (2.0 to 4.0)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.037
Method	stratified log-rank test

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1596
Method	stratified log-rank test

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	189
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0407
Method	stratified log-rank test

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1802
Method	stratified log-rank test

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0523
Method	stratified log-rank test

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0444
Method	stratified log-rank test

Secondary: Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: TWA Change From Baseline Viral Load (Seronegative mFAS) in NP Samples up to Day 11 Based on Seronegative mFAS

End point title	Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: TWA Change From Baseline Viral Load (Seronegative mFAS) in NP Samples
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End point description:

TWA change from baseline in viral load up to Day 11 was calculated for each participant using the trapezoidal rule as the area under the curve for change from baseline at each time point divided by the time interval for the observation period. TWA change from baseline viral load in NP samples through Day 11, was measured by RT-qPCR in NP swab samples was reported. Baseline was defined as the last non-missing value measured prior to dosing. Negative changes indicate improvement in viral load.

End point type	Secondary
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End point timeframe:

Day 1 to Day 11

Notes:

[99] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 2 Cohort 1A: Combined	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	59	80	167	76
Units: log10 copies/mL				
least squares mean (standard error)	-1.52 (± 0.17)	-1.28 (± 0.14)	-1.95 (± 0.10)	-2.03 (± 0.15)

End point values	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	154	79	88
Units: log10 copies/mL				
least squares mean (standard error)	-1.95 (± 0.15)	-2.00 (± 0.10)	-1.88 (± 0.14)	-2.01 (± 0.14)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	135
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0245
Method	ANCOVA

Statistical analysis title	Placebo vs. 8000mg IV
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Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0554
Method	ANCOVA

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0179
Method	ANCOVA

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0035
Method	ANCOVA

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0003
Method	ANCOVA

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined

Number of subjects included in analysis	247
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	ANCOVA

Secondary: Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: TWA Change From Baseline Viral Load (Seronegative mFAS) in NP Samples up to Day 29

End point title	Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: TWA Change From Baseline Viral Load (Seronegative mFAS) in NP Samples up to Day 29 ^[100]
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End point description:

TWA change from baseline in viral load up to Day 29 was calculated for each participant using the trapezoidal rule as the area under the curve for change from baseline at each time point divided by the time interval for the observation period. TWA change from baseline viral load in NP samples through Day 29, was measured by quantitative RT-qPCR in NP swab samples was reported. Baseline was defined as the last non-missing value measured prior to dosing. Negative changes indicate improvement in viral load.

End point type	Secondary
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End point timeframe:

Day 1 to Day 29

Notes:

[100] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	84	77	79
Units: log ₁₀ copies/mL				
least squares mean (standard error)	-2.72 (± 0.22)	-2.66 (± 0.21)	-3.68 (± 0.20)	-3.69 (± 0.20)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	156	82	93	175
Units: log ₁₀ copies/mL				
least squares mean (standard error)	-3.69 (± 0.14)	-3.31 (± 0.21)	-3.58 (± 0.20)	-3.45 (± 0.14)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0013
Method	ANCOVA

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0014
Method	ANCOVA

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.025
Method	ANCOVA

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0012
Method	ANCOVA

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)

Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	ANCOVA

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	220
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	ANCOVA

Secondary: Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: Change From Baseline in Viral Load (Seronegative mFAS) as Measured by RT-qPCR in NP Swabs Over Time

End point title	Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: Change From Baseline in Viral Load (Seronegative mFAS) as Measured by RT-qPCR in NP Swabs Over Time ^[101]
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End point description:

Change from baseline in viral load as measured by RT-qPCR in NP swabs over time was reported. Baseline was defined as the last non-missing value measured prior to dosing. Negative changes indicates improvement in viral load.

End point type	Secondary
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End point timeframe:

Days 3, 5, 7, 9, 11, 13, 15, 22 and 29

Notes:

[101] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: log10 copies/mL				
least squares mean (standard error)				
Change at Day 3	-1.10 (± 0.22)	-0.85 (± 0.21)	-0.90 (± 0.19)	-0.93 (± 0.19)
Change at Day 5	-1.97 (± 0.27)	-1.55 (± 0.25)	-2.28 (± 0.23)	-1.91 (± 0.25)
Change at Day 7	-1.97 (± 0.30)	-2.29 (± 0.26)	-2.92 (± 0.26)	-3.22 (± 0.25)
Change at Day 9	-2.56 (± 0.32)	-2.90 (± 0.28)	-3.89 (± 0.27)	-4.16 (± 0.27)
Change at Day 11	-3.22 (± 0.35)	-3.88 (± 0.32)	-4.23 (± 0.29)	-4.57 (± 0.30)
Change at Day 13	-3.76 (± 0.35)	-4.22 (± 0.31)	-5.18 (± 0.30)	-5.00 (± 0.29)
Change at Day 15	-4.42 (± 0.32)	-4.14 (± 0.28)	-5.41 (± 0.28)	-5.25 (± 0.27)
Change at Day 22	-5.29 (± 0.30)	-5.37 (± 0.30)	-5.74 (± 0.24)	-5.95 (± 0.24)
Change at Day 29	-5.90 (± 0.24)	-5.77 (± 0.27)	-6.46 (± 0.18)	-6.60 (± 0.18)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: log10 copies/mL				
least squares mean (standard error)				
Change at Day 3	-0.92 (± 0.14)	-1.03 (± 0.20)	-1.41 (± 0.19)	-1.23 (± 0.14)
Change at Day 5	-2.11 (± 0.17)	-2.21 (± 0.26)	-2.24 (± 0.24)	-2.21 (± 0.18)
Change at Day 7	-3.09 (± 0.18)	-3.06 (± 0.25)	-3.49 (± 0.24)	-3.27 (± 0.17)
Change at Day 9	-4.03 (± 0.19)	-3.75 (± 0.26)	-3.85 (± 0.24)	-3.80 (± 0.18)
Change at Day 11	-4.41 (± 0.21)	-4.76 (± 0.30)	-4.34 (± 0.27)	-4.52 (± 0.2)
Change at Day 13	-5.10 (± 0.21)	-4.56 (± 0.29)	-5.05 (± 0.27)	-4.82 (± 0.20)
Change at Day 15	-5.34 (± 0.19)	-5.03 (± 0.27)	-5.23 (± 0.25)	-5.14 (± 0.18)
Change at Day 22	-5.85 (± 0.17)	-5.75 (± 0.29)	-5.77 (± 0.25)	-5.75 (± 0.19)
Change at Day 29	-6.54 (± 0.13)	-6.34 (± 0.26)	-6.36 (± 0.23)	-6.35 (± 0.17)

Statistical analyses

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1206
Method	MMRM

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0911
Method	MMRM

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined

Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0193
Method	MMRM

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0623
Method	MMRM

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0203
Method	MMRM

Statistical analysis title	Difference vs. Placebo by Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0645
Method	MMRM

Secondary: Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: Percent Change From Baseline in Viral Load (Seronegative mFAS) as Measured by RT-qPCR in NP Swabs Over Time

End point title	Phase 3 [Cohort 1] and Phase 2 [Cohort 1A]: Percent Change From Baseline in Viral Load (Seronegative mFAS) as Measured by RT-qPCR in NP Swabs Over Time ^[102]
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End point description:

Percent change from baseline in viral load as measured by RT-qPCR in NP swabs over time was reported. Baseline was defined as the last non-missing value measured prior to dosing. Negative changes indicates improvement in viral load.

