

**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 Ambulatory Patients With COVID-19****Summary**

EudraCT number	2020-003690-21
Trial protocol	RO
Global end of trial date	09 June 2022

Results information

Result version number	v1 (current)
This version publication date	24 December 2022
First version publication date	24 December 2022

Trial information**Trial identification**

Sponsor protocol code	R10933-10987-COV-2067
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04425629
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Regeneron
Sponsor organisation address	777 Old Saw Mill River Road, Tarrytown, United States, 10591
Public contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 8447346643,
Scientific contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002964-PIP01-21, EMA-002965-PIP01-21
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 June 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study is an adaptive phase 1/2/3, randomized, double-blinded, placebo-controlled trial to evaluate the efficacy and safety of co-administered REGN10933+REGN10987 combination therapy ("REGN10933+REGN10987") in outpatient (ie, ambulatory) adults with COVID-19

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the International Council for Harmonisation (ICH) guidelines for Good Clinical Practice (GCP) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 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	United States: 9359
Country: Number of subjects enrolled	Romania: 103
Country: Number of subjects enrolled	Mexico: 603
Worldwide total number of subjects	10065
EEA total number of subjects	103

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)	2
Children (2-11 years)	102
Adolescents (12-17 years)	103
Adults (18-64 years)	8874
From 65 to 84 years	940

85 years and over	44
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

10065 were randomized, 135 randomized but not treated

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, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	Phase 1 Symptomatic: Placebo
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Arm description:

Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single IV dose of placebo

Arm title	Phase 1 Symptomatic: 2.4 IV
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Arm description:

2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2400 mg total (1200 mg of each mAb)

Arm title	Phase 1 Symptomatic: 8.0 IV
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Arm description:

8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

8000 mg total (4000 mg of each mAb)

Arm title	Phase 2 Symptomatic: Placebo
Arm description: Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Single IV dose of placebo	
Arm title	Phase 2 Symptomatic: 2.4 IV
Arm description: 2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 2400 mg total (1200 mg of each mAb)	
Arm title	Phase 2 Symptomatic: 8.0 IV
Arm description: 8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 8000 mg total (4000 mg of each mAb)	
Arm title	Phase 2 Asymptomatic: Placebo
Arm description: Placebo of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Single IV dose of placebo	
Arm title	Phase 2 Asymptomatic: 2.4 IV
Arm description: 2.4g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Arm type	Experimental

Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 2400 mg total (1200 mg of each mAb)	
Arm title	Phase 2 Asymptomatic: 8.0 IV
Arm description: 8.0g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 8000 mg total (4000 mg of each mAb)	
Arm title	Phase 3 Age>=18: Placebo
Arm description: Placebo of R10933 + R10987 Participants >= 18 with COVID-19, not pregnant at randomization	
Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Single IV dose of placebo	
Arm title	Phase 3 Age>=18: 1.2 IV
Arm description: 1.2g of R10933 + R10987 Participants >= 18 with COVID-19, not pregnant at randomization	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 1200 mg total (600 mg of each mAb)	
Arm title	Phase 3 Age>=18: 2.4 IV
Arm description: 2.4g of R10933 + R10987 Participants >= 18 with COVID-19, not pregnant at randomization	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
2400 mg total (1200 mg of each mAb)

Arm title	Phase 3 Age ≥ 18: 8.0 IV
Arm description: 8.0g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 8000 mg total (4000 mg of each mAb)	
Arm title	Phase 3 Age <18: Placebo
Arm description: Placebo of R10933 + R10987 Participants <18 with COVID-19, not pregnant at randomization	
Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Single IV dose of placebo	
Arm title	Phase 3 Age <18: 1.2 IV
Arm description: 1.2g of R10933 + R10987 Participants <18 with COVID-19	
Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: For patients <18 years, weight-tiered dosing was employed: 1200 mg IV treatment group ≥40 kg: 1200 mg total ≥20 kg to <40 kg: 450 mg total ≥10 kg to <20 kg: 224 mg total ≥5 kg to <10 kg: 120 mg total ≥2.5 kg to <5 kg: 60 mg total <2.5 kg: 30 mg total	
Arm title	Phase 3 Age <18: 2.4 IV
Arm description: 2.4g of R10933 + R10987 Participants <18 with COVID-19	
Arm type	Experimental

Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

For patients <18 years, weight-tiered dosing was employed:

2400 mg IV treatment group
 ≥40 kg: 2400 mg total
 ≥20 kg to <40 kg: 900 mg total
 ≥10 kg to <20 kg: 450 mg total
 ≥5 kg to <10 kg: 240 mg total
 ≥2.5 kg to <5 kg: 120 mg total
 <2.5 kg: 60 mg total

Arm title	Phase 3 Pregnant Placebo
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Arm description:

Placebo of R10933 + R10987 Participants who are pregnant with COVID-19

Arm type	Placebo
Investigational medicinal product name	Placebo for Casirivimab and Placebo for Imdevimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single IV dose of placebo

Arm title	Phase 3 Pregnant 1.2 IV
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Arm description:

1.2g of R10933 + R10987 Participants who are pregnant with COVID-19

Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1200 mg total (600 mg of each mAb)

Arm title	Phase 3 Pregnant: 2.4 IV
------------------	--------------------------

Arm description:

2.4g of R10933 + R10987 Participants who are pregnant with COVID-19

Arm type	Experimental
Investigational medicinal product name	Casirivimab (R10933) + Imdevimab (R10987)
Investigational medicinal product code	R10933 + R10987
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2400 mg total (1200 mg of each mAb)

Number of subjects in period 1	Phase 1 Symptomatic: Placebo	Phase 1	Phase 1
		Symptomatic: 2.4 IV	Symptomatic: 8.0 IV
Started	24	24	24
Completed	23	19	22
Not completed	1	5	2
Physician decision	-	-	-
Subject Decision	-	2	1
Adverse event, non-fatal	-	-	-
Death	-	-	-
Lost to follow-up	1	3	1
Sponsor Request	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Phase 2 Symptomatic: Placebo	Phase 2	Phase 2
		Symptomatic: 2.4 IV	Symptomatic: 8.0 IV
Started	242	242	243
Completed	230	232	233
Not completed	12	10	10
Physician decision	-	-	-
Subject Decision	3	6	6
Adverse event, non-fatal	-	1	-
Death	-	-	-
Lost to follow-up	7	1	2
Sponsor Request	2	2	2
Lack of efficacy	-	-	-

Number of subjects in period 1	Phase 2 Asymptomatic: Placebo	Phase 2	Phase 2
		Asymptomatic: 2.4 IV	Asymptomatic: 8.0 IV
Started	76	76	76
Completed	71	73	74
Not completed	5	3	2
Physician decision	-	-	-
Subject Decision	3	3	1
Adverse event, non-fatal	-	-	-
Death	-	-	-
Lost to follow-up	1	-	1
Sponsor Request	1	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Phase 3 Age>=18: Placebo	Phase 3 Age>=18: 1.2 IV	Phase 3 Age>=18: 2.4 IV
	2378	2156	3189

Completed	2217	1974	2947
Not completed	161	182	242
Physician decision	4	3	5
Subject Decision	70	95	124
Adverse event, non-fatal	3	2	1
Death	11	2	4
Lost to follow-up	64	70	98
Sponsor Request	9	9	10
Lack of efficacy	-	1	-

Number of subjects in period 1	Phase 3 Age >=18: 8.0 IV	Phase 3 Age <18: Placebo	Phase 3 Age <18: 1.2 IV
Started	1027	2	129
Completed	962	2	123
Not completed	65	0	6
Physician decision	1	-	-
Subject Decision	25	-	1
Adverse event, non-fatal	1	-	-
Death	-	-	-
Lost to follow-up	30	-	5
Sponsor Request	8	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Phase 3 Age <18: 2.4 IV	Phase 3 Pregnant Placebo	Phase 3 Pregnant 1.2 IV
Started	75	3	43
Completed	65	2	40
Not completed	10	1	3
Physician decision	1	-	-
Subject Decision	4	1	-
Adverse event, non-fatal	-	-	-
Death	-	-	-
Lost to follow-up	4	-	3
Sponsor Request	1	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Phase 3 Pregnant: 2.4 IV
Started	36
Completed	33
Not completed	3
Physician decision	-
Subject Decision	2
Adverse event, non-fatal	-
Death	-