End point type	Secondary
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End point timeframe:

Days 3, 5, 7, 9, 11, 13, 15, 22 and 29

Notes:

[102] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 Cohort 1: 2400 mg IV	Phase 3 Cohort 1: 8000 mg IV
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	70	90	80	82
Units: Percent Change				
least squares mean (confidence interval 95%)				
Percent change at Day 3	-92.04 (-97.12 to -78.01)	-85.92 (-94.47 to -64.12)	-87.52 (-94.82 to -69.93)	-88.15 (-95.07 to -71.52)
Percent change at Day 5	-98.92 (-99.68 to -96.35)	-97.18 (-99.09 to -91.23)	-99.48 (-99.82 to -98.50)	-98.76 (-99.59 to -96.20)
Percent change at Day 7	-98.92 (-99.73 to -95.76)	-99.49 (-99.84 to -98.36)	-99.88 (-99.96 to -99.62)	-99.94 (-99.98 to -99.82)
Percent change at Day 9	-99.72 (-99.94 to -98.80)	-99.87 (-99.96 to -99.56)	-99.99 (-100.00 to -99.96)	-99.99 (-100.00 to -99.98)
Percent change at Day 11	-99.94 (-99.99 to -99.70)	-99.99 (-100.00 to -99.94)	-99.99 (-100.00 to -99.98)	-100.00 (-100.00 to -99.99)
Percent change at Day 13	-99.98 (-100.00 to -99.91)	-99.99 (-100.00 to -99.98)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 15	-100.00 (-100.00 to -99.98)	-99.99 (-100.00 to -99.97)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 22	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 29	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)

End point values	Phase 3 Cohort 1: Combined	Phase 2 Cohort 1A: 2400 mg IV	Phase 2 Cohort 1A: 8000 mg IV	Phase 2 Cohort 1A: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	162	92	106	198
Units: Percent Change				
least squares mean (confidence interval 95%)				
Percent change at Day 3	-87.94 (-93.51 to -77.61)	-90.65 (-96.19 to -77.01)	-96.15 (-98.37 to -90.90)	-94.15 (-96.86 to -89.09)
Percent change at Day 5	-99.23 (-99.64 to -98.34)	-99.38 (-99.81 to -97.96)	-99.42 (-99.81 to -98.26)	-99.39 (-99.73 to -98.63)
Percent change at Day 7	-99.92 (-99.96 to -99.82)	-99.91 (-99.97 to -99.73)	-99.97 (-99.99 to -99.90)	-99.95 (-99.98 to -99.88)
Percent change at Day 9	-99.99 (-100.00 to -99.98)	-99.98 (-99.99 to -99.94)	-99.99 (-100.00 to -99.96)	-99.98 (-99.99 to -99.97)

Percent change at Day 11	-100.00 (-100.00 to -99.99)	-100.00 (-100.00 to -99.99)	-100.00 (-100.00 to -99.98)	-100.00 (-100.00 to -99.99)
Percent change at Day 13	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -99.99)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 15	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 22	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)
Percent change at Day 29	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)

Statistical analyses

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 2400 mg IV
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0623
Method	MMRM

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: 8000 mg IV
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0203
Method	MMRM

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: Combined
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0645
Method	MMRM

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 2400 mg IV

Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1206
Method	MMRM

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 Cohort 1A: 8000 mg IV
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0911
Method	MMRM

Statistical analysis title	Percent Difference vs. Placebo at Day 29
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 Cohort 1: Combined
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0193
Method	MMRM

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Went on Mechanical Ventilation by Day 29 Based on High Viral Load mFAS ^[103]
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End point description:

Percentage of participants who went on mechanical ventilation in phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

by Day 29

Notes:

[103] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	126	103	129	118
Units: Percentage of Participants				
number (confidence interval 95%)	17.5 (11.3 to 25.2)	3.9 (1.1 to 9.6)	8.5 (4.3 to 14.7)	16.9 (10.7 to 25.0)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	247	102	118	220
Units: Percentage of Participants				
number (confidence interval 95%)	12.6 (8.7 to 17.3)	2.9 (0.6 to 8.4)	0.0 (0.0 to 0.0)	1.4 (0.3 to 3.9)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	255
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0481 ^[104]
Method	Cochran-Mantel-Haenszel

Notes:

[104] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p <= 5$ or $n(1-p) <= 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.988 ^[105]
Method	Cochran-Mantel-Haenszel

Notes:

[105] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p <= 5$ or $n(1-p) <= 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A):

	R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0457 ^[106]
Method	Cochran-Mantel-Haenszel

Notes:

[106] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	
P-value	= 1 ^[107]
Method	Cochran-Mantel-Haenszel

Notes:

[107] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2153 ^[108]
Method	Cochran-Mantel-Haenszel

Notes:

[108] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2498 ^[109]
Method	Cochran-Mantel-Haenszel

Notes:

[109] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died from Day 6 to Day 29 Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died from Day 6 to Day 29 Based on High Viral Load mFAS ^[110]
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End point description:

Percentage of participants who died in phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
End point timeframe:	
Day 6 to Day 29	
Notes:	
[110] - 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 is only applicable to participants in specified phases/cohorts	

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	122	100	128	115
Units: Percentage of Participants				
number (confidence interval 95%)	18.0 (11.7 to 26.0)	7.0 (2.9 to 13.9)	10.2 (5.5 to 16.7)	15.7 (9.5 to 23.6)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	243	98	113	211
Units: Percentage of Participants				
number (confidence interval 95%)	12.8 (8.8 to 17.6)	3.1 (0.6 to 8.7)	4.4 (1.5 to 10.0)	3.8 (1.7 to 7.3)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	250
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0811 ^[111]
Method	Cochran-Mantel-Haenszel

Notes:

[111] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If np <= 5 or n(1-p) <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)

Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6701 ^[112]
Method	Cochran-Mantel-Haenszel

Notes:

[112] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	365
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2006 ^[113]
Method	Cochran-Mantel-Haenszel

Notes:

[113] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3313 ^[114]
Method	Cochran-Mantel-Haenszel

Notes:

[114] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5542 ^[115]
Method	Cochran-Mantel-Haenszel

Notes:

[115] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): Combined R10933+R10987 IV

Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2214 ^[116]
Method	Cochran-Mantel-Haenszel

Notes:

[116] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died from Day 1 to Day 29 Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died from Day 1 to Day 29 Based on High Viral Load mFAS ^[117]
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End point description:

Percentage of participants who died in phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

Day 1 to Day 29

Notes:

[117] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	126	103	129	118
Units: Percentage of Participants				
number (confidence interval 95%)	20.6 (13.9 to 28.8)	6.8 (2.8 to 13.5)	10.9 (6.1 to 17.5)	16.9 (10.7 to 25.0)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	247	102	118	220
Units: Percentage of Participants				
number (confidence interval 95%)	13.8 (9.7 to 18.7)	2.9 (0.6 to 8.4)	5.1 (1.9 to 10.7)	4.1 (1.9 to 7.6)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1):

	R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	255
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0389 ^[118]
Method	Cochran-Mantel-Haenszel

Notes:

[118] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3036 ^[119]
Method	Cochran-Mantel-Haenszel

Notes:

[119] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3315 ^[120]
Method	Cochran-Mantel-Haenszel

Notes:

[120] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5797 ^[121]
Method	Cochran-Mantel-Haenszel

Notes:

[121] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)

Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5208 ^[122]
Method	Cochran-Mantel-Haenszel

Notes:

[122] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If np < =5 or n(1-p) <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1079 ^[123]
Method	Cochran-Mantel-Haenszel

Notes:

[123] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If np < =5 or n(1-p) <= 5 in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Were Discharged by Day 29 Based on High Viral Load mFAS ^[124]
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End point description:

Percentage of participants who were discharged in phase 3 (Cohort 1) and phase 2 (Cohort 1A) was reported.

End point type	Secondary
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End point timeframe:

by Day 29

Notes:

[124] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	126	103	129	118
Units: Percentage of Participants				
number (confidence interval 95%)	72.2 (63.5 to 79.8)	90.3 (82.9 to 95.2)	83.7 (76.2 to 89.6)	78.8 (70.3 to 85.8)

End point values	Phase 3 (Cohort 1): Combined R10933+R109	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg	Phase 2 (Cohort 1A): Combined R10933+R109
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	87 IV	IV)	IV)	87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	247	102	118	220
Units: Percentage of Participants				
number (confidence interval 95%)	81.4 (76.0 to 86.0)	96.1 (90.3 to 98.9)	94.9 (89.3 to 98.1)	95.5 (91.8 to 97.8)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	255
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0364 ^[125]
Method	Cochran-Mantel-Haenszel

Notes:

[125] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2795 ^[126]
Method	Cochran-Mantel-Haenszel

Notes:

[126] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0588 ^[127]
Method	Cochran-Mantel-Haenszel

Notes:

[127] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p \leq 5$ or $n(1-p) \leq 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0364 ^[128]
Method	Cochran-Mantel-Haenszel

Notes:

[128] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2795 ^[129]
Method	Cochran-Mantel-Haenszel

Notes:

[129] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): Combined R10933+R10987 IV
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0588 ^[130]
Method	Cochran-Mantel-Haenszel

Notes:

[130] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $np < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital Over Time Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Percentage of Participants Who Died or Were Readmitted to Hospital Over Time Based on High Viral Load mFAS ^[131]
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End point description:

Percentage of participants who died or were readmitted to hospital in phase 3 (Cohort 1) and phase 2 (Cohort 1A) over time were reported. Readmission to hospital was based on investigator report.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[131] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	126	103	129	118
Units: Percentage of Participants				
number (confidence interval 95%)	24.6 (17.4 to 33.1)	16.5 (9.9 to 25.1)	18.6 (12.3 to 26.4)	22.9 (15.7 to 31.5)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	247	102	118	220
Units: Percentage of Participants				
number (confidence interval 95%)	20.6 (15.8 to 26.2)	10.8 (5.5 to 18.5)	11.9 (6.6 to 19.1)	11.4 (7.5 to 16.3)

Statistical analyses

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	255
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2635 ^[132]
Method	Cochran-Mantel-Haenszel

Notes:

[132] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8013 ^[133]
Method	Cochran-Mantel-Haenszel

Notes:

[133] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < = 5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A):

	Combined R10933+R10987 IV
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1981 ^[134]
Method	Cochran-Mantel-Haenszel

Notes:

[134] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 2400mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (2400 mg IV)
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2194 ^[135]
Method	Cochran-Mantel-Haenszel

Notes:

[135] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. 8000mg IV
Comparison groups	Phase 2: Cohort 1A (Placebo) v Phase 2 (Cohort 1A): R10933+R10987 (8000 mg IV)
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.324 ^[136]
Method	Cochran-Mantel-Haenszel

Notes:

[136] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Statistical analysis title	Placebo vs. Combined
Comparison groups	Phase 3: Cohort 1 (Placebo) v Phase 3 (Cohort 1): Combined R10933+R10987 IV
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.416 ^[137]
Method	Cochran-Mantel-Haenszel

Notes:

[137] - P-value is derived Cochran-Mantel-Haenszel (CMH) test stratified by the type of background standard-of-care (antiviral therapies and non-antiviral therapies). If $n_p < =5$ or $n(1-p) < = 5$ in any treatment group, p-value is based on Fisher Exact Test.

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death Over Time Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death Over Time Based on High Viral Load mFAS ^[138]
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End point description:

Cumulative Incidence of Death Over Time in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were

reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
End point timeframe:	
Up to Day 29	

Notes:

[138] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	96	85	110	90
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	21.1 (14.9 to 29.4)	7.2 (3.5 to 14.4)	11.2 (6.8 to 18.2)	17.9 (11.9 to 26.3)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	200	91	100	191
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	14.3 (10.5 to 19.5)	3.1 (1.0 to 9.4)	5.3 (2.4 to 11.5)	4.3 (2.3 to 8.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation Over Time Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Mechanical Ventilation Over Time Based on High Viral Load mFAS ^[139]
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End point description:

Cumulative Incidence of Mechanical Ventilation Over Time in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
End point timeframe:	
Up to Day 29	

Notes:

[139] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	87	83	100	104
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	18.1 (12.3 to 26.2)	4.0 (1.5 to 10.4)	0.0 (0.0 to 0.0)	8.8 (5.0 to 15.3)

End point values	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	83	187	90	190
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	18.0 (12.0 to 26.5)	13.1 (9.4 to 18.1)	3.1 (1.0 to 9.2)	1.5 (0.5 to 4.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation Over Time Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Cumulative Incidence of Death or Mechanical Ventilation Over Time Based on High Viral Load mFAS ^[140]
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End point description:

Cumulative Incidence of Death or Mechanical Ventilation Over Time in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported. Cumulative incidence percentage was estimated using Kaplan-Meier method.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[140] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	87	83	100	104
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	27.2 (20.2 to	9.1 (4.9 to	5.3 (2.4 to	15.0 (9.8 to

35.9)	16.8)	11.5)	22.5)
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End point values	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	83	187	90	190
Units: Cumulative Incidence Percentage				
number (confidence interval 95%)	24.4 (17.6 to 33.4)	19.5 (15.0 to 25.1)	4.1 (1.6 to 10.5)	4.8 (2.6 to 8.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge Based on High Viral Load mFAS

End point title	Phase 3 (Cohort 1) and Phase 2 (Cohort 1A): Time to Discharge Based on High Viral Load mFAS ^[141]
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End point description:

Time to Discharge in phase 3 (Cohort 1) and phase 2 (Cohort 1A) were reported.

End point type	Secondary
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End point timeframe:

Up to Day 56

Notes:

[141] - 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 is only applicable to participants in specified phases/cohorts

End point values	Phase 3: Cohort 1 (Placebo)	Phase 2: Cohort 1A (Placebo)	Phase 3 (Cohort 1): R10933+R109 87 (2400 mg IV)	Phase 3 (Cohort 1): R10933+R109 87 (8000 mg IV)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	126	103	129	118
Units: days				
median (confidence interval 95%)	7.0 (5.0 to 10.0)	4.0 (3.0 to 4.0)	7.0 (5.0 to 8.0)	7.0 (5.0 to 8.0)

End point values	Phase 3 (Cohort 1): Combined R10933+R109 87 IV	Phase 2 (Cohort 1A): R10933+R109 87 (2400 mg IV)	Phase 2 (Cohort 1A): R10933+R109 87 (8000 mg IV)	Phase 2 (Cohort 1A): Combined R10933+R109 87 IV
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	247	102	118	220
Units: days				
median (confidence interval 95%)	7.0 (6.0 to 8.0)	3.0 (2.0 to 4.0)	3.0 (2.0 to 3.0)	3.0 (3.0 to 3.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Time-weighted Average (TWA) Change in Viral Load in Nasopharyngeal (NP) Samples Over Time Based on Seronegative mFAS

End point title	Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Time-weighted Average (TWA) Change in Viral Load in Nasopharyngeal (NP) Samples Over Time Based on Seronegative mFAS
End point description:	Time-weighted average daily change over time up to Day 29 in viral load (log ₁₀ copies/mL), as measured by reverse transcription quantitative polymerase chain reaction (RT-qPCR) in nasopharyngeal (NP) swab samples.
End point type	Secondary
End point timeframe:	Up to Day 29

End point values	Pooled (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	68	79	70	149
Units: log ₁₀ copies/milliliter (mL)				
least squares mean (standard error)				
TWA change from BL: Day 1 to Day 3	-0.33 (± 0.11)	-0.40 (± 0.11)	-0.60 (± 0.12)	-0.50 (± 0.08)
TWA change from BL: Day 1 to Day 5	-0.55 (± 0.14)	-0.86 (± 0.14)	-0.92 (± 0.14)	-0.89 (± 0.10)
TWA change from BL: Day 1 to Day 7	-0.70 (± 0.14)	-1.23 (± 0.14)	-1.23 (± 0.14)	-1.23 (± 0.10)
TWA change from BL: Day 1 to Day 9	-0.93 (± 0.16)	-1.47 (± 0.15)	-1.58 (± 0.16)	-1.52 (± 0.11)
TWA change from BL: Day 1 to Day 11	-1.12 (± 0.16)	-1.72 (± 0.16)	-1.78 (± 0.17)	-1.75 (± 0.12)
TWA change from BL: Day 1 to Day 13	-1.33 (± 0.18)	-1.96 (± 0.17)	-1.95 (± 0.18)	-1.96 (± 0.12)
TWA change from BL: Day 1 to Day 15	-1.50 (± 0.19)	-2.19 (± 0.18)	-2.16 (± 0.19)	-2.18 (± 0.13)
TWA change from BL: Day 1 to Day 22	-1.89 (± 0.22)	-2.62 (± 0.21)	-2.64 (± 0.22)	-2.63 (± 0.15)
TWA change from BL: Day 1 to Day 29	-2.35 (± 0.24)	-2.98 (± 0.23)	-2.95 (± 0.24)	-2.97 (± 0.17)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Change From Baseline as Measured by RT-qPCR in NP Swabs Over Time Based on Seronegative mFAS

End point title	Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Change From Baseline as Measured by RT-qPCR in NP Swabs Over Time Based on Seronegative mFAS
End point description: Change from baseline in viral load as measured by RT-qPCR in NP swabs over time was reported. Baseline was defined as the last non-missing value measured prior to dosing. Negative changes indicates improvement in viral load.	
End point type	Secondary
End point timeframe: Days 3, 5, 7, 9, 11, 13, 15, 22 and 29	

End point values	Pooled (Phase 1 [Cohort 1] and Phase 2 [Cohort 1]): Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	68	79	70	149
Units: log10 copies/milliliter (mL)				
least squares mean (standard error)				
TWA change from BL: Day 1 to Day 3	-0.66 (± 0.22)	-0.81 (± 0.21)	-1.08 (± 0.23)	-0.94 (± 0.16)
TWA change from BL: Day 1 to Day 5	-1.18 (± 0.26)	-2.08 (± 0.26)	-2.28 (± 0.27)	-2.18 (± 0.19)
TWA change from BL: Day 1 to Day 7	-1.62 (± 0.30)	-2.76 (± 0.27)	-2.56 (± 0.29)	-2.67 (± 0.20)
TWA change from BL: Day 1 to Day 9	-2.68 (± 0.34)	-3.24 (± 0.31)	-3.16 (± 0.32)	-3.20 (± 0.22)
TWA change from BL: Day 1 to Day 11	-3.55 (± 0.39)	-3.74 (± 0.38)	-3.94 (± 0.37)	-3.87 (± 0.26)
TWA change from BL: Day 1 to Day 13	-3.04 (± 0.38)	-5.01 (± 0.35)	-4.25 (± 0.39)	-4.68 (± 0.26)
TWA change from BL: Day 1 to Day 15	-4.60 (± 0.39)	-4.67 (± 0.35)	-5.01 (± 0.36)	-4.84 (± 0.25)
TWA change from BL: Day 1 to Day 22	-5.89 (± 0.37)	-5.21 (± 0.31)	-5.25 (± 0.32)	-5.23 (± 0.22)
TWA change from BL: Day 1 to Day 29	-6.01 (± 0.32)	-6.04 (± 0.27)	-6.16 (± 0.28)	-6.10 (± 0.20)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 [Cohort 1] and Phase 2 [Cohort 1]: Percentage of Participants Who Died or Went On Mechanical Ventilation by Day 29 Based on Seronegative mFAS

End point title	Phase 1 [Cohort 1] and Phase 2 [Cohort 1]: Percentage of Participants Who Died or Went On Mechanical Ventilation by Day 29 Based on Seronegative mFAS
End point description:	
End point type	Secondary
End point timeframe: Through Day 29	

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 2400 mg IV	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: 8000 mg IV	Ph.1 Cohort 1 + Ph.2 Cohort 1: Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	62	59	121
Units: Percentage of Participants				
number (confidence interval 80%)	26.9 (19.0 to 34.8)	17.7 (11.5 to 24.0)	22.0 (15.1 to 28.9)	19.8 (15.2 to 24.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 [Cohort 1] and Phase 2 [Cohort 1]: Percentage of Participants Who Died or Went On Mechanical Ventilation by Day 29 Based on High Viral Load mFAS

End point title	Phase 1 [Cohort 1] and Phase 2 [Cohort 1]: Percentage of Participants Who Died or Went On Mechanical Ventilation by Day 29 Based on High Viral Load mFAS
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End point description:

End point type	Secondary
End point timeframe:	
Through Day 29	

End point values	Pooled Ph.1 Cohort 1 + Ph.2 Cohort 1: Placebo	Pooled(Ph1C1 and Ph2C1): R10933+R10987(2400mg IV)	Pooled (Ph1C1 and Ph2C1): R10933+R10987 (8000 mg IV)	Ph1C1 and Ph2C1: Combined R10933+R10987 IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78	77	80	157
Units: Percentage of Participants				
number (confidence interval 80%)	23.1 (17.0 to 29.2)	23.4 (17.2 to 29.6)	13.8 (8.8 to 18.7)	18.5 (14.5 to 22.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 [Cohort 1]: Area Under the Concentration-Time Curve from Time 0 to 28 days Post-dose (AUC0-28)

End point title	Phase 1 [Cohort 1]: Area Under the Concentration-Time Curve
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End point description:

End point type Secondary

End point timeframe:

Up to Day 28

End point values	Phase 1 [Cohort 1]: R10983+10987 2400mg IV	Phase 1 [Cohort 1]: R10983+10987 8000mg IV		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	20		
Units: day*mg/L				
arithmetic mean (standard deviation)				
AUC0-28 of Casirivimab	3026 (± 719)	9678 (± 3362)		
AUC0-28 of Imdevimab	2582 (± 581)	8680 (± 2930)		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration at the End of Infusion (Cei)

End point title Concentration at the End of Infusion (Cei)

End point description:

End point type Secondary

End point timeframe:

Day 1

End point values	Phase 1 [Cohort 1]: R10983+10987 2400mg IV	Phase 1 [Cohort 1]: R10983+10987 8000mg IV	Phase 2 (Cohort 1A): R10933+R109 87 2400mg IV	Phase 2 (Cohort 1A): R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	20	167	155
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)				
Cei of Casirivimab	231 (± 110)	776 (± 372)	272 (± 124)	847 (± 300)
Cei of Imdevimab	243 (± 117)	795 (± 371)	283 (± 127)	868 (± 298)

End point values	Phase 2 (Cohort 1):	Phase 2 (Cohort 1):	Phase 2 (Cohort 2):	Phase 2 (Cohort 2):
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	R10933+R109 87 2400mg IV	R10933+R109 87 8000mg IV	R10933+R109 87 2400mg IV	R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	181	178	55	50
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)				
Ceoi of Casirivimab	288 (± 86.8)	848 (± 261)	286 (± 93.5)	921 (± 262)
Ceoi of Imdevimab	300 (± 87.3)	880 (± 268)	302 (± 94.0)	946 (± 244)

End point values	Phase 2 (Cohort 3): R10933+R109 87 2400mg IV	Phase 2 (Cohort 3): R10933+R109 87 8000mg IV	Phase 3 (Cohort 1): R10933+R109 87 2400mg IV	Phase 3 (Cohort 1): R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	11	214	207
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)				
Ceoi of Casirivimab	284 (± 69.3)	708 (± 128)	307 (± 153)	908 (± 338)
Ceoi of Imdevimab	290 (± 81.7)	738 (± 124)	312 (± 157)	945 (± 351)

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration at Day 28 (C28)

End point title	Concentration at Day 28 (C28)
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End point description:

End point type	Secondary
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End point timeframe:

Day 28

End point values	Phase 1 [Cohort 1]: R10983+10987 2400mg IV	Phase 1 [Cohort 1]: R10983+10987 8000mg IV	Phase 2 (Cohort 1A): R10933+R109 87 2400mg IV	Phase 2 (Cohort 1A): R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	9	9	91	96
Units: mg/L				
arithmetic mean (standard deviation)				
C28 of Casirivimab	50.7 (± 19.5)	166 (± 108)	64.8 (± 35.9)	174 (± 65.1)
C28 of Imdevimab	36.1 (± 16.1)	131 (± 84.1)	54.7 (± 37.6)	150 (± 62.9)

End point values	Phase 2 (Cohort 1): R10933+R109 87 2400mg IV	Phase 2 (Cohort 1): R10933+R109 87 8000mg IV	Phase 2 (Cohort 2): R10933+R109 87 2400mg IV	Phase 2 (Cohort 2): R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	91	93	25	26
Units: mg/L				
arithmetic mean (standard deviation)				
C28 of Casirivimab	50.0 (± 20.4)	144 (± 89.8)	26.4 (± 18.5)	79.4 (± 61.4)
C28 of Imdevimab	39.8 (± 18.9)	113 (± 68.8)	18.7 (± 14.7)	60.0 (± 53.9)

End point values	Phase 2 (Cohort 3): R10933+R109 87 2400mg IV	Phase 2 (Cohort 3): R10933+R109 87 8000mg IV	Phase 3 (Cohort 1): R10933+R109 87 2400mg IV	Phase 3 (Cohort 1): R10933+R109 87 8000mg IV
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	5	149	146
Units: mg/L				
arithmetic mean (standard deviation)				
C28 of Casirivimab	9.06 (± 2.64)	67.8 (± 31.1)	49.1 (± 40.4)	140 (± 66.1)
C28 of Imdevimab	5.25 (± 4.12)	52.4 (± 24.7)	40.8 (± 48.3)	114 (± 62.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by anti-drug antibodies (ADAs) to REGN10933

End point title	Immunogenicity as measured by anti-drug antibodies (ADAs) to REGN10933
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End point description:

End point type	Secondary
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End point timeframe:

Through Day 169

End point values	Pooled Placebo	Pooled R10933+R109 87 2400mg IV	Pooled REGN10933+R EGN10987 8000mg IV	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	503	504	497	
Units: Participants	489	471	484	