Lost to follow-up	1
Sponsor Request	-
Lack of efficacy	-

Baseline characteristics

Reporting groups

Reporting group title	Phase 1 Symptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 1 Symptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 1 Symptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Asymptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 2 Asymptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 2 Asymptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 3 Age ≥ 18: Placebo
Reporting group description: Placebo of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 1.2 IV
Reporting group description: 1.2g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age < 18: Placebo
Reporting group description: Placebo of R10933 + R10987 Participants < 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age < 18: 1.2 IV
Reporting group description: 1.2g of R10933 + R10987 Participants < 18 with COVID-19	
Reporting group title	Phase 3 Age < 18: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Participants < 18 with COVID-19	

Reporting group title	Phase 3 Pregnant Placebo
Reporting group description: Placebo of R10933 + R10987 Participants who are pregnant with COVID-19	
Reporting group title	Phase 3 Pregnant 1.2 IV
Reporting group description: 1.2g of R10933 + R10987 Participants who are pregnant with COVID-19	
Reporting group title	Phase 3 Pregnant: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Participants who are pregnant with COVID-19	

Reporting group values	Phase 1 Symptomatic: Placebo	Phase 1 Symptomatic: 2.4 IV	Phase 1 Symptomatic: 8.0 IV
Number of subjects	24	24	24
Age Categorical Units: Participants			
<18	0	0	0
>=18, <65	22	23	23
>=65	2	1	1
Age Continuous Units: years			
median	40.5	39.5	39.0
full range (min-max)	18 to 72	18 to 65	20 to 72
Gender Categorical Units: Subjects			
Female	10	14	10
Male	14	10	14
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	8	11	17
Not Hispanic or Latino	16	12	6
Not Reported	0	1	1
Race Units: Subjects			
White	20	16	23
Black or African American	3	7	0
Asian	0	0	0
American Indian or Alaska Native	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Unknown	0	0	0
Not Reported	0	1	1
Age Continous Units: years			
arithmetic mean	43.8	38.9	40.4
standard deviation	± 14.42	± 11.11	± 11.83

Reporting group values	Phase 2 Symptomatic: Placebo	Phase 2 Symptomatic: 2.4 IV	Phase 2 Symptomatic: 8.0 IV
Number of subjects	242	242	243

Age Categorical Units: Participants			
<18	0	0	0
>=18, <65	226	223	228
>=65	16	19	15
Age Continuous Units: years			
median	42.0	43.0	42.0
full range (min-max)	18 to 89	18 to 85	19 to 80
Gender Categorical Units: Subjects			
Female	122	130	136
Male	120	112	107
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	129	121	117
Not Hispanic or Latino	112	121	126
Not Reported	1	0	0
Race Units: Subjects			
White	207	208	207
Black or African American	21	20	23
Asian	4	6	4
American Indian or Alaska Native	2	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Unknown	3	1	3
Not Reported	5	6	5
Age Continous Units: years			
arithmetic mean	42.5	42.7	41.7
standard deviation	± 15.21	± 15.59	± 14.38

Reporting group values	Phase 2 Asymptomatic: Placebo	Phase 2 Asymptomatic: 2.4 IV	Phase 2 Asymptomatic: 8.0 IV
Number of subjects	76	76	76
Age Categorical Units: Participants			
<18	0	0	0
>=18, <65	71	62	65
>=65	5	14	11
Age Continuous Units: years			
median	43.5	44.5	44.5
full range (min-max)	18 to 80	18 to 75	18 to 84
Gender Categorical Units: Subjects			
Female	40	37	32
Male	36	39	44

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	34	43	35
Not Hispanic or Latino	40	33	39
Not Reported	2	0	2
Race			
Units: Subjects			
White	65	69	65
Black or African American	6	3	5
Asian	1	4	3
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Unknown	2	0	3
Not Reported	2	0	0
Age Continuous			
Units: years			
arithmetic mean	43.5	44.8	44.0
standard deviation	± 15.51	± 16.70	± 17.43

Reporting group values	Phase 3 Age>=18: Placebo	Phase 3 Age>=18: 1.2 IV	Phase 3 Age>=18: 2.4 IV
Number of subjects	2378	2156	3189
Age Categorical			
Units: Participants			
<18	0	0	0
>=18, <65	2159	1937	2843
>=65	219	219	346
Age Continuous			
Units: years			
median	46.0	48.0	46.0
full range (min-max)	18 to 92	18 to 93	18 to 96
Gender Categorical			
Units: Subjects			
Female	1227	1117	1635
Male	1151	1039	1554
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1002	1140	1413
Not Hispanic or Latino	1357	992	1740
Not Reported	19	24	36
Race			
Units: Subjects			
White	2010	1704	2612
Black or African American	110	112	172
Asian	89	71	96
American Indian or Alaska Native	30	72	84
Native Hawaiian or Other Pacific Islander	3	7	6
Unknown	82	138	143
Not Reported	54	52	76

Age Continuous Units: years arithmetic mean standard deviation	45.4 ± 14.61	46.7 ± 14.59	46.1 ± 14.89
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Reporting group values	Phase 3 Age ≥ 18: 8.0 IV	Phase 3 Age < 18: Placebo	Phase 3 Age < 18: 1.2 IV
Number of subjects	1027	2	129
Age Categorical Units: Participants			
<18	0	2	129
≥18, <65	911	0	0
≥65	116	0	0
Age Continuous Units: years median full range (min-max)	44.0 18 to 90	14.0 12 to 16	11.0 0 to 17
Gender Categorical Units: Subjects			
Female	518	2	69
Male	509	0	60
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	316	0	87
Not Hispanic or Latino	701	2	42
Not Reported	10	0	0
Race Units: Subjects			
White	889	1	115
Black or African American	46	1	8
Asian	45	0	1
American Indian or Alaska Native	5	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Unknown	21	0	3
Not Reported	21	0	2
Age Continuous Units: years arithmetic mean standard deviation	44.8 ± 15.09	14.0 ± 2.83	10.9 ± 4.14

Reporting group values	Phase 3 Age < 18: 2.4 IV	Phase 3 Pregnant Placebo	Phase 3 Pregnant 1.2 IV
Number of subjects	75	3	43
Age Categorical Units: Participants			
<18	75	0	0
≥18, <65	0	3	43
≥65	0	0	0
Age Continuous Units: years median full range (min-max)	12.0 3 to 17	33.0 27 to 33	30.0 19 to 41

Gender Categorical			
Units: Subjects			
Female	22	3	43
Male	53	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	40	0	6
Not Hispanic or Latino	33	2	37
Not Reported	2	1	0
Race			
Units: Subjects			
White	63	2	35
Black or African American	7	1	4
Asian	1	0	0
American Indian or Alaska Native	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	1
Unknown	2	0	1
Not Reported	2	0	1
Age Continuous			
Units: years			
arithmetic mean	12.2	31.0	28.9
standard deviation	± 3.36	± 3.46	± 5.87

Reporting group values	Phase 3 Pregnant: 2.4 IV	Total	
Number of subjects	36	10065	
Age Categorical			
Units: Participants			
<18	1	207	
>=18, <65	35	8874	
>=65	0	984	
Age Continuous			
Units: years			
median	28.0		
full range (min-max)	17 to 41	-	
Gender Categorical			
Units: Subjects			
Female	36	5203	
Male	0	4862	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	8	4527	
Not Hispanic or Latino	28	5439	
Not Reported	0	99	
Race			
Units: Subjects			
White	33	8344	
Black or African American	2	551	
Asian	0	325	
American Indian or Alaska Native	0	197	

Native Hawaiian or Other Pacific Islander	0	17	
Unknown	0	402	
Not Reported	1	229	
Age Continuous			
Units: years			
arithmetic mean	28.3		
standard deviation	± 6.02	-	

End points

End points reporting groups

Reporting group title	Phase 1 Symptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 1 Symptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 1 Symptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Symptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19	
Reporting group title	Phase 2 Asymptomatic: Placebo
Reporting group description: Placebo of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 2 Asymptomatic: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 2 Asymptomatic: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection	
Reporting group title	Phase 3 Age ≥ 18: Placebo
Reporting group description: Placebo of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 1.2 IV
Reporting group description: 1.2g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 2.4 IV
Reporting group description: 2.4g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age ≥ 18: 8.0 IV
Reporting group description: 8.0g of R10933 + R10987 Participants ≥ 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age < 18: Placebo
Reporting group description: Placebo of R10933 + R10987 Participants < 18 with COVID-19, not pregnant at randomization	
Reporting group title	Phase 3 Age < 18: 1.2 IV
Reporting group description: 1.2g of R10933 + R10987 Participants < 18 with COVID-19	
Reporting group title	Phase 3 Age < 18: 2.4 IV

Reporting group description:

2.4g of R10933 + R10987 Participants <18 with COVID-19

Reporting group title	Phase 3 Pregnant Placebo
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Reporting group description:

Placebo of R10933 + R10987 Participants who are pregnant with COVID-19

Reporting group title	Phase 3 Pregnant 1.2 IV
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Reporting group description:

1.2g of R10933 + R10987 Participants who are pregnant with COVID-19

Reporting group title	Phase 3 Pregnant: 2.4 IV
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Reporting group description:

2.4g of R10933 + R10987 Participants who are pregnant with COVID-19

Subject analysis set title	Phase 1 + Phase 2 Symptomatic (Placebo)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Combined Phase 1 + Phase 2 Symptomatic Placebo Participants

Subject analysis set title	Phase 1 + Phase 2 Symptomatic (2.4g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Combined Phase 1 + Phase 2 Symptomatic 2.4g IV Participants

Subject analysis set title	Phase 1 + Phase 2 Symptomatic (8.0g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Combined Phase 1 + Phase 2 Symptomatic 8.0g IV Participants

Subject analysis set title	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Pooled analysis of Phases 1, 2, & 3 Cohort 1 Symptomatic Participants for Placebo

Subject analysis set title	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Pooled analysis of Phases 1, 2, & 3 Cohort 1 Symptomatic Participants for dosage of 1.2g IV

Subject analysis set title	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Pooled analysis of Phases 1, 2, & 3 Cohort 1 Symptomatic Participants for dosage of 2.4g IV

Subject analysis set title	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Pooled analysis of Phases 1, 2, & 3 Cohort 1 Symptomatic Participants for dosage of 8.0g IV

Subject analysis set title	Phase 3 Cohort 2 Pediatric (Placebo)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Phase 3 Cohort 2 Pediatric (Placebo)

Subject analysis set title	Phase 3 Cohort 2 Pediatric (1.2g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Phase 3 Cohort 2 Pediatric (1.2g IV)

Subject analysis set title	Phase 3 Cohort 2 Pediatric (2.4g IV)
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Phase 3 Cohort 2 Pediatric (2.4g IV)

Subject analysis set title	Phase 3 Cohort 3 Pregnant (Placebo)
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Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 3 Pregnant (Placebo)	
Subject analysis set title	Phase 3 Cohort 3 Pregnant (1.2g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 3 Pregnant (1.2g IV)	
Subject analysis set title	Phase 3 Cohort 3 Pregnant (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 3 Pregnant (2.4g IV)	
Subject analysis set title	Phase 3 Cohort 1 (Placebo) >=18
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (Placebo)	
Subject analysis set title	Phase 3 Cohort 1 (1.2g IV) >= 18
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (1.2g IV)	
Subject analysis set title	Phase 3 Cohort 1 (2.4g IV) >= 18
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (2.4g IV)	
Subject analysis set title	Phase 3 Cohort 1 (8.0g IV) >= 18
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (8.0g IV)	
Subject analysis set title	Phase 3 Cohort 1 (Placebo)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (Placebo) - Post PA6 mFAS	
Subject analysis set title	Phase 3 Cohort 1 (1.2 g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 3 Cohort 1 (1.2 g IV) - Post PA6 mFAS	
Subject analysis set title	Phase 1 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 1 (2.4g IV) - PK Analysis Set	
Subject analysis set title	Phase 1 (8.0g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 1 (8.0g IV) - PK Analysis Set	
Subject analysis set title	Phase 2 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 2 (2.4g IV) - PK Analysis Set	
Subject analysis set title	Phase 2 (8.0g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 2 (8.0g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 1 (1.2g IV)

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 1 (1.2g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 1 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 1 (2.4g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 1 (8.0g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 1 (8.0g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 3 (1.2g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 3 (1.2g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 3 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 3 (2.4g IV) - PK Analysis Set	
Subject analysis set title	Phase 3 Cohort 2 (Placebo)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 2 (Placebo) - ADA Analysis Set	
Subject analysis set title	Phase 3 Cohort 2 (1.2g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 2 (1.2g IV) - ADA Analysis Set	
Subject analysis set title	Phase 3 Cohort 2 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 2 (2.4g IV) - ADA Analysis Set	
Subject analysis set title	Phase 3 Cohort 3 (Placebo)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 3 (Placebo) - ADA Analysis Set	
Subject analysis set title	Phase 3 Cohort 3 (1.2g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 3 (1.2g IV) - ADA Analysis Set	
Subject analysis set title	Phase 3 Cohort 3 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase 3 Cohort 3 (2.4g IV) - ADA Analysis Set	
Subject analysis set title	Next Phase 2 (Placebo)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Next Phase 2 Placebo Participants	
Subject analysis set title	Next Phase 2 (2.4g IV)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Next Phase 2 Participants 2.4g IV	
Subject analysis set title	Next Phase 2 (8.0g IV)

Subject analysis set type	Sub-group analysis
Subject analysis set description: Next Phase 2 Participants 8.0g IV	
Subject analysis set title	Phase 1 PK-AS
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase 1 PK-AS (Pharmacokinetic Analysis Set)	

Primary: Number of Participants with treatment-emergent serious adverse events (SAEs) - [Ph1, Ph2, Ph3 Cohort 1 - Cohort 3]

End point title	Number of Participants with treatment-emergent serious adverse events (SAEs) - [Ph1, Ph2, Ph3 Cohort 1 - Cohort 3] ^[1]
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End point description:

Primary:

Phase 1, Phase 3 (Cohort 2 and Cohort 3)

Secondary:

Phase 2, Phase 3 (Cohort 1)

Pooled analysis of the symptomatic patients only, randomized up to 24-Feb with ≥ 1 risk factor

End point type	Primary
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End point timeframe:

Through Day 29

Notes:

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

Justification: No statistical analyses for this end point

End point values	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2609	1329	2614	1272
Units: Participant	97	14	31	19

End point values	Phase 3 Cohort 2 Pediatric (Placebo)	Phase 3 Cohort 2 Pediatric (1.2g IV)	Phase 3 Cohort 2 Pediatric (2.4g IV)	Phase 3 Cohort 3 Pregnant (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	129	71	2
Units: Participant	0	2	0	0

End point values	Phase 3 Cohort 3 Pregnant (1.2g IV)	Phase 3 Cohort 3 Pregnant (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	35		
Units: Participant	2	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with infusion-related reactions (Ph1, Ph2, Ph3 Cohort 1 - Cohort 3)