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by anti-drug antibodies (ADAs) to REGN10987

End point title Immunogenicity as measured by anti-drug antibodies (ADAs) to REGN10987

End point description:

End point type Secondary

End point timeframe:

Through Day 169

End point values	Pooled Placebo	Pooled R10933+R10987 2400mg IV	Pooled REGN10933+REGN10987 8000mg IV	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	503	504	497	
Units: Participants	467	444	463	

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by Neutralizing antibody status (NAb) to REGN10933

End point title Immunogenicity as measured by Neutralizing antibody status (NAb) to REGN10933

End point description:

End point type Secondary

End point timeframe:

Through Day 57

End point values	Pooled (Phase 2/3) Placebo	Pooled (Phase 2/3) R10933+R10987 2400mg IV	Pooled (Phase 2/3) REGN10933+REGN10987 8000mg IV	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	503	504	497	
Units: Participants				
Anti-drug Antibody (ADA) Negative	489	471	484	
Neutralizing antibody (NAb) Positive	1	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by Neutralizing antibody status (NAb) to REGN10987

End point title	Immunogenicity as measured by Neutralizing antibody status (NAb) to REGN10987
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End point description:

End point type	Secondary
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End point timeframe:

Through Day 57

End point values	Pooled (Phase 2/3) Placebo	Pooled (Phase 2/3) R10933+R10987 2400mg IV	Pooled (Phase 2/3) REGN10933+REGN10987 8000mg IV	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	503	504	497	
Units: Participants				
Anti-drug Antibody (ADA) Negative	467	444	463	
Neutralizing antibody (NAb) Positive	9	10	4	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug to Day 169

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Phase 2 Cohort 1A: Placebo IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 1)

Reporting group title	Phase 1 Cohort 1: Cas+Imdev 8000mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 1 (Cohort 1).

Reporting group title	Phase 1 Cohort 1: Cas+Imdev 2400mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 1 (Cohort 1).

Reporting group title	Phase 1 Cohort 1: Placebo IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 1 (Cohort 1).

Reporting group title	Phase 2 Cohort 1: Cas+Imdev 2400mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 3 (Cohort 1)

Reporting group title	Phase 2 Cohort 1: Placebo IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1)

Reporting group title	Phase 2 Cohort 1A: Cas+Imdev 8000mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1)

Reporting group title	Phase 2 Cohort 1A: Cas+Imdev 2400mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 2 (Cohort 1)

Reporting group title	Phase 2 Cohort 1: Cas+Imdev 8000mg IV
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Reporting group description:

Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 1)

Reporting group title	Phase 2 Cohort 2: Cas+Imdev 8000mg IV
Reporting group description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2 Cohort 2: Cas+Imdev 2400mg IV
Reporting group description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2 Cohort 2: Placebo IV
Reporting group description: Participants on high-flow oxygen therapy but not on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 2).	
Reporting group title	Phase 2 Cohort 3: Placebo IV
Reporting group description: Participants on mechanical ventilation received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 2 (Cohort 3).	
Reporting group title	Phase 2 Cohort 3: Cas+Imdev 2400mg IV
Reporting group description: Participants on mechanical ventilation received single dose of R10933+R10987 2400 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Reporting group title	Phase 3 Cohort 1: Cas+Imdev 2400mg IV
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 2400 milligrams (mg) intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 3 Cohort 1: Placebo IV
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of placebo matching to R10933+R10987 intravenously on Day 1 in Phase 3 (Cohort 1)	
Reporting group title	Phase 2 Cohort 3: Cas+Imdev 8000mg IV
Reporting group description: Participants on mechanical ventilation received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 2 (Cohort 3).	
Reporting group title	Phase 3 Cohort 1: Cas+Imdev 8000mg IV
Reporting group description: Participants with O2 saturation > 93% on low-flow oxygen via nasal cannula, simple face mask, or other similar device received single dose of R10933+R10987 8000 mg intravenously on Day 1 in Phase 3 (Cohort 1)	

Serious adverse events	Phase 2 Cohort 1A: Placebo IV	Phase 1 Cohort 1: Cas+Imdev 8000mg IV	Phase 1 Cohort 1: Cas+Imdev 2400mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 198 (21.72%)	2 / 20 (10.00%)	3 / 18 (16.67%)
number of deaths (all causes)	15	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Appendix cancer			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Colon cancer			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Distributive shock			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Embolism venous			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Haematoma			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypertensive urgency			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypotension			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Shock			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Venous thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Chest pain			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Chills			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Death			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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

Fatigue			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Generalised oedema			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Sudden cardiac death			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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

Hypersensitivity			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 transplant rejection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Dyspnoea			
subjects affected / exposed	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	3 / 198 (1.52%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Acute respiratory failure			
subjects affected / exposed	5 / 198 (2.53%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Alveolar lung disease			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Aspiration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Atelectasis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Dyspnoea exertional			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Haemoptysis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Laryngeal stenosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Organising pneumonia			

subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Pleural effusion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pleuritic pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pneumomediastinum			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 aspiration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pneumothorax			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Pneumothorax spontaneous			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pulmonary embolism			

subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Pulmonary oedema			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 arrest			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 distress			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Tachypnoea			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Anxiety			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Delirium			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Mental status changes			
subjects affected / exposed	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Blood glucose increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Fibrin D dimer increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Inflammatory marker increased			

subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
International normalised ratio increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Klebsiella test positive			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Brain herniation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Endotracheal intubation complication			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Fall			

subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Head injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pancreatic leak			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Post procedural complication			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Rib fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Stomal hernia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Subdural haematoma			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Toxicity to various agents			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Acute left ventricular failure			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Angina pectoris			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Atrial fibrillation			
subjects affected / exposed	1 / 198 (0.51%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Atrial tachycardia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Bradycardia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 arrest			
subjects affected / exposed	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Cardiac failure acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 chronic			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Cardiogenic shock			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Chronic left ventricular failure			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Myocarditis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pulseless electrical activity			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Tachycardia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 infarction			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Dizziness			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Encephalopathy			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hydrocephalus			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypoaesthesia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Ischaemic stroke			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis relapse			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Seizure			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Syncope			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Toxic encephalopathy			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Unresponsive to stimuli			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 198 (0.51%)	1 / 20 (5.00%)	0 / 18 (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
Febrile neutropenia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypercoagulation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Sickle cell anaemia with crisis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Thrombocytopenia			
subjects affected / exposed	1 / 198 (0.51%)	1 / 20 (5.00%)	0 / 18 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Abdominal distension			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Abdominal pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Abdominal pain upper			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Dysphagia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Haematemesis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Haematochezia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Ileus			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 gastric emptying			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 obstruction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Pancreatitis acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Retroperitoneal haematoma			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Cholelithiasis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Ischaemic hepatitis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pruritus			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Subcutaneous emphysema			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 198 (0.51%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Haematuria			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Renal failure			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Renal impairment			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 tubular injury			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Ureterolithiasis			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Compartment syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Muscular weakness			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Myalgia			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Neck pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	7 / 198 (3.54%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 bacterial			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Aspergillus infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
COVID-19 pneumonia			
subjects affected / exposed	4 / 198 (2.02%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Candida sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Device related bacteraemia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Encephalitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Enterococcal infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Fungaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Herpes simplex			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Herpes zoster			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Osteomyelitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Osteomyelitis fungal			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Perirectal abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pneumococcal infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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 bacterial			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 klebsiella			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 serratia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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 staphylococcal			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Post procedural infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Scrotal abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 198 (0.51%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Serratia infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Staphylococcal infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Superinfection bacterial			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Urinary tract candidiasis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Urinary tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
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 enterococcal			

subjects affected / exposed	1 / 198 (0.51%)	0 / 20 (0.00%)	0 / 18 (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
Urosepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Viral myocarditis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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			
Acidosis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Calciphylaxis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Decreased appetite			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Dehydration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Failure to thrive			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hyperglycaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hyperkalaemia			
subjects affected / exposed	2 / 198 (1.01%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypervolaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypoglycaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypokalaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Hypophosphataemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Metabolic acidosis			

subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (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	Phase 1 Cohort 1: Placebo IV	Phase 2 Cohort 1: Cas+Imdev 2400mg IV	Phase 2 Cohort 1: Placebo IV
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 18 (16.67%)	47 / 206 (22.82%)	63 / 204 (30.88%)
number of deaths (all causes)	2	25	28
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Appendix cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Colon cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Arteriosclerosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Distributive shock			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Embolism venous			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypertensive urgency			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	2 / 206 (0.97%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Shock			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shock haemorrhagic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			

Asthenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Chills			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Death			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	3 / 204 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 3
Fatigue			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Generalised oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Sudden cardiac death			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypersensitivity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 transplant rejection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Dyspnoea			
subjects affected / exposed	1 / 18 (5.56%)	1 / 206 (0.49%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 18 (5.56%)	3 / 206 (1.46%)	7 / 204 (3.43%)
occurrences causally related to treatment / all	0 / 1	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2

Pneumonitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 206 (0.00%)	0 / 204 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory failure			
subjects affected / exposed	0 / 18 (0.00%)	10 / 206 (4.85%)	6 / 204 (2.94%)
occurrences causally related to treatment / all	0 / 0	1 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	1 / 8	0 / 3
Alveolar lung disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Aspiration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Atelectasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Dyspnoea exertional			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laryngeal stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Organising pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pleuritic pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pneumomediastinum			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 aspiration			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pneumothorax spontaneous			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	5 / 206 (2.43%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 arrest			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 distress			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 18 (0.00%)	4 / 206 (1.94%)	9 / 204 (4.41%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 5
Tachypnoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Product issues			
Device occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Blood glucose increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Fibrin D dimer increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Inflammatory marker increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
International normalised ratio increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Klebsiella test positive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Oxygen saturation decreased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Brain herniation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Endotracheal intubation complication			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Fall			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 stoma complication			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Head injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pancreatic leak			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Post procedural complication			

subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Rib fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Stomal hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Subdural haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Toxicity to various agents			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Acute left ventricular failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	3 / 204 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Atrial tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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 arrest			
subjects affected / exposed	0 / 18 (0.00%)	3 / 206 (1.46%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Cardiac failure acute			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiogenic shock			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Chronic left ventricular failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Myocarditis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pulseless electrical activity			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 206 (0.97%)	0 / 204 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Dizziness			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Encephalopathy			
subjects affected / exposed	0 / 18 (0.00%)	2 / 206 (0.97%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hydrocephalus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypoaesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 sclerosis relapse			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Seizure			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	3 / 204 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Unresponsive to stimuli			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Febrile neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypercoagulation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Sickle cell anaemia with crisis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Abdominal distension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Dysphagia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Haematemesis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Ileus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 gastric emptying			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Retroperitoneal haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Cholelithiasis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Subcutaneous emphysema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 18 (5.56%)	2 / 206 (0.97%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 failure			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal impairment			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 tubular injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Ureterolithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Compartment syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Muscular weakness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Myalgia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Neck pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 18 (5.56%)	4 / 206 (1.94%)	6 / 204 (2.94%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 3
Appendicitis perforated			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 bacterial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Aspergillus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 206 (0.97%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Candida infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Candida sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Device related bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Encephalitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Fungaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Herpes simplex			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Osteomyelitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Osteomyelitis fungal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Perirectal abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pneumococcal infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	5 / 204 (2.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 18 (0.00%)	4 / 206 (1.94%)	3 / 204 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 serratia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
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 staphylococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Post procedural infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pulmonary sepsis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Scrotal abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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 / 18 (0.00%)	1 / 206 (0.49%)	4 / 204 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 18 (0.00%)	2 / 206 (0.97%)	3 / 204 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Serratia infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Staphylococcal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Staphylococcal sepsis			

subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Superinfection bacterial			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Urinary tract candidiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Urinary tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	2 / 204 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Urosepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Viral myocarditis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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			
Acidosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Calciphylaxis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Decreased appetite			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Failure to thrive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
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 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			

subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	0 / 204 (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
Hypoglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Hypokalaemia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 206 (0.49%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Metabolic acidosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	1 / 204 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2 Cohort 1A: Cas+Imdev 8000mg IV	Phase 2 Cohort 1A: Cas+Imdev 2400mg IV	Phase 2 Cohort 1: Cas+Imdev 8000mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 197 (16.24%)	29 / 202 (14.36%)	47 / 205 (22.93%)
number of deaths (all causes)	7	8	21
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Appendix cancer			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Colon cancer			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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			
Arteriosclerosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Deep vein thrombosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Distributive shock			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Embolism venous			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haematoma			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hypertensive urgency			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Venous thrombosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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			
Asthenia			
subjects affected / exposed	0 / 197 (0.00%)	2 / 202 (0.99%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Chills			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Death			
subjects affected / exposed	0 / 197 (0.00%)	2 / 202 (0.99%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1

Fatigue			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Generalised oedema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Sudden cardiac death			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypersensitivity			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 transplant rejection			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 197 (1.52%)	0 / 202 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 197 (0.51%)	1 / 202 (0.50%)	7 / 205 (3.41%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pneumonitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	2 / 197 (1.02%)	2 / 202 (0.99%)	5 / 205 (2.44%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 5
Alveolar lung disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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

Aspiration			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Atelectasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Dyspnoea exertional			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haemoptysis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Laryngeal stenosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Organising pneumonia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pleural effusion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pleuritic pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 aspiration			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pneumothorax			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pulmonary embolism			

subjects affected / exposed	0 / 197 (0.00%)	2 / 202 (0.99%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 arrest			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 distress			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 197 (0.00%)	2 / 202 (0.99%)	6 / 205 (2.93%)
occurrences causally related to treatment / all	0 / 0	0 / 3	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 3
Tachypnoea			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Confusional state			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Mental status changes			
subjects affected / exposed	2 / 197 (1.02%)	0 / 202 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Fibrin D dimer increased			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Inflammatory marker increased			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
International normalised ratio increased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Klebsiella test positive			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Brain herniation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Endotracheal intubation complication			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Fall			

subjects affected / exposed	0 / 197 (0.00%)	2 / 202 (0.99%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Head injury			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Pancreatic leak			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Stomal hernia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Subdural haematoma			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Toxicity to various agents			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Acute left ventricular failure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Angina pectoris			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Atrial fibrillation			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Atrial tachycardia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Bradycardia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 arrest			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Cardiac failure acute			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 chronic			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Cardiogenic shock			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Chronic left ventricular failure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Myocarditis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pulseless electrical activity			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Tachycardia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 infarction			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Dizziness			
subjects affected / exposed	1 / 197 (0.51%)	1 / 202 (0.50%)	0 / 205 (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
Encephalopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Hydrocephalus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hypoaesthesia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ischaemic stroke			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 sclerosis relapse			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Seizure			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Syncope			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Toxic encephalopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Unresponsive to stimuli			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Febrile neutropenia			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Hypercoagulation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Abdominal pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Abdominal pain upper			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Dysphagia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haematemesis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haematochezia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ileus			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 gastric emptying			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 obstruction			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Retroperitoneal haematoma			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Cholelithiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pruritus			

subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Subcutaneous emphysema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
End stage renal disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Haematuria			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 failure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 impairment			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 tubular injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ureterolithiasis			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Compartment syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Muscular weakness			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Myalgia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Neck pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 197 (3.05%)	0 / 202 (0.00%)	7 / 205 (3.41%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Appendicitis perforated			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 bacterial			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Aspergillus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Candida infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Candida sepsis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Device related bacteraemia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Encephalitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Enterococcal infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Fungaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Herpes simplex			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Herpes zoster			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Osteomyelitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Osteomyelitis fungal			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Perirectal abscess			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 serratia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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 staphylococcal			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Post procedural infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Scrotal abscess			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Sepsis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Staphylococcal infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Superinfection bacterial			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Urinary tract candidiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Urinary tract infection			
subjects affected / exposed	2 / 197 (1.02%)	1 / 202 (0.50%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Urosepsis			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Viral myocarditis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Calciphylaxis			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Decreased appetite			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Dehydration			
subjects affected / exposed	0 / 197 (0.00%)	1 / 202 (0.50%)	0 / 205 (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
Failure to thrive			

subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Hyperglycaemia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Hyperkalaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hypoglycaemia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 202 (0.00%)	0 / 205 (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
Hypokalaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Hypophosphataemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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
Metabolic acidosis			

subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 202 (0.00%)	0 / 205 (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	Phase 2 Cohort 2: Cas+Imdev 8000mg IV	Phase 2 Cohort 2: Cas+Imdev 2400mg IV	Phase 2 Cohort 2: Placebo IV
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 54 (48.15%)	31 / 56 (55.36%)	20 / 51 (39.22%)
number of deaths (all causes)	19	25	13
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Appendix cancer			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Colon cancer			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Arteriosclerosis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Embolism venous			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haematoma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypertensive urgency			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypotension			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Shock			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Venous thrombosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Venous thrombosis limb			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			