End point title	Number of Participants with infusion-related reactions (Ph1, Ph2, Ph3 Cohort 1 - Cohort 3) ^[2]
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End point description:

Primary:

Phase 1, Phase 3 (Cohort 2 and Cohort 3)

Secondary:

Phase 2, Phase 3 (Cohort 1)

End point type	Primary
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End point timeframe:

Through Day 4

Notes:

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

Justification: No statistical analyses for this end point

End point values	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2609	1329	2614	1272
Units: Participants	2	1	4	7

End point values	Phase 3 Cohort 2 Pediatric (Placebo)	Phase 3 Cohort 2 Pediatric (1.2g IV)	Phase 3 Cohort 2 Pediatric (2.4g IV)	Phase 3 Cohort 3 Pregnant (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	129	71	2
Units: Participants	0	0	1	0

End point values	Phase 3 Cohort 3 Pregnant (1.2g IV)	Phase 3 Cohort 3 Pregnant (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	35		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with hypersensitivity reactions (Ph1, Ph2, Ph3 Cohort 1 - Cohort 3)

End point title	Number of participants with hypersensitivity reactions (Ph1, Ph2, Ph3 Cohort 1 - Cohort 3) ^[3]
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End point description:

Primary:

Phase 1, Phase 3 (Cohort 2 and Cohort 3)

Secondary:

Phase 2, Phase 3 (Cohort 1)

End point type	Primary
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End point timeframe:

Through Day 29

Notes:

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

Justification: No statistical analyses for this end point

End point values	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2609	1329	2614	1272
Units: Participants	3	1	1	0

End point values	Phase 3 Cohort 2 Pediatric (Placebo)	Phase 3 Cohort 2 Pediatric (1.2g IV)	Phase 3 Cohort 2 Pediatric (2.4g IV)	Phase 3 Cohort 3 Pregnant (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	129	71	2
Units: Participants	0	1	0	0

End point values	Phase 3 Cohort 3 Pregnant (1.2g IV)	Phase 3 Cohort 3 Pregnant (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	35		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Time-weighted average change from baseline in viral load (log₁₀ copies/mL) from Day 1 to Day 7, as measured by quantitative reverse transcription quantitative polymerase chain reaction (RT-qPCR) in nasopharyngeal (NP) swab samples (Ph1, Ph2)

End point title	Time-weighted average change from baseline in viral load (log ₁₀ copies/mL) from Day 1 to Day 7, as measured by quantitative reverse transcription quantitative polymerase chain reaction (RT-qPCR) in nasopharyngeal (NP) swab samples (Ph1, Ph2)
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End point description:

Primary:

Phase 1, Phase 2

All randomized patients with qualitatively positive RT-qPCR in NP swab samples at randomization or collected within 2 hours after study drug infusion was initiated;

End point type	Primary
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End point timeframe:

Baseline up to Day 7

End point values	Phase 1 + Phase 2 Symptomatic (Placebo)	Phase 1 + Phase 2 Symptomatic (2.4g IV)	Phase 1 + Phase 2 Symptomatic (8.0g IV)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	224	211	214	
Units: log ₁₀ copies/mL				
arithmetic mean (standard deviation)	-1.32 (± 1.047)	-1.65 (± 0.977)	-1.67 (± 1.157)	

Statistical analyses

Statistical analysis title	Difference vs. Placebo by Day 7
Comparison groups	Phase 1 + Phase 2 Symptomatic (Placebo) v Phase 1 + Phase 2 Symptomatic (2.4g IV)

Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	ANCOVA
Parameter estimate	LS Mean
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	-0.14
Variability estimate	Standard error of the mean
Dispersion value	0.1

Statistical analysis title	Difference vs. Placebo by Day 7
Comparison groups	Phase 1 + Phase 2 Symptomatic (Placebo) v Phase 1 + Phase 2 Symptomatic (8.0g IV)
Number of subjects included in analysis	438
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.56
upper limit	-0.19
Variability estimate	Standard error of the mean
Dispersion value	0.1

Primary: Proportion of participants with at least one (≥ 1) COVID-19-related hospitalization or all-cause death (Ph3 Cohort 1- 1.2g vs Placebo)

End point title	Proportion of participants with at least one (≥ 1) COVID-19-related hospitalization or all-cause death (Ph3 Cohort 1- 1.2g vs Placebo)
End point description: Phase 3 Cohort 1	
End point type	Primary
End point timeframe: Through Day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (1.2g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	748	736		
Units: Percentage of Participants				
number (confidence interval 95%)	3.2 (2.1 to 4.7)	1.0 (0.4 to 1.9)		

Statistical analyses

Statistical analysis title	1.2g IV vs. Placebo
Comparison groups	Phase 3 Cohort 1 (Placebo) ≥ 18 v Phase 3 Cohort 1 (1.2g IV) ≥ 18
Number of subjects included in analysis	1484
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0024
Method	Cochran-Mantel-Haenszel

Primary: Proportion of participants with at least one (≥ 1) COVID-19-related hospitalization or all-cause death (Ph3 Cohort 1 - 2.4g vs Placebo)

End point title	Proportion of participants with at least one (≥ 1) COVID-19-related hospitalization or all-cause death (Ph3 Cohort 1 - 2.4g vs Placebo)
End point description:	
Primary:	
Phase 3 (Cohort 1)	
End point type	Primary
End point timeframe:	
Through Day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (2.4g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1341	1355		
Units: Percentage of Participants				
number (confidence interval 95%)	4.6 (3.6 to 5.9)	1.3 (0.8 to 2.1)		

Statistical analyses

Statistical analysis title	2.4g IV vs. Placebo
Comparison groups	Phase 3 Cohort 1 (2.4g IV) ≥ 18 v Phase 3 Cohort 1 (Placebo) ≥ 18

Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Primary: Concentration of REGN10983 + REGN10987 in Serum over time (Ph3 Cohort 2)

End point title	Concentration of REGN10983 + REGN10987 in Serum over time (Ph3 Cohort 2) ^[4]
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End point description:

Phase 3 Cohort 2

[Nominal Sampling Time] = [Clinical Study Time (Visit Day - 1)]

End point type	Primary
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End point timeframe:

Up to Nominal Sampling Day 28

Notes:

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

Justification: No statistical analyses for this end point

End point values	Phase 3 Cohort 2 Pediatric (1.2g IV)	Phase 3 Cohort 2 Pediatric (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	64		
Units: mg/L				
arithmetic mean (standard deviation)				
Day 0: End of Infusion (n=107, 51)	402 (± 196)	710 (± 275)		
Nominal Sampling Day 28 (n= 94, 48)	108 (± 60.1)	198 (± 78.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to COVID-19 Symptoms Resolution (Ph3 Cohort 1 - 1.2g vs Placebo)

End point title	Time to COVID-19 Symptoms Resolution (Ph3 Cohort 1 - 1.2g vs Placebo)
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End point description:

Phase 3 Cohort 1

End point type	Secondary
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End point timeframe:

Up to Day 29

End point values	Phase 3 Cohort 1 (Placebo)	Phase 3 Cohort 1 (1.2 g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	680	673		
Units: Days				
median (confidence interval 95%)	14.0 (13.0 to 16.0)	10.0 (9.0 to 12.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to COVID-19 symptoms resolution (Ph3 Cohort 1 - 2.4g vs Placebo)

End point title	Time to COVID-19 symptoms resolution (Ph3 Cohort 1 - 2.4g vs Placebo) ^[5]
End point description:	
Phase 3 (Cohort 1)	
End point type	Secondary
End point timeframe:	
Through Day 29	
Notes:	
[5] - 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: No statistical analyses for the baseline portion for these arms	

End point values	Phase 3 Age ≥ 18: Placebo	Phase 3 Age ≥ 18: 2.4 IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1197	1214		
Units: Days				
median (confidence interval 95%)	14.0 (13.0 to 15.0)	10.0 (10.0 to 11.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with ≥1 COVID-19-related hospitalization or all-cause death from Day 4 through Day 29 (Ph3 Cohort 1 - 1.2g vs. Placebo)

End point title	Proportion of participants with ≥1 COVID-19-related hospitalization or all-cause death from Day 4 through Day 29 (Ph3 Cohort 1 - 1.2g vs. Placebo)
End point description:	
Phase 3 (Cohort 1)	
End point type	Secondary
End point timeframe:	
Day 4 thru Day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (1.2g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	735	748		
Units: Number of Participants	5	18		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with ≥ 1 COVID-19-related hospitalization or all-cause death from Day 4 through Day 29 (Ph3 Cohort 1 - 2.4g vs. Placebo)

End point title	Proportion of participants with ≥ 1 COVID-19-related hospitalization or all-cause death from Day 4 through Day 29 (Ph3 Cohort 1 - 2.4g vs. Placebo)
End point description:	
Phase 3 (Cohort 1)	
End point type	Secondary
End point timeframe:	
From Day 4 Through Day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (2.4g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1340	1351		
Units: Number of Participants	46	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in viral load at each visit, as measured by RT-qPCR in nasopharyngeal swabs (Next Phase 2 Cohort)

End point title	Change from baseline in viral load at each visit, as measured by RT-qPCR in nasopharyngeal swabs (Next Phase 2 Cohort)
End point description:	
Next Phase 2 Symptomatic	
End point type	Secondary
End point timeframe:	
Day 5, Day 7, Day 15, Day 29	

End point values	Next Phase 2 (Placebo)	Next Phase 2 (2.4g IV)	Next Phase 2 (8.0g IV)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	151	145	146	
Units: log10 copies/mL				
least squares mean (standard error)				
Day 5 (n=141, 139, 137, 54, 45, 47)	-1.79 (± 0.14)	-2.33 (± 0.14)	-2.28 (± 0.14)	
Day 7 (n=141, 139, 134, 55, 48, 48)	-2.54 (± 0.13)	-2.79 (± 0.13)	-3.08 (± 0.13)	
Day 15 (n=138, 140, 134, 56, 47, 50)	-4.56 (± 0.14)	-4.67 (± 0.14)	-4.58 (± 0.14)	
Day 29 (n=139, 136, 140, 54, 46, 46)	-5.42 (± 0.10)	-5.60 (± 0.10)	-5.45 (± 0.10)	

Statistical analyses

Statistical analysis title	Difference vs. Placebo at Day 29
Comparison groups	Next Phase 2 (Placebo) v Next Phase 2 (2.4g IV)
Number of subjects included in analysis	296
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1903
Method	Mixed models analysis

Statistical analysis title	Difference vs. Placebo at Day 29
Comparison groups	Next Phase 2 (Placebo) v Next Phase 2 (8.0g IV)
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8431
Method	Mixed models analysis

Secondary: Time-weighted average change from baseline in viral load (log10 copies/mL) from day 1 to post-baseline study days (Ph1, Ph2)

End point title	Time-weighted average change from baseline in viral load (log10 copies/mL) from day 1 to post-baseline study days (Ph1, Ph2)
End point description:	
Phase 1, Phase 2	
End point type	Secondary
End point timeframe:	
Day 1 to Day 29	

End point values	Phase 1 + Phase 2 Symptomatic (Placebo)	Phase 1 + Phase 2 Symptomatic (2.4g IV)	Phase 1 + Phase 2 Symptomatic (8.0g IV)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	151	145	146	
Units: log10 copies/mL				
least squares mean (standard error)				
TWA Change from BL: Day 1 to Day 5	-0.91 (± 0.09)	-1.25 (± 0.09)	-1.19 (± 0.09)	
TWA Change from BL: Day 1 to Day 7	-1.34 (± 0.09)	-1.71 (± 0.09)	-1.68 (± 0.09)	
TWA Change from BL: Day 1 to Day 15	-2.58 (± 0.09)	-2.96 (± 0.09)	-2.99 (± 0.09)	
TWA Change from BL: Day 1 to Day 29	-3.76 (± 0.08)	-4.05 (± 0.08)	-4.08 (± 0.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with ≥1 COVID-19-related medically-attended visit through Day 29 (Ph1, Ph2)

End point title	Proportion of participants with ≥1 COVID-19-related medically-attended visit through Day 29 (Ph1, Ph2)
End point description:	
Phase 1, Phase 2	
End point type	Secondary
End point timeframe:	
Through Day 29	

End point values	Phase 1 + Phase 2 Symptomatic (Placebo)	Phase 1 + Phase 2 Symptomatic (2.4g IV)	Phase 1 + Phase 2 Symptomatic (8.0g IV)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	232	219	220	
Units: Number of Visits				
number (confidence interval 95%)	7.8 (4.7 to 12.0)	3.2 (1.3 to 6.5)	2.7 (1.0 to 5.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants with ≥1 COVID-19 related Hospitalization, Emergency Room, or Urgent Care visit through Day 29 (Ph1, Ph2)

End point title	Proportion of Participants with ≥ 1 COVID-19 related Hospitalization, Emergency Room, or Urgent Care visit through Day 29 (Ph1, Ph2)
End point description: Phase 1, Phase 2	
End point type	Secondary
End point timeframe: Through Day 29	

End point values	Phase 1 + Phase 2 Symptomatic (Placebo)	Phase 1 + Phase 2 Symptomatic (2.4g IV)	Phase 1 + Phase 2 Symptomatic (8.0g IV)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	232	219	220	
Units: Percentage of Visits				
number (confidence interval 95%)	4.7 (2.4 to 8.3)	2.7 (1.0 to 5.9)	2.3 (0.7 to 5.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first onset of symptoms consistent with COVID-19 (Phase 2 asymptomatic cohort only)

End point title	Time to first onset of symptoms consistent with COVID-19 (Phase 2 asymptomatic cohort only) ^[6]
End point description: Phase 2 Only	
End point type	Secondary
End point timeframe: Up to Day 29	

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analyses for the baseline portion for these arms

End point values	Phase 2 Asymptomatic: 2.4 IV	Phase 2 Asymptomatic: 8.0 IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Time to Onset				
arithmetic mean (confidence interval 95%)	0.76 (0.41 to 1.41)	1.00 (0.57 to 1.77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with ≥ 1 COVID-19-related hospitalization, emergency room visit, or all-cause death (Ph3 Cohort 1) - Placebo vs. 1.2g IV

End point title	Proportion of participants with ≥ 1 COVID-19-related hospitalization, emergency room visit, or all-cause death (Ph3 Cohort 1) - Placebo vs. 1.2g IV
End point description: Phase 3 Cohort 1 - Placebo vs. 1.2 g IV	
End point type	Secondary
End point timeframe: Through Day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (1.2g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	748	736		
Units: Number of Participants	51	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with ≥ 1 COVID-19-related hospitalization, emergency room visit, or all-cause death (Ph3 Cohort 1) - Placebo vs. 2.4g IV

End point title	Proportion of participants with ≥ 1 COVID-19-related hospitalization, emergency room visit, or all-cause death (Ph3 Cohort 1) - Placebo vs. 2.4g IV
End point description: Phase 3 (Cohort 1)	
End point type	Secondary
End point timeframe: Through day 29	

End point values	Phase 3 Cohort 1 (Placebo) ≥ 18	Phase 3 Cohort 1 (2.4g IV) ≥ 18		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1341	1355		
Units: Number of Participants	62	18		

Statistical analyses

Secondary: Concentration of REGN10933 + REGN10987 in serum over time (Ph1 Cohort 1, Ph2 Cohort 1, Ph3 Cohort 1 and Cohort 3)

End point title	Concentration of REGN10933 + REGN10987 in serum over time (Ph1 Cohort 1, Ph2 Cohort 1, Ph3 Cohort 1 and Cohort 3)
End point description:	
Secondary:	
Phase 1, Phase 2, Phase 3 (Cohort 1 and Cohort 3) - Symptomatic Participants	
[Nominal Sampling Time] = [Clinical Study Time (Visit Day - 1)]	
End point type	Secondary
End point timeframe:	
Up to Nominal Sampling Day 28	

End point values	Phase 1 (2.4g IV)	Phase 1 (8.0g IV)	Phase 2 (2.4g IV)	Phase 2 (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	21	218	225
Units: mg/L				
arithmetic mean (standard deviation)				
Day 0: EOI n=17,21,194,199,415,1214,881,29,24	594 (± 276)	1652 (± 928)	701 (± 287)	2142 (± 815)
Day 28 n=18,20,218,225,491,1174,710,32,24	141 (± 97.5)	384 (± 143)	142 (± 62.5)	453 (± 179)

End point values	Phase 3 Cohort 1 (1.2g IV)	Phase 3 Cohort 1 (2.4g IV)	Phase 3 Cohort 1 (8.0g IV)	Phase 3 Cohort 3 (1.2g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	491	1214	881	32
Units: mg/L				
arithmetic mean (standard deviation)				
Day 0: EOI n=17,21,194,199,415,1214,881,29,24	415 (± 178)	669 (± 236)	2239 (± 740)	305 (± 80.8)
Day 28 n=18,20,218,225,491,1174,710,32,24	85.1 (± 36.9)	143 (± 55.1)	463 (± 166)	63.7 (± 25.9)

End point values	Phase 3 Cohort 3 (2.4g IV)			
Subject group type	Subject analysis set			
Number of subjects analysed	24			
Units: mg/L				
arithmetic mean (standard deviation)				
Day 0: EOI n=17,21,194,199,415,1214,881,29,24	536 (± 165)			
Day 28 n=18,20,218,225,491,1174,710,32,24	119 (± 31.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Assessment of pharmacokinetic (PK) parameter: maximum serum concentration observed (C_{max}) of REGN10933+REGN10987 (Phase 1)

End point title	Assessment of pharmacokinetic (PK) parameter: maximum serum concentration observed (C _{max}) of REGN10933+REGN10987 (Phase 1)
End point description:	
Phase 1 Only	
End point type	Secondary
End point timeframe:	
Through Day 29	

End point values	Phase 1 PK-AS			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: mg/L				
arithmetic mean (standard deviation)				
2.4g IV n=22	689 (± 391)			
8.0g IV n=23	1805 (± 720)			

Statistical analyses

No statistical analyses for this end point

Secondary: Assessment of PK parameter: Time to C_{max} (t_{max}) for REGN10933+REGN10987 (Phase 1)

End point title	Assessment of PK parameter: Time to C _{max} (t _{max}) for REGN10933+REGN10987 (Phase 1)
End point description:	
Phase 1 Only	
End point type	Secondary
End point timeframe:	
Through Day 29	

End point values	Phase 1 PK-AS			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: day				
median (full range (min-max))				
2.4g IV (n = 22)	27.7 (0.0847 to 28.2)			
8.0g IV (n = 23)	0.0854 (0.0431 to 2.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Assessment of PK parameter: Area Under the Curve (AUC) computed from time zero to Day 28 concentration (AUC 0-28) for REGN10933+REGN10987 (Phase 1)

End point title	Assessment of PK parameter: Area Under the Curve (AUC) computed from time zero to Day 28 concentration (AUC 0-28) for REGN10933+REGN10987 (Phase 1)
End point description:	
Phase 1 Only	
End point type	Secondary
End point timeframe:	
Through Day 29	

End point values	Phase 1 PK-AS			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: day*mg/L				
arithmetic mean (standard deviation)				
2.4g IV (n = 19)	7158 (± 4255)			
8.0g IV (n = 20)	19084 (± 5172)			

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by anti-drug (ADA) to REGN10933 (Ph1 Cohort 1, Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)

End point title	Immunogenicity as measured by anti-drug (ADA) to REGN10933 (Ph1 Cohort 1, Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)
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End point description:

Phase 1, Phase 2, Phase 3 (Cohort 1) - Symptomatic Participants
Phase 3 Cohort 2 Participants
Phase 3 Cohort 3 Participants

End point type	Secondary
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End point timeframe:

Through Day 29

End point values	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2353	1935	3087	1170
Units: Participants w/TreatmentEmergentResponse	17	29	20	1

End point values	Phase 3 Cohort 2 (Placebo)	Phase 3 Cohort 2 (1.2g IV)	Phase 3 Cohort 2 (2.4g IV)	Phase 3 Cohort 3 (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	123	64	1
Units: Participants w/TreatmentEmergentResponse	0	1	0	0

End point values	Phase 3 Cohort 3 (1.2g IV)	Phase 3 Cohort 3 (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	33		
Units: Participants w/TreatmentEmergentResponse	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by ADA to REGN10987 (Ph1 Cohort 1, Ph2 Cohort 1 - Cohort 3, Ph3 Cohort 1 and Cohort 3)

End point title	Immunogenicity as measured by ADA to REGN10987 (Ph1 Cohort 1, Ph2 Cohort 1 - Cohort 3, Ph3 Cohort 1 and Cohort 3)
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End point description:

Phase 1, Phase 2, Phase 3 (Cohort 1) - Symptomatic Participants
Phase 3 Cohort 2 Participants
Phase 3 Cohort 3 Participants

End point type	Secondary
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End point timeframe:

Through Day 29

End point values	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (Placebo)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (1.2g IV)	Combined Phases 1, 2, & 3 Cohort 1 Symptomatic (2.4g IV)	Combined Phases 1,2, & 3 Cohort 1 Symptomatic (8.0g IV)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2351	1934	3084	1168
Units: Participants w/TreatmentEmergentResponse	59	56	54	2

End point values	Phase 3 Cohort 2 (Placebo)	Phase 3 Cohort 2 (1.2g IV)	Phase 3 Cohort 2 (2.4g IV)	Phase 3 Cohort 3 (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	123	64	1
Units: Participants w/TreatmentEmergentResponse	0	1	0	0

End point values	Phase 3 Cohort 3 (1.2g IV)	Phase 3 Cohort 3 (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	33		
Units: Participants w/TreatmentEmergentResponse	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by neutralizing antibodies (NABs) to REGN10933 (Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)

End point title	Immunogenicity as measured by neutralizing antibodies (NABs) to REGN10933 (Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)
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End point description:

Phase 2 and Phase 3 (Cohort 1) - Symptomatic Participants

Phase 3 Cohort 2 Participants

Phase 3 Cohort 3 Participants

(TE&TB+;NAb+) = TE = Treatment-emergent; TB = Treatment-boosted; NAb+ = Positive in NAB assay

End point type	Secondary
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End point timeframe:

Through Day 29

End point values	Phase 3 Cohort 2 (Placebo)	Phase 3 Cohort 2 (1.2g IV)	Phase 3 Cohort 2 (2.4g IV)	Phase 3 Cohort 3 (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	123	64	1
Units: Participants				
TE&TB+;NAb+ Participants	0	0	0	0

End point values	Phase 3 Cohort 3 (1.2g IV)	Phase 3 Cohort 3 (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	33		
Units: Participants				
TE&TB+;NAb+ Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunogenicity as measured by NAbS to REGN10987 (Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)

End point title	Immunogenicity as measured by NAbS to REGN10987 (Ph2 Cohort 1, Ph3 Cohort 1 - Cohort 3)
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End point description:

Phase 2 and Phase 3 (Cohort 1) - Symptomatic Participants

Phase 3 Cohort 2 Participants

Phase 3 Cohort 3 Participants

(TE&TB+;NAb+) = TE = Treatment-emergent; TB = Treatment-boostered; NAb+ = Positive in NAb assay

End point type	Secondary
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End point timeframe:

Through Day 29

End point values	Phase 3 Cohort 2 (Placebo)	Phase 3 Cohort 2 (1.2g IV)	Phase 3 Cohort 2 (2.4g IV)	Phase 3 Cohort 3 (Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	123	64	1
Units: Participants				
TE&TB+;NAb+ Participants	0	1	0	0

End point values	Phase 3 Cohort 3 (1.2g IV)	Phase 3 Cohort 3 (2.4g IV)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	33		
Units: Participants				
TE&TB+;NAb+ Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose to end of study (approx. 8 months)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Phase 2 Symptomatic Placebo
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Reporting group description:

Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 1 Symptomatic R10933+R10987 8.0g IV
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Reporting group description:

8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 1 Symptomatic R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 1 Symptomatic Placebo
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Reporting group description:

Placebo of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 2 Symptomatic R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 2 Asymptomatic R10933+R10987 8.0g IV
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Reporting group description:

8.0g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection

Reporting group title	Phase 2 Asymptomatic R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection

Reporting group title	Phase 2 Asymptomatic Placebo
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Reporting group description:

Placebo of R10933 + R10987 Adult Participants with asymptomatic SARS-CoV-2 infection

Reporting group title	Phase 2 Symptomatic R10933+R10987 8.0g IV
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Reporting group description:

8.0g of R10933 + R10987 Adult Symptomatic Participants with COVID-19

Reporting group title	Phase 3 Age \geq 18 Placebo
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Reporting group description:

Placebo of R10933 + R10987 Participants \geq 18 with COVID-19, not pregnant at randomization

Reporting group title	Phase 3 Age \geq 18 R10933+R10987 1.2g IV
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Reporting group description:

1.2g of R10933 + R10987 Participants \geq 18 with COVID-19, not pregnant at randomization

Reporting group title	Phase 3 Age \geq 18 R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Participants \geq 18 with COVID-19, not pregnant at randomization

Reporting group title	Phase 3 Age \geq 18 R10933+R10987 8.0g IV
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Reporting group description:

8.0g of R10933 + R10987 Participants \geq 18 with COVID-19, not pregnant at randomization

Reporting group title	Phase 3 Age $<$ 18 Placebo
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Reporting group description:

Placebo of R10933 + R10987 Participants <18 with COVID-19, not pregnant at randomization

Reporting group title	Phase 3 Age<18 R10933+R10987 1.2g IV
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Reporting group description:

1.2g of R10933 + R10987 Participants <18 with COVID-19

Reporting group title	Phase 3 Age<18 R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Participants <18 with COVID-19

Reporting group title	Phase 3 Pregnant Placebo
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Reporting group description:

Placebo of R10933 + R10987 Participants who are pregnant with COVID-19

Reporting group title	Phase 3 Pregnant R10933+R10987 1.2g IV
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Reporting group description:

1.2g of R10933 + R10987 Participants who are pregnant with COVID-19

Reporting group title	Phase 3 Pregnant R10933+R10987 2.4g IV
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Reporting group description:

2.4g of R10933 + R10987 Participants who are pregnant with COVID-19

Serious adverse events	Phase 2 Symptomatic Placebo	Phase 1 Symptomatic R10933+R10987 8.0g IV	Phase 1 Symptomatic R10933+R10987 2.4g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 238 (2.52%)	0 / 23 (0.00%)	1 / 22 (4.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 238 (0.42%)	0 / 23 (0.00%)	0 / 22 (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
May-Thurner syndrome			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Hospitalisation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Death			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.84%)	0 / 23 (0.00%)	0 / 22 (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
Interstitial lung disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 congestion			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 mass			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinatal depression			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Continuous glucose monitoring			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 anastomotic stenosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia neonatal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve calcification			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Haemorrhagic stroke			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 thrombocytopenia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 retention			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhabdomyolysis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	1 / 238 (0.42%)	0 / 23 (0.00%)	0 / 22 (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	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.84%)	0 / 23 (0.00%)	0 / 22 (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
Pneumonia viral			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			

subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
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 Symptomatic Placebo	Phase 2 Symptomatic R10933+R10987 2.4g IV	Phase 2 Asymptomatic R10933+R10987 8.0g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	3 / 236 (1.27%)	0 / 75 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	1 / 236 (0.42%)	0 / 75 (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
May-Thurner syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Hospitalisation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Death			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 congestion			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinatal depression			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Continuous glucose monitoring			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 anastomotic stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	1 / 236 (0.42%)	0 / 75 (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
Arrhythmia neonatal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve calcification			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Haemorrhagic stroke			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 retention			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhabdomyolysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	2 / 236 (0.85%)	0 / 75 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			

subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 / 24 (0.00%)	1 / 236 (0.42%)	0 / 75 (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
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 236 (0.00%)	0 / 75 (0.00%)
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 Asymptomatic R10933+R10987 2.4g IV	Phase 2 Asymptomatic Placebo	Phase 2 Symptomatic R10933+R10987 8.0g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	2 / 237 (0.84%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
May-Thurner syndrome			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Hospitalisation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Death			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 congestion			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 mass			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinatal depression			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Continuous glucose monitoring			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 anastomotic stenosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia neonatal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve calcification			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Haemorrhagic stroke			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 thrombocytopenia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 retention			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhabdomyolysis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 viral			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	0 / 237 (0.00%)
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 Age≥18 Placebo	Phase 3 Age≥18 R10933+R10987 1.2g IV	Phase 3 Age≥18 R10933+R10987 2.4g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	103 / 2347 (4.39%)	39 / 2130 (1.83%)	52 / 3157 (1.65%)
number of deaths (all causes)	11	2	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Rectal neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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			
Deep vein thrombosis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Hypertension			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
May-Thurner syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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			
Hospitalisation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Fever neonatal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 healing			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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	2 / 2347 (0.09%)	0 / 2130 (0.00%)	0 / 3157 (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
Non-cardiac chest pain			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2130 (0.05%)	2 / 3157 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 failure			
subjects affected / exposed	5 / 2347 (0.21%)	0 / 2130 (0.00%)	2 / 3157 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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 / 2347 (0.04%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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			
subjects affected / exposed	10 / 2347 (0.43%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	6 / 2347 (0.26%)	1 / 2130 (0.05%)	2 / 3157 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 congestion			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2130 (0.09%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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	2 / 2347 (0.09%)	0 / 2130 (0.00%)	0 / 3157 (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
Respiratory failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Depression			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Mental status changes			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Perinatal depression			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Continuous glucose monitoring			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Ankle fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Cervical vertebral fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Facial bones fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Fractured sacrum			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 anastomotic stenosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Pelvic fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Spinal compression fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Tibia fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Upper limb fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angina pectoris			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia neonatal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Atrial fibrillation			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2130 (0.05%)	0 / 3157 (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
Cardiac failure acute			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery disease			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Mitral valve calcification			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Nervous system disorders			
Haemorrhagic stroke			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Immune thrombocytopenia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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 pain			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
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 wall haematoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Umbilical hernia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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			
Cholecystitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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 / 2347 (0.04%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 retention			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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

Rhabdomyolysis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Abscess neck			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Appendicitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Breast abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
COVID-19			
subjects affected / exposed	20 / 2347 (0.85%)	3 / 2130 (0.14%)	9 / 3157 (0.29%)
occurrences causally related to treatment / all	0 / 21	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	19 / 2347 (0.81%)	5 / 2130 (0.23%)	6 / 3157 (0.19%)
occurrences causally related to treatment / all	0 / 21	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Clostridium difficile colitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Gastroenteritis			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2130 (0.00%)	0 / 3157 (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
Kidney infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Lung abscess			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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	19 / 2347 (0.81%)	5 / 2130 (0.23%)	6 / 3157 (0.19%)
occurrences causally related to treatment / all	0 / 20	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	2 / 3157 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
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 / 2347 (0.09%)	0 / 2130 (0.00%)	2 / 3157 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2130 (0.05%)	0 / 3157 (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
Diabetes mellitus			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	0 / 3157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Gout			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2130 (0.05%)	0 / 3157 (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
Hyperglycaemia			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2130 (0.00%)	1 / 3157 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypokalaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2130 (0.00%)	0 / 3157 (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
Hyponatraemia			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2130 (0.00%)	0 / 3157 (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

Serious adverse events	Phase 3 Age \geq 18 R10933+R10987 8.0g IV	Phase 3 Age<18 Placebo	Phase 3 Age<18 R10933+R10987 1.2g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 1012 (1.88%)	0 / 2 (0.00%)	3 / 129 (2.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
May-Thurner syndrome			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Hospitalisation			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Death			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Atelectasis			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Cough			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Haemothorax			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Interstitial lung disease			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 congestion			

subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 mass			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	1 / 129 (0.78%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinatal depression			

subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	1 / 129 (0.78%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Continuous glucose monitoring			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 anastomotic stenosis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia neonatal			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve calcification			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Haemorrhagic stroke			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyporesponsive to stimuli			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Migraine			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 thrombocytopenia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 pain			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Pancreatitis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Peptic ulcer perforation			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Nephrolithiasis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 retention			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	1 / 129 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhabdomyolysis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
subjects affected / exposed	5 / 1012 (0.49%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	5 / 1012 (0.49%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Lung abscess			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	1 / 129 (0.78%)
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	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			

subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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
Sepsis			
subjects affected / exposed	1 / 1012 (0.10%)	0 / 2 (0.00%)	0 / 129 (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 bacteraemia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 1012 (0.00%)	0 / 2 (0.00%)	0 / 129 (0.00%)
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 Age<18 R10933+R10987 2.4g IV	Phase 3 Pregnant Placebo	Phase 3 Pregnant R10933+R10987 1.2g IV
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	11 / 43 (25.58%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
May-Thurner syndrome			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Hospitalisation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	3 / 43 (6.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Death			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever neonatal			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 congestion			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 mass			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinatal depression			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Continuous glucose monitoring			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 anastomotic stenosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Anal atresia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Craniosynostosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malformation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
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 disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia neonatal			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve calcification			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Haemorrhagic stroke			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 thrombocytopenia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 pain			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 wall haematoma			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ischaemic			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Hyperhidrosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 retention			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rhabdomyolysis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 viral			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			

subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 2 (0.00%)	0 / 43 (0.00%)
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 Pregnant R10933+R10987 2.4g IV		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 35 (20.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal neoplasm			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
May-Thurner syndrome			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ectopic pregnancy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal growth restriction			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Pre-eclampsia				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Premature baby				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Premature separation of placenta				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ruptured ectopic pregnancy				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Death				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fever neonatal				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atelectasis			

subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemothorax				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax spontaneous				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perinatal depression			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Continuous glucose monitoring			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Fall				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured sacrum				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal anastomotic stenosis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic fracture				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Anal atresia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Craniosynostosis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal malformation			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Macrocephaly			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia neonatal			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve calcification			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Haemorrhagic stroke			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyporesponsive to stimuli			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Colitis ischaemic				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer perforation				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia neonatal			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Rhabdomyolysis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast abscess			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			

subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung abscess				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus pneumonia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gout			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 2 Symptomatic Placebo	Phase 1 Symptomatic R10933+R10987 8.0g IV	Phase 1 Symptomatic R10933+R10987 2.4g IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 238 (0.84%)	0 / 23 (0.00%)	0 / 22 (0.00%)
Pregnancy, puerperium and perinatal conditions			
Gestational diabetes			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 238 (0.84%)	0 / 23 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Phase 1 Symptomatic Placebo	Phase 2 Symptomatic R10933+R10987 2.4g IV	Phase 2 Asymptomatic R10933+R10987 8.0g IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	1 / 236 (0.42%)	0 / 75 (0.00%)

Pregnancy, puerperium and perinatal conditions Gestational diabetes subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 236 (0.00%) 0	0 / 75 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 236 (0.00%) 0	0 / 75 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 236 (0.42%) 1	0 / 75 (0.00%) 0

Non-serious adverse events	Phase 2 Asymptomatic R10933+R10987 2.4g IV	Phase 2 Asymptomatic Placebo	Phase 2 Symptomatic R10933+R10987 8.0g IV
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	1 / 237 (0.42%)
Pregnancy, puerperium and perinatal conditions Gestational diabetes subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	0 / 237 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	0 / 237 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	1 / 237 (0.42%) 1

Non-serious adverse events	Phase 3 Age>=18 Placebo	Phase 3 Age>=18 R10933+R10987 1.2g IV	Phase 3 Age>=18 R10933+R10987 2.4g IV
Total subjects affected by non-serious adverse events subjects affected / exposed	16 / 2347 (0.68%)	16 / 2130 (0.75%)	19 / 3157 (0.60%)
Pregnancy, puerperium and perinatal conditions Gestational diabetes			

subjects affected / exposed occurrences (all)	0 / 2347 (0.00%) 0	0 / 2130 (0.00%) 0	0 / 3157 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 2347 (0.00%) 0	0 / 2130 (0.00%) 0	7 / 3157 (0.22%) 7
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	16 / 2347 (0.68%) 16	16 / 2130 (0.75%) 17	12 / 3157 (0.38%) 12

Non-serious adverse events	Phase 3 Age \geq 18 R10933+R10987 8.0g IV	Phase 3 Age<18 Placebo	Phase 3 Age<18 R10933+R10987 1.2g IV
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 1012 (0.40%)	1 / 2 (50.00%)	0 / 129 (0.00%)
Pregnancy, puerperium and perinatal conditions Gestational diabetes subjects affected / exposed occurrences (all)	0 / 1012 (0.00%) 0	0 / 2 (0.00%) 0	0 / 129 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 1012 (0.10%) 1	0 / 2 (0.00%) 0	0 / 129 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	3 / 1012 (0.30%) 3	1 / 2 (50.00%) 1	0 / 129 (0.00%) 0

Non-serious adverse events	Phase 3 Age<18 R10933+R10987 2.4g IV	Phase 3 Pregnant Placebo	Phase 3 Pregnant R10933+R10987 1.2g IV
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 71 (1.41%)	0 / 2 (0.00%)	5 / 43 (11.63%)
Pregnancy, puerperium and perinatal conditions Gestational diabetes subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 2 (0.00%) 0	1 / 43 (2.33%) 1
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 2 (0.00%) 0	3 / 43 (6.98%) 3
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	0 / 2 (0.00%) 0	1 / 43 (2.33%) 1

Non-serious adverse events	Phase 3 Pregnant R10933+R10987 2.4g IV		
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 35 (8.57%)		
Pregnancy, puerperium and perinatal conditions Gestational diabetes subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	1 / 35 (2.86%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 June 2020	Mandatory sequestering is only applicable to patients in the phase 1 sentinel safety group
19 June 2020	Grade 3 or 4 treatment-emergent AEs will be collected (phase 1 only)
04 July 2020	Virologic efficacy in phase 2 will be assessed using nasopharyngeal (NP) swab samples. Phase 3 secondary endpoints have also been updated for potential inclusion of NP swab samples
11 July 2020	Nasal swabs and saliva samples will no longer be collected in phase 2 and are no longer planned for phase 3
08 August 2020	Added new cohort of patients in phase 2 to evaluate asymptomatic patients with SARS-CoV-2 infection
20 November 2020	Adapt the phase 3 portion of the study and add major adaptations to the patient population, treatment arms, objectives/endpoints, and sample size.
18 December 2020	To modify the phase 3 portion of the study in response to health authority feedback
12 March 2021	Change in primary and key secondary endpoints

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
09 June 2022	Study terminated due to emerging SARS-CoV-2 variants impacting susceptibility to study drug	-

Notes:

Limitations and caveats

None reported