Asthenia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Chest pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Chills			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Death			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Fatigue			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Generalised oedema			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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	1 / 54 (1.85%)	1 / 56 (1.79%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pain			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Sudden cardiac death			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypersensitivity			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 transplant rejection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Dyspnoea			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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	2 / 54 (3.70%)	1 / 56 (1.79%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 1

Pneumonitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 54 (3.70%)	4 / 56 (7.14%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute respiratory failure			
subjects affected / exposed	3 / 54 (5.56%)	7 / 56 (12.50%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 7	0 / 0
Alveolar lung disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Aspiration			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Atelectasis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Dyspnoea exertional			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haemoptysis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Laryngeal stenosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Organising pneumonia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pleural effusion			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pneumomediastinum			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pneumothorax			
subjects affected / exposed	0 / 54 (0.00%)	2 / 56 (3.57%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pulmonary embolism			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Pulmonary oedema			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 arrest			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 distress			
subjects affected / exposed	1 / 54 (1.85%)	1 / 56 (1.79%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory failure			

subjects affected / exposed	5 / 54 (9.26%)	4 / 56 (7.14%)	5 / 51 (9.80%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 4
Tachypnoea			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Anxiety			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Delirium			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Product issues			
Device occlusion			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Blood glucose increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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

ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Inflammatory marker increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
International normalised ratio increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Klebsiella test positive			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Oxygen saturation decreased			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Brain herniation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Endotracheal intubation complication			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Fall			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 stoma complication			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Head injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pancreatic leak			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Post procedural complication			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Rib fracture			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Stomal hernia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Subdural haematoma			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Toxicity to various agents			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Acute left ventricular failure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Acute myocardial infarction			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Atrial fibrillation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Atrial flutter			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Atrial tachycardia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 56 (1.79%)	0 / 51 (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
Bradycardia			
subjects affected / exposed	1 / 54 (1.85%)	1 / 56 (1.79%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	3 / 54 (5.56%)	2 / 56 (3.57%)	2 / 51 (3.92%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 acute			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 chronic			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Cardiogenic shock			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Chronic left ventricular failure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Myocarditis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pulseless electrical activity			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Tachycardia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 infarction			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (1.85%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Dizziness			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Encephalopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hydrocephalus			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypoaesthesia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ischaemic stroke			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 sclerosis relapse			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Seizure			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Toxic encephalopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Unresponsive to stimuli			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Febrile neutropenia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypercoagulation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Sickle cell anaemia with crisis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Abdominal distension			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Abdominal pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Abdominal pain upper			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Dysphagia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haematemesis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haematochezia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ileus			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal obstruction			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Retroperitoneal haematoma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Cholelithiasis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pruritus			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Subcutaneous emphysema			
subjects affected / exposed	1 / 54 (1.85%)	1 / 56 (1.79%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 54 (7.41%)	1 / 56 (1.79%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Haematuria			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 failure			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
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 impairment			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 tubular injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ureterolithiasis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 56 (1.79%)	0 / 51 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Compartment syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Muscular weakness			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Myalgia			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Neck pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	8 / 54 (14.81%)	7 / 56 (12.50%)	4 / 51 (7.84%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 7	0 / 6	0 / 2
Appendicitis perforated			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 bacterial			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Aspergillus infection			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
COVID-19 pneumonia			
subjects affected / exposed	3 / 54 (5.56%)	2 / 56 (3.57%)	3 / 51 (5.88%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 3
Candida infection			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Cytomegalovirus infection			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Device related bacteraemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Encephalitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Enterococcal infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Escherichia urinary tract infection			

subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Fungaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Herpes simplex			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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
Osteomyelitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Osteomyelitis fungal			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Perirectal abscess			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pneumococcal infection			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
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 klebsiella			
subjects affected / exposed	1 / 54 (1.85%)	0 / 56 (0.00%)	0 / 51 (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 serratia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 staphylococcal			
subjects affected / exposed	0 / 54 (0.00%)	1 / 56 (1.79%)	0 / 51 (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
Post procedural infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pulmonary sepsis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Scrotal abscess			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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 / 54 (0.00%)	1 / 56 (1.79%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 54 (1.85%)	2 / 56 (3.57%)	2 / 51 (3.92%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Serratia infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 56 (1.79%)	0 / 51 (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
Staphylococcal infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	2 / 51 (3.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Superinfection bacterial			
subjects affected / exposed	0 / 54 (0.00%)	1 / 56 (1.79%)	0 / 51 (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
Urinary tract candidiasis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Urinary tract infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Urosepsis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Viral myocarditis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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			
Acidosis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Calciophylaxis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Decreased appetite			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Dehydration			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Failure to thrive			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hyperglycaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hyperkalaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypernatraemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypervolaemia			

subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypoglycaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypokalaemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Hypophosphataemia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Metabolic acidosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (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	Phase 2 Cohort 3: Placebo IV	Phase 2 Cohort 3: Cas+Imdev 2400mg IV	Phase 3 Cohort 1: Cas+Imdev 2400mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	11 / 12 (91.67%)	56 / 246 (22.76%)
number of deaths (all causes)	7	8	24
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Appendix cancer			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Colon cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Arteriosclerosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Distributive shock			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Embolism venous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Hypertensive urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypovolaemic shock			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Shock			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2

Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Sudden cardiac death			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 246 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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

Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 transplant rejection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	8 / 246 (3.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory failure			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	6 / 246 (2.44%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Alveolar lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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

Aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Atelectasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Laryngeal stenosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 246 (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
Organising pneumonia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pleuritic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pneumomediastinum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pneumothorax			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pulmonary embolism			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 246 (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
Respiratory distress			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	7 / 246 (2.85%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 3
Tachypnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Delirium			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Mental status changes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Blood glucose increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Fibrin D dimer increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Inflammatory marker increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Klebsiella test positive			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Oxygen saturation decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Brain herniation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Endotracheal intubation complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Fall			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 246 (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
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Head injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pancreatic leak			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Post procedural complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Stomal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Subdural haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Toxicity to various agents			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Atrial flutter			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Atrial tachycardia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 arrest			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiogenic shock			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chronic left ventricular failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Myocarditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pulseless electrical activity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 infarction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Encephalopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hydrocephalus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Ischaemic stroke			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple sclerosis relapse			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Unresponsive to stimuli			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypercoagulation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Ileus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 gastric emptying			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Retroperitoneal haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ischaemic hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pruritus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Subcutaneous emphysema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
End stage renal disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 tubular injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Ureterolithiasis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Compartment syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	5 / 246 (2.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Appendicitis perforated			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Aspergillus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Candida sepsis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Device related bacteraemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Encephalitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Enterococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Fungaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Osteomyelitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Perirectal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pneumococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 klebsiella			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 serratia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 staphylococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Post procedural infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Scrotal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Serratia infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Staphylococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Superinfection bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Urinary tract candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Urosepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 246 (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
Viral myocarditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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			
Acidosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Calciphylaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Failure to thrive			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypernatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypervolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 246 (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	Phase 3 Cohort 1: Placebo IV	Phase 2 Cohort 3: Cas+Imdev 8000mg IV	Phase 3 Cohort 1: Cas+Imdev 8000mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	65 / 247 (26.32%)	5 / 11 (45.45%)	69 / 246 (28.05%)
number of deaths (all causes)	42	4	37
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Appendix cancer			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Colon cancer			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Arteriosclerosis			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Embolism venous			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haematoma			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypertensive urgency			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Hypovolaemic shock			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Orthostatic hypotension			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Shock			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Shock haemorrhagic			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Venous thrombosis			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Surgical and medical procedures			
Ileostomy closure			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			

Asthenia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Chest pain			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Death			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Fatigue			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Generalised oedema			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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	3 / 247 (1.21%)	0 / 11 (0.00%)	6 / 246 (2.44%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 6
Non-cardiac chest pain			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pain			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypersensitivity			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung transplant rejection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Dyspnoea			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	8 / 247 (3.24%)	0 / 11 (0.00%)	5 / 246 (2.03%)
occurrences causally related to treatment / all	1 / 9	0 / 0	2 / 6
deaths causally related to treatment / all	1 / 2	0 / 0	1 / 1

Pneumonitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory failure			
subjects affected / exposed	11 / 247 (4.45%)	1 / 11 (9.09%)	5 / 246 (2.03%)
occurrences causally related to treatment / all	0 / 12	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 9	0 / 1	0 / 3
Alveolar lung disease			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Aspiration			
subjects affected / exposed	0 / 247 (0.00%)	1 / 11 (9.09%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dyspnoea exertional			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haemoptysis			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Laryngeal stenosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Organising pneumonia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pleural effusion			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pleuritic pain			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pneumomediastinum			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 aspiration			

subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Pneumothorax			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pulmonary embolism			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 distress			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	7 / 247 (2.83%)	0 / 11 (0.00%)	5 / 246 (2.03%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 3
Tachypnoea			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Anxiety			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Delirium			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Mental status changes			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Product issues			
Device occlusion			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Blood glucose increased			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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

ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Fibrin D dimer increased			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haemoglobin decreased			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory marker increased			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
International normalised ratio increased			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Klebsiella test positive			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Mean arterial pressure increased			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Oxygen saturation decreased			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Endotracheal intubation complication			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Fall			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Head injury			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic leak			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Post procedural complication			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Rib fracture			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Stomal hernia			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Subdural haematoma			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Toxicity to various agents			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Acute left ventricular failure			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Acute myocardial infarction			

subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Angina pectoris			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Atrial fibrillation			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Atrial flutter			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Atrial tachycardia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Bradycardia			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Cardiac arrest			
subjects affected / exposed	2 / 247 (0.81%)	1 / 11 (9.09%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure acute			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 chronic			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.00%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			
subjects affected / exposed	3 / 247 (1.21%)	0 / 11 (0.00%)	2 / 246 (0.81%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Cardiogenic shock			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chronic left ventricular failure			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Myocarditis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Tachycardia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 infarction			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Dementia Alzheimer's type			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Encephalopathy			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypoaesthesia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Ischaemic stroke			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 sclerosis relapse			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Seizure			

subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Syncope			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Transverse sinus thrombosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Unresponsive to stimuli			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypercoagulation			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Sickle cell anaemia with crisis			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Abdominal distension			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Abdominal pain			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Dysphagia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haematemesis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haematochezia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 gastric emptying			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 obstruction			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Retroperitoneal haematoma			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal obstruction			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Cholelithiasis			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pruritus			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Subcutaneous emphysema			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 247 (1.62%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Haematuria			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 failure			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 impairment			
subjects affected / exposed	0 / 247 (0.00%)	1 / 11 (9.09%)	0 / 246 (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
Renal tubular injury			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Ureterolithiasis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Compartment syndrome			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Muscular weakness			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Myalgia			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Neck pain			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	10 / 247 (4.05%)	2 / 11 (18.18%)	8 / 246 (3.25%)
occurrences causally related to treatment / all	0 / 10	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 7
Appendicitis perforated			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 bacterial			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Aspergillus infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Burkholderia cepacia complex infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
COVID-19 pneumonia			
subjects affected / exposed	5 / 247 (2.02%)	0 / 11 (0.00%)	7 / 246 (2.85%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Candida infection			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Candida sepsis			
subjects affected / exposed	0 / 247 (0.00%)	1 / 11 (9.09%)	0 / 246 (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
Cellulitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Device related bacteraemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Emphysematous cholecystitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Enterococcal infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Escherichia urinary tract infection			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Fungaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Herpes zoster			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Osteomyelitis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Osteomyelitis fungal			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Perirectal abscess			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pneumococcal infection			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	3 / 246 (1.22%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia bacterial			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 klebsiella			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 serratia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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 staphylococcal			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Post procedural infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Pulmonary sepsis			

subjects affected / exposed	3 / 247 (1.21%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Scrotal abscess			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Septic shock			
subjects affected / exposed	6 / 247 (2.43%)	0 / 11 (0.00%)	5 / 246 (2.03%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Serratia infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Staphylococcal infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Staphylococcal sepsis			

subjects affected / exposed	0 / 247 (0.00%)	1 / 11 (9.09%)	0 / 246 (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
Superinfection bacterial			
subjects affected / exposed	2 / 247 (0.81%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Urinary tract candidiasis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Urinary tract infection			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Urosepsis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Viral cardiomyopathy			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Viral myocarditis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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			
Acidosis			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Calciphylaxis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Decreased appetite			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Dehydration			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Failure to thrive			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	0 / 246 (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
Hyperglycaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hyperkalaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypernatraemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypervolaemia			

subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypoglycaemia			
subjects affected / exposed	1 / 247 (0.40%)	0 / 11 (0.00%)	1 / 246 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Hypophosphataemia			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Metabolic acidosis			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 247 (0.00%)	0 / 11 (0.00%)	0 / 246 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Phase 2 Cohort 1A: Placebo IV	Phase 1 Cohort 1: Cas+Imdev 8000mg IV	Phase 1 Cohort 1: Cas+Imdev 2400mg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 198 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0
Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	1 / 20 (5.00%) 1	0 / 18 (0.00%) 0
Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 198 (0.00%) 0	0 / 20 (0.00%) 0	0 / 18 (0.00%) 0

Non-serious adverse events	Phase 1 Cohort 1: Placebo IV	Phase 2 Cohort 1: Cas+Imdev 2400mg IV	Phase 2 Cohort 1: Placebo IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 18 (0.00%)	0 / 206 (0.00%)	0 / 204 (0.00%)
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0

Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 206 (0.00%) 0	0 / 204 (0.00%) 0

Non-serious adverse events	Phase 2 Cohort 1A: Cas+Imdev 8000mg IV	Phase 2 Cohort 1A: Cas+Imdev 2400mg IV	Phase 2 Cohort 1: Cas+Imdev 8000mg IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0

Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 197 (0.00%) 0	0 / 202 (0.00%) 0	0 / 205 (0.00%) 0

Non-serious adverse events	Phase 2 Cohort 2: Cas+Imdev 8000mg IV	Phase 2 Cohort 2: Cas+Imdev 2400mg IV	Phase 2 Cohort 2: Placebo IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 54 (0.00%)	0 / 56 (0.00%)	0 / 51 (0.00%)
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0

Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	0 / 56 (0.00%) 0	0 / 51 (0.00%) 0

Non-serious adverse events	Phase 2 Cohort 3: Placebo IV	Phase 2 Cohort 3: Cas+Imdev 2400mg IV	Phase 3 Cohort 1: Cas+Imdev 2400mg IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 246 (0.41%)
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 2	0 / 246 (0.00%) 0
Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 246 (0.00%) 0
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 246 (0.00%) 0
Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 246 (0.00%) 0
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 246 (0.00%) 0

Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 246 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	1 / 246 (0.41%) 1
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	0 / 246 (0.00%) 0

Non-serious adverse events	Phase 3 Cohort 1: Placebo IV	Phase 2 Cohort 3: Cas+Imdev 8000mg IV	Phase 3 Cohort 1: Cas+Imdev 8000mg IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 247 (0.00%)	1 / 11 (9.09%)	2 / 246 (0.81%)
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	0 / 246 (0.00%) 0
Nervous system disorders Peroneal nerve palsy subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	1 / 11 (9.09%) 1	0 / 246 (0.00%) 0
Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	0 / 246 (0.00%) 0
Psychiatric disorders Delirium subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	1 / 246 (0.41%) 1
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	0 / 246 (0.00%) 0
Enterocolitis infectious subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	0 / 246 (0.00%) 0
Urinary tract infection			

subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	1 / 246 (0.41%) 1
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 247 (0.00%) 0	0 / 11 (0.00%) 0	1 / 246 (0.41%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 August 2020	To broaden patient eligibility and better align with the evolving epidemiology of when patients present to the hospital relative to COVID-19 symptom onset. To enroll patients at earlier stages of the disease and enable broader assessment of treatment impact on viral burden and other measures.
21 December 2020	The primary purpose of this amendment is to update the planned statistical analysis for the phase 1/2 portion of the study prior to unblinding.
07 July 2021	The primary purpose of this amendment is to update the planned statistical analysis for the final analysis, including changes to the objectives and endpoints, following early termination of the study

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported