Clinical trial results:
A Phase 3, Multi-Center, Randomized, Double-Masked, Sham-Controlled Study to Compare the Efficacy and Safety of Intravitreal Pegcetacoplan Therapy with Sham Injections in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Summary

EudraCT number	2018-001435-52
Trial protocol	GB DE NL ES IT
Global end of trial date	28 June 2022

Results information

Result version number	v1 (current)
This version publication date	16 July 2023
First version publication date	16 July 2023

Trial information

Trial identification

Sponsor protocol code	APL2-304

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03525613
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Apellis Pharmaceuticals, Inc
Sponsor organisation address	100 5th Ave, Waltham, Massachusetts, United States, 02451
Public contact	Apellis Clinical Trial Information Line, Apellis Pharmaceuticals, Inc, +1 833-284-6361, clinicaltrials@apellis.com
Scientific contact	Apellis Clinical Trial Information Line, Apellis Pharmaceuticals, Inc, +1 833-284-6361, clinicaltrials@apellis.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of pegcetacoplan compared to sham injection in subjects with geographic atrophy (GA) secondary to age-related macular degeneration (AMD) assessed by change in the total area of GA lesions in the study eye from baseline as measured by fundus autofluorescence (FAF) images.

Protection of trial subjects:

This research was carried out in accordance with the protocol, applicable regulations, the ethical principles set forth in the Declaration of Helsinki, and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Harmonised Guideline for Good Clinical Practice E6 Revision 2. An external, independent data monitoring committee assessed the safety and tolerability data of the study periodically.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 August 2018
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	Australia: 34
Country: Number of subjects enrolled	Brazil: 1
Country: Number of subjects enrolled	Czechia: 21
Country: Number of subjects enrolled	France: 44
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Israel: 6
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Netherlands: 4
Country: Number of subjects enrolled	New Zealand: 4
Country: Number of subjects enrolled	Poland: 20
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	United States: 453
Worldwide total number of subjects	637
EEA total number of subjects	128

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	24
From 65 to 84 years	466
85 years and over	147

Subject disposition

Recruitment

Recruitment details:

This Phase III, randomized, double-masked, sham injection-controlled study was conducted in subjects with GA secondary to AMD at 110 investigational sites. A total of 637 subjects were enrolled in this study.

Pre-assignment

Screening details:

This study consisted of a screening period (up to 30 days), a randomization visit on Day 1, and a treatment period (up to 24 months). Subjects were randomized in a 2:2:1:1 ratio on Day 1 to receive treatment with pegcetacoplan monthly, pegcetacoplan every other month (EOM), sham injection monthly or sham injection EOM, respectively.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Pegcetacoplan Monthly

Arm description:

Subjects received intravitreal (IVT) injections of pegcetacoplan 15 milligram (mg)/0.1 milliliter (mL) once monthly for 24 months.

Arm type	Experimental
Investigational medicinal product name	Pegcetacoplan
Investigational medicinal product code	APL-2
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Subjects received IVT injections of pegcetacoplan 15 mg/0.1 mL once monthly by only qualified study staff. Administration of pegcetacoplan was only allowed if preinjection intraocular pressure (IOP) was <=21 millimeter of mercury (mm Hg).

Arm title	Pegcetacoplan EOM

Arm description:

Subjects received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.

Arm type	Experimental
Investigational medicinal product name	Pegcetacoplan
Investigational medicinal product code	APL-2
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Subjects received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM by only qualified study staff. Administration of pegcetacoplan was only allowed if preinjection IOP was <=21 mm Hg.

Arm title	Sham Monthly

Arm description:

Subjects received sham injections once monthly for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Sham EOM

Arm description:

Subjects received sham injections EOM for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Monthly
Started	213	212	106
Completed	144	169	76
Not completed	69	43	30
Consent withdrawn by subject	25	16	12
Physician decision	-	1	-
Adverse event, non-fatal	11	8	3
Death	20	9	7
Due to Coronavirus Disease-2019 (COVID-19) impact	9	4	5
Lost to follow-up	4	5	3

Number of subjects in period 1	Sham EOM
Started	106
Completed	82
Not completed	24
Consent withdrawn by subject	9
Physician decision	1
Adverse event, non-fatal	3
Death	1
Due to Coronavirus Disease-2019 (COVID-19) impact	8
Lost to follow-up	2

Baseline characteristics

Reporting groups	
Reporting group title	Pegcetacoplan Monthly
Reporting group description:	
Subjects received intravitreal (IVT) injections of pegcetacoplan 15 milligram (mg)/0.1 milliliter (mL) once monthly for 24 months.	
Reporting group title	Pegcetacoplan EOM
Reporting group description:	
Subjects received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.	
Reporting group title	Sham Monthly
Reporting group description:	
Subjects received sham injections once monthly for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	
Reporting group title	Sham EOM
Reporting group description:	
Subjects received sham injections EOM for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	

Reporting group values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Monthly
Number of subjects	213	212	106
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	79.0	78.1	78.4
standard deviation	± 7.21	± 7.81	± 7.32
Gender categorical Units: Subjects			
Female	134	122	65
Male	79	90	41
Race Units: Subjects			
White	193	196	98
Not Reported	14	12	5
Unknown	1	3	3
Asian	3	1	0
Black or African American	2	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	5	7	4
Not Hispanic or Latino	191	193	95
Not Reported	17	12	7
Region of Enrollment Units: Subjects			
United States	152	148	75
France	15	14	5
Australia	10	14	6

Germany	7	8	6
Czechia	9	7	3
Poland	6	5	5
United Kingdom	2	5	3
Italy	3	3	2
Israel	3	2	1
Netherlands	3	1	0
New Zealand	1	2	0
Spain	1	3	0
Brazil	1	0	0
GA Lesion Size FAF in the Study Eye Units: millimeter square (mm^2)			
arithmetic mean	8.2150	8.3452	7.8560
standard deviation	± 3.91483	± 3.95679	± 3.62392

Reporting group values	Sham EOM	Total	
Number of subjects	106	637	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	78.8		
standard deviation	± 7.10	-	
Gender categorical Units: Subjects			
Female	71	392	
Male	35	245	
Race Units: Subjects			
White	95	582	
Not Reported	9	40	
Unknown	0	7	
Asian	2	6	
Black or African American	0	2	
Ethnicity Units: Subjects			
Hispanic or Latino	0	16	
Not Hispanic or Latino	97	576	
Not Reported	9	45	
Region of Enrollment Units: Subjects			
United States	78	453	
France	10	44	
Australia	4	34	
Germany	5	26	
Czechia	2	21	
Poland	4	20	
United Kingdom	1	11	
Italy	1	9	
Israel	0	6	

Netherlands	0	4	
New Zealand	1	4	
Spain	0	4	
Brazil	0	1	
GA Lesion Size FAF in the Study Eye			
Units: millimeter square (mm^2)			
arithmetic mean	8.4602		
standard deviation	± 3.76226	-	

Subject analysis sets

Subject analysis set title	Sham Pooled
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Sham Monthly: Subjects received sham injections once monthly for 24 months.

Sham EOM: Subjects received sham injections EOM for 24 months.

The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Subject analysis set title	Sham Pooled
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Sham Monthly: Subjects received sham injections once monthly for 24 months.

Sham EOM: Subjects received sham injections EOM for 24 months.

The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Reporting group values	Sham Pooled	Sham Pooled	
Number of subjects	207	212	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean		78.6	
standard deviation	±	± 7.20	
Gender categorical			
Units: Subjects			
Female		136	
Male		76	
Race			
Units: Subjects			
White		193	
Not Reported		14	
Unknown		3	
Asian		2	
Black or African American		0	
Ethnicity			
Units: Subjects			
Hispanic or Latino		4	
Not Hispanic or Latino		192	

Not Reported		16	
Region of Enrollment Units: Subjects			
United States		153	
France		15	
Australia		10	
Germany		11	
Czechia		5	
Poland		9	
United Kingdom		4	
Italy		3	
Israel		1	
Netherlands		0	
New Zealand		1	
Spain		0	
Brazil		0	
GA Lesion Size FAF in the Study Eye Units: millimeter square (mm^2)			
arithmetic mean		8.1581	
standard deviation	±	± 3.69739	

End points

End points reporting groups

Reporting group title	Pegcetacoplan Monthly
Reporting group description:	
Subjects received intravitreal (IVT) injections of pegcetacoplan 15 milligram (mg)/0.1 milliliter (mL) once monthly for 24 months.	

Reporting group title	Pegcetacoplan EOM
Reporting group description:	
Subjects received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.	

Reporting group title	Sham Monthly
Reporting group description:	
Subjects received sham injections once monthly for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	

Reporting group title	Sham EOM
Reporting group description:	
Subjects received sham injections EOM for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	

Subject analysis set title	Sham Pooled
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Sham Monthly: Subjects received sham injections once monthly for 24 months. Sham EOM: Subjects received sham injections EOM for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	

Subject analysis set title	Sham Pooled
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Sham Monthly: Subjects received sham injections once monthly for 24 months. Sham EOM: Subjects received sham injections EOM for 24 months. The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.	

Primary: Least Squares (LS) Mean Change From Baseline in Total Area of GA Lesions in the Study Eye at Month 12

End point title	Least Squares (LS) Mean Change From Baseline in Total Area of GA Lesions in the Study Eye at Month 12[1]
End point description:	
The GA lesion area was measured by a quantified central reading center based on FAF images. FAF is a noninvasive retinal imaging modality used in clinical practice to provide a density map of lipofuscin. LS mean was calculated using a mixed effect model for repeated measure (MMRM) model. Baseline was defined as the last available, non-missing observation prior to first study drug administration. The modified intent-to-treat (mITT) analysis set included all subjects assigned to treatment who received at least 1 injection of pegcetacoplan or sham and had baseline and at least 1 post-baseline value of GA lesion area in the study eye as assessed by FAF. Subjects with a baseline and at least 1 post-baseline value of the outcome at a scheduled visit by Month 12 were included in the analysis.	

End point type	Primary
End point timeframe:	
Baseline (screening) and Month 12	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	202	204	205	
Units: mm^2				
least squares mean (standard error)	1.5579 (± 0.08350)	1.6512 (± 0.08118)	1.9692 (± 0.08218)	

Statistical analyses

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Model included treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) + analysis visit + presence of choroidal neovascularization (CNV) in the fellow eye (yes or no) + analysis visit × treatment + baseline GA lesion area × analysis visit.

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	407
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	MMRM model
Parameter estimate	LS Mean Difference
Point estimate	-0.4114
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6397
upper limit	-0.1831

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Model included treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) + analysis visit + presence of CNV in the fellow eye (yes or no) + analysis visit × treatment + baseline GA lesion area × analysis visit.

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0055
Method	MMRM model
Parameter estimate	LS Mean Difference
Point estimate	-0.318
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5423
upper limit	-0.0937

Secondary: LS Mean Change From Baseline in Total Area of GA Lesions in the Study Eye at Month 24

End point title	LS Mean Change From Baseline in Total Area of GA Lesions in the Study Eye at Month 24[2]

End point description:

The GA lesion area was measured by a quantified central reading center based on FAF images. LS mean was calculated using a mixed effect model for repeated measure model. Baseline was defined as the last available, non-missing observation prior to first study drug administration. The mITT analysis set included all subjects assigned to treatment who received at least 1 injection of pegcetacoplan or sham and had baseline and at least 1 post-baseline value of GA lesion area in the study eye as assessed by FAF. Subjects with a baseline and at least 1 post-baseline value of the outcome at a scheduled visit by Month 24 were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline (screening) and Month 24

Notes:

[2] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	202	204	206	
Units: mm^2				
least squares mean (standard error)	3.1237 (± 0.14327)	3.2826 (± 0.13238)	4.0252 (± 0.14642)	

Statistical analyses

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Model included treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) + analysis visit + baseline presence of CNV in the fellow eye (yes or no) + analysis visit × treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) × analysis visit.

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	408
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	MMRM model
Parameter estimate	LS Mean Difference
Point estimate	-0.9015
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3026
upper limit	-0.5004

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Model included treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) + analysis visit + baseline presence of CNV in the fellow eye (yes or no) + analysis visit × treatment + baseline GA lesion area (<7.5 mm^2 or ≥7.5 mm^2) × analysis visit.

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	410
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	MMRM model
Parameter estimate	LS Mean Difference
Point estimate	-0.7426
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1282
upper limit	-0.357

Secondary: Mean Change in Total Area of GA Lesions in the Study Eye Through Month 24

End point title	Mean Change in Total Area of GA Lesions in the Study Eye Through Month 24[3]

End point description:

The mean change in GA lesion area through Month 24 was measured by assuming a piecewise linear trend in time with knots by FAF images at Months 6, 12, 18, and 24 and was calculated using a MMRM model. Baseline was defined as the last available, non-missing observation prior to first study drug administration. The mITT analysis set included all subjects assigned to treatment who received at least 1 injection of pegcetacoplan or sham and had baseline and at least 1 post-baseline value of GA lesion area in the study eye as assessed by FAF.

End point type	Secondary

End point timeframe:

From Baseline (screening) through Month 24

Notes:

[3] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	202	205	207	
Units: mm^2				
arithmetic mean (standard error)				
From Baseline to Month 6	0.7604 (± 0.04629)	0.8220 (± 0.04346)	0.9838 (± 0.04666)	
From Month 6 to Month 12	0.7848 (± 0.05958)	0.8184 (± 0.05660)	0.9710 (± 0.05163)	

From Month 12 to Month 18	0.8004 (± 0.05034)	0.8682 (± 0.04959)	1.0269 (± 0.05288)	
From Month 18 to Month 24	0.7617 (± 0.6650)	0.7499 (± 0.04372)	0.9958 (± 0.05824)	
From Baseline to Month 24	3.1073 (± 0.14841)	3.2586 (± 0.13420)	3.9775 (± 0.14310)	

Statistical analyses

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Baseline to Month 6: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.0007
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.2234
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3522
upper limit	-0.0946

Notes:

[4] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Baseline to Month 6: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.0116
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.1618

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2874
upper limit	-0.0361

Notes:

[5] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 6 to Month 12: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.0181
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.1862
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3406
upper limit	-0.0318

Notes:

[6] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 6 to Month 12: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.0467
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.1526

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.303
upper limit	-0.0023

Notes:

[7] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 12 to Month 18: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.0019
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.2265
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3696
upper limit	-0.0834

Notes:

[8] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 12 to Month 18: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.0288
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.1586

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3009
upper limit	-0.0164

Notes:

[9] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 18 to Month 24: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.008
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.2341
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4071
upper limit	-0.0611

Notes:

[10] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Month 18 to Month 24: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.0007
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.2459

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3886
upper limit	-0.1031

Notes:

[11] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Baseline to Month 24: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan Monthly v Sham Pooled
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	< 0.0001
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.8702
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.274
upper limit	-0.4664

Notes:

[12] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Statistical analysis title	Treatment difference in total area of GA lesions

Statistical analysis description:

Estimates for Baseline to Month 24: Model included Treatment + Baseline GA lesion area (< 7.5 mm^2 or >= 7.5 mm^2) + Time (continuous) + Time Spline at Month 6 (continuous) + Time Spline at Month 12 (continuous) + Time Spline at Month 18 (continuous) + Presence of CNV in the fellow eye (Yes or No) + Time (continuous) x Treatment + Time Spline at Month 6 (continuous) x Treatment + Time Spline at Month 12 (continuous) x Treatment + Time Spline at Month 18 (continuous) x Treatment +

Comparison groups	Pegcetacoplan EOM v Sham Pooled
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	= 0.0003
Method	MMRM model
Parameter estimate	Mean Difference
Point estimate	-0.7189

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1039
upper limit	-0.3339

Notes:

[13] - Baseline GA lesion area x Time (continuous) + Baseline GA lesion area x Time Spline at Month 6 (continuous) + Baseline GA lesion area x Time Spline at Month 12 (continuous) + Baseline GA lesion area x Time Spline at Month 18 (continuous). A heterogeneous autoregressive covariance matrix was used to model within-subject errors.

Secondary: LS Mean Change From Baseline in Mean Threshold Sensitivity of All Points of the Study Eye at Month 24

End point title	LS Mean Change From Baseline in Mean Threshold Sensitivity of All Points of the Study Eye at Month 24[14]

End point description:

Mean threshold sensitivity of all points was determined from the mesopic microperimetry as an assessment of macular functional response. Microperimetry offers option to test retinal light sensitivity while directly observing fundus and allows for monitoring of macular function loss associated with GA progression. The microperimetry reading center overlaid the baseline FAF images with GA lesions traced by the imaging reading center and the corresponding macular integrity assessment microperimetry baseline scanning laser ophthalmoscope image and identified perilesional (within 500 microns outside the atrophy border), paralesional (beyond 500 microns outside the atrophy border), and extralesional (outside the atrophy border) loci on the microperimetry grid to determine the mean threshold sensitivity for these 3 areas. LS mean was calculated using a MMRM model. Baseline was defined as last available, non-missing observation prior to first study drug administration. The mITT analysis set.

End point type	Secondary

End point timeframe:

Baseline (screening) and Month 24

Notes:

[14] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	179	187	186	
Units: decibels (dB)				
least squares mean (standard error)	-3.319 (± 0.2969)	-3.064 (± 0.2331)	-2.954 (± 0.2156)	

Statistical analyses

No statistical analyses for this end point

Secondary: LS Mean Change From Baseline in Monocular Maximum Reading Speed of the Study Eye at Month 24

End point title	LS Mean Change From Baseline in Monocular Maximum Reading Speed of the Study Eye at Month 24[15]

End point description:

The maximum reading speed of the study eye was calculated per Minnesota Low-Vision Reading Test (MNREAD) or Radner Reading Charts user manuals, with no adjustment for reading inaccuracy. An additional step to cap resulting reading speed values at a maximum of 300 words per minute (wpm) was implemented. Maximum reading speed was calculated as the mean of the 3 highest non-zero reading

speeds (or 2, or 1 value, as available), except when all wpm were calculated as 0 then the maximum reading speed was calculated as 0. LS mean was calculated using a MMRM model. Baseline was defined as the last available, non-missing observation prior to first study drug administration. The mITT analysis set. Subjects with a baseline and at least 1 post-baseline value of the outcome at a scheduled visit by Month 24 were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline (screening) and Month 24

Notes:

[15] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	168	181	181	
Units: wpm				
least squares mean (standard error)	-22.446 (± 3.0329)	-17.533 (± 3.2886)	-16.211 (± 3.8129)	

Statistical analyses

No statistical analyses for this end point

Secondary: LS Mean Change From Baseline in Mean Functional Reading Independence (FRI) Index Score at Month 24

End point title	LS Mean Change From Baseline in Mean Functional Reading Independence (FRI) Index Score at Month 24[16]

End point description:

The FRI was an interviewer-administered questionnaire with 7 items on functional reading activities most relevant to GA AMD subjects. It had 1 total index score. For each FRI Index reading activity performed in the past 7 days, subjects were asked about the extent to which they required assistance beyond eyeglasses/contact lenses, including the use of low-vision aids, adjustments in the activity, or help from another subject. Mean FRI Index scores ranged from 1 (unable to do independently) to 4 (totally independent), with higher scores indicating higher functional reading independence. A negative change from baseline indicated a decrease in the FRI; disease worsening. LS mean was calculated using a MMRM model. Baseline was defined as the last available, non-missing observation prior to first study drug administration. The mITT analysis set. Subjects with a baseline and at least 1 post-baseline value of the outcome at a scheduled visit by Month 24 were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline (screening) and Month 24

Notes:

[16] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	185	193	195	
Units: score on a scale				
least squares mean (standard error)	-0.287 (± 0.0563)	-0.379 (± 0.0536)	-0.273 (± 0.0554)	

Statistical analyses

No statistical analyses for this end point

Secondary: LS Mean Change From Baseline in Normal-Luminance Best-Corrected Visual Acuity (NL-BCVA) Score of the Study Eye at Month 24

End point title	LS Mean Change From Baseline in Normal-Luminance Best-Corrected Visual Acuity (NL-BCVA) Score of the Study Eye at Month 24[17]

End point description:

The NL-BCVA was assessed by early treatment diabetic retinopathy study (ETDRS) chart prior to dilating the eyes at a starting distance of 4 meters and ranged from 0 (least score) to 100 (best score). If the 4-meter score was >19 letters read correctly, the visual acuity score was the sum of total letters correctly read at 4 meters plus the addition of 30. If the 4-meter score was ≤19 letters read correctly, the visual acuity score was the sum of total letters read correctly at 4 meters and total letters read correctly at the 1-meter distance. If no letters were read correctly at either the 4-meter distance or the 1-meter distance, the visual acuity score was 0. A positive change in the value indicated improvement in visual acuity. LS mean was calculated using a MMRM model. The mITT analysis set. Subjects with a baseline and at least 1 post-baseline value of the outcome at a scheduled visit by Month 24 were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline (screening) and Month 24

Notes:

[17] - 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: Subjects who received sham injections were pooled in this endpoint analysis.

End point values	Pegcetacoplan Monthly	Pegcetacoplan EOM	Sham Pooled	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	202	205	207	
Units: ETDRS letters score				
least squares mean (standard error)	-7.477 (± 1.0512)	-8.526 (± 1.0525)	-7.660 (± 1.0734)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) were reported from first dose (Day 1) up to 30 and 60 days after the last dose for the monthly and EOM treatment groups, respectively. A maximum of 24 months.

Adverse event reporting additional description:

The safety analysis set included all subjects randomly assigned to treatment who received at least 1 injection of pegcetacoplan or sham. Ocular TEAEs are presented separately for the study and fellow eyes, and non-ocular (systemic) TEAEs are also presented.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Pegcetacoplan Monthly: Ocular Study Eye

Reporting group description:

Ocular TEAEs were summarized for the study eye for all subjects who received IVT injections of pegcetacoplan 15 mg/0.1 mL once monthly for 24 months.

Reporting group title	Pegcetacoplan EOM: Ocular Study Eye

Reporting group description:

Ocular TEAEs were summarized for the study eye for all subjects who received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.

Reporting group title	Sham Pooled: Ocular Study Eye

Reporting group description:

Ocular TEAEs were summarized for the study eye for all subjects who were randomized to sham monthly and sham EOM treatment groups.

Sham Monthly: Subjects received sham injections once monthly for 24 months.

Sham EOM: Subjects received sham injections EOM for 24 months.

The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Reporting group title	Pegcetacoplan Monthly: Ocular Fellow Eye

Reporting group description:

Ocular TEAEs were summarized for the fellow eye for all subjects who received IVT injections of pegcetacoplan 15 mg/0.1 mL once monthly for 24 months.

Reporting group title	Pegcetacoplan EOM: Ocular Fellow Eye

Reporting group description:

Ocular TEAEs were summarized for the fellow eye for all subjects who received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.

Reporting group title	Sham Pooled: Ocular Fellow Eye

Reporting group description:

Ocular TEAEs were summarized for the fellow eye for all subjects who were randomized to sham monthly and sham EOM treatment groups.

Sham Monthly: Subjects received sham injections once monthly for 24 months.

Sham EOM: Subjects received sham injections EOM for 24 months.

The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Reporting group title	Pegcetacoplan Monthly: Non-ocular

Reporting group description:

Non-ocular (systemic) TEAEs were summarized for all subjects who received IVT injections of

pegcetacoplan 15 mg/0.1 mL once monthly for 24 months.

Reporting group title	Pegcetacoplan EOM: Non-ocular

Reporting group description:

Non-ocular (systemic) TEAEs were summarized for all subjects who received IVT injections of pegcetacoplan 15 mg/0.1 mL EOM for 24 months.

Reporting group title	Sham Pooled: Non-ocular

Reporting group description:

Non-ocular (systemic) TEAEs were summarized for all subjects who were randomized to sham monthly and sham EOM treatment groups.

Sham Monthly: Subjects received sham injections once monthly for 24 months.

Sham EOM: Subjects received sham injections EOM for 24 months.

The procedure for sham injection was the same as that used for IVT injection until the actual injection but no actual injection occurred.

Serious adverse events	Pegcetacoplan Monthly: Ocular Study Eye	Pegcetacoplan EOM: Ocular Study Eye	Sham Pooled: Ocular Study Eye
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 213 (2.35%)	4 / 212 (1.89%)	1 / 211 (0.47%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 myeloid leukaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrosarcoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 adenocarcinoma			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 adenocarcinoma stage III			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to thorax			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Aortic aneurysm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease complication			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspiration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 consolidation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Panic attack			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Haemoglobin decreased			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Anaemia postoperative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyphaema			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Jaw fracture			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 injuries			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 postoperative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 incompetence			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem stroke			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	0 / 211 (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
Papilloedema			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Retinal detachment			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Visual acuity reduced			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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 hernia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 ulcerative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 ulcer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 oral			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Cholangitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cirrhosis alcoholic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Eczema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary symptom			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Acute sinusitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blastocystis infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 infection			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	2 / 213 (0.94%)	3 / 212 (1.42%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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	Pegcetacoplan Monthly: Ocular Fellow Eye	Pegcetacoplan EOM: Ocular Fellow Eye	Sham Pooled: Ocular Fellow Eye
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	2 / 211 (0.95%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 myeloid leukaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrosarcoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 adenocarcinoma stage III			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to thorax			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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-small cell lung cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral cancer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Aortic aneurysm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease complication			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 consolidation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery thrombosis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Panic attack			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Haemoglobin decreased			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Anaemia postoperative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyphaema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 injuries			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 postoperative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 incompetence			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem stroke			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Visual acuity reduced			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 hernia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 ulcerative			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 ulcer			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 oral			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Cholangitis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cirrhosis alcoholic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Eczema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary symptom			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Acute sinusitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blastocystis infection			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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			
Decreased appetite			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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	Pegcetacoplan Monthly: Non-ocular	Pegcetacoplan EOM: Non-ocular	Sham Pooled: Non-ocular

Total subjects affected by serious adverse events			
subjects affected / exposed	77 / 213 (36.15%)	56 / 212 (26.42%)	55 / 211 (26.07%)
number of deaths (all causes)	20	9	8
number of deaths resulting from adverse events	3	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	0 / 211 (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
Adenocarcinoma of colon			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Basal cell carcinoma			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Benign lung neoplasm			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Brain cancer metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain neoplasm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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 myeloid leukaemia			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colon cancer			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Fibrosarcoma			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Lymphoma			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Malignant melanoma			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Metastases to thorax			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Ovarian cancer			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Prostate cancer			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Skin cancer			

subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	0 / 211 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral cancer			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Hypertensive urgency			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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			
Asthenia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	2 / 213 (0.94%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Disease complication			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
General physical health deterioration			
subjects affected / exposed	0 / 213 (0.00%)	2 / 212 (0.94%)	0 / 211 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Sudden death			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Prostatomegaly			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Vaginal prolapse			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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 failure			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aspiration			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 213 (0.94%)	1 / 212 (0.47%)	0 / 211 (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
Hypoxia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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 consolidation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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 aspiration			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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 artery thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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	2 / 213 (0.94%)	2 / 212 (0.94%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tachypnoea			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Psychiatric disorders			
Panic attack			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Investigations			
Haemoglobin decreased			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Injury, poisoning and procedural complications			
Anaemia postoperative			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Ankle fracture			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Cervical vertebral fracture			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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

Face injury			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 213 (0.00%)	2 / 212 (0.94%)	0 / 211 (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
Hip fracture			
subjects affected / exposed	0 / 213 (0.00%)	2 / 212 (0.94%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyphaema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Joint dislocation			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Lower limb fracture			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Meniscus injury			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Multiple injuries			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Muscle strain			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Post procedural haematuria			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Postoperative thrombosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Procedural pain			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Rib fracture			

subjects affected / exposed	1 / 213 (0.47%)	3 / 212 (1.42%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	2 / 213 (0.94%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Subcutaneous haematoma			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 213 (0.94%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 213 (0.00%)	2 / 212 (0.94%)	0 / 211 (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
Angina pectoris			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Arrhythmia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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	7 / 213 (3.29%)	1 / 212 (0.47%)	6 / 211 (2.84%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure acute			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			

subjects affected / exposed	3 / 213 (1.41%)	3 / 212 (1.42%)	3 / 211 (1.42%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Coronary artery disease			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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 stenosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Mitral valve incompetence			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Myocardial infarction			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Right ventricular failure			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Supraventricular extrasystoles			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Supraventricular tachycardia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Aphasia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Brain stem stroke			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Cerebellar stroke			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	3 / 213 (1.41%)	1 / 212 (0.47%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Intracranial haematoma			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Loss of consciousness			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Metabolic encephalopathy			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 213 (0.47%)	2 / 212 (0.94%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 2	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	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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 loss anaemia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Splenic infarction			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Ear and labyrinth disorders			

Vertigo positional			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual acuity reduced			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
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 hernia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Abdominal pain			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Ascites			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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

Colitis			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (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
Diverticular perforation			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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 ulcer			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia oral			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Large intestine polyp			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Oesophagitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Cholecystitis			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Cholelithiasis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Cirrhosis alcoholic			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Stasis dermatitis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary symptom			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Haematuria			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Hydronephrosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Osteoarthritis			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Rheumatoid arthritis			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Spinal stenosis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Arthritis infective			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Blastocystis infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Bronchitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	7 / 213 (3.29%)	3 / 212 (1.42%)	4 / 211 (1.90%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 1
COVID-19 pneumonia			
subjects affected / exposed	2 / 213 (0.94%)	1 / 212 (0.47%)	4 / 211 (1.90%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Diverticulitis			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Endophthalmitis			

subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Localised infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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	12 / 213 (5.63%)	3 / 212 (1.42%)	3 / 211 (1.42%)
occurrences causally related to treatment / all	0 / 12	0 / 3	0 / 4
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 1
Pneumonia bacterial			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Postoperative wound infection			

subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	0 / 211 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 213 (0.94%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 213 (0.00%)	3 / 212 (1.42%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 213 (0.47%)	0 / 212 (0.00%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
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			
Decreased appetite			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	1 / 211 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	2 / 211 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 213 (0.00%)	1 / 212 (0.47%)	0 / 211 (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
Malnutrition			
subjects affected / exposed	1 / 213 (0.47%)	1 / 212 (0.47%)	0 / 211 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

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

Non-serious adverse events	Pegcetacoplan Monthly: Ocular Study Eye	Pegcetacoplan EOM: Ocular Study Eye	Sham Pooled: Ocular Study Eye
Total subjects affected by non-serious adverse events			
subjects affected / exposed	100 / 213 (46.95%)	95 / 212 (44.81%)	59 / 211 (27.96%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	4 / 213 (1.88%)	11 / 212 (5.19%)	5 / 211 (2.37%)
occurrences (all)	4	11	6
Cataract			
subjects affected / exposed	8 / 213 (3.76%)	4 / 212 (1.89%)	11 / 211 (5.21%)
occurrences (all)	8	5	11
Conjunctival haemorrhage			
subjects affected / exposed	22 / 213 (10.33%)	19 / 212 (8.96%)	10 / 211 (4.74%)
occurrences (all)	39	25	10
Dry eye			
subjects affected / exposed	14 / 213 (6.57%)	14 / 212 (6.60%)	7 / 211 (3.32%)
occurrences (all)	15	15	7
Eye pain			
subjects affected / exposed	17 / 213 (7.98%)	16 / 212 (7.55%)	14 / 211 (6.64%)
occurrences (all)	19	18	18
Low luminance best-corrected visual acuity decreased			
subjects affected / exposed	7 / 213 (3.29%)	5 / 212 (2.36%)	10 / 211 (4.74%)
occurrences (all)	7	5	11
Neovascular age-related macular degeneration			

subjects affected / exposed	20 / 213 (9.39%)	14 / 212 (6.60%)	3 / 211 (1.42%)
occurrences (all)	21	15	3
Punctate keratitis			
subjects affected / exposed	16 / 213 (7.51%)	6 / 212 (2.83%)	0 / 211 (0.00%)
occurrences (all)	16	6	0
Retinal haemorrhage			
subjects affected / exposed	9 / 213 (4.23%)	6 / 212 (2.83%)	4 / 211 (1.90%)
occurrences (all)	10	7	5
Visual acuity reduced			
subjects affected / exposed	17 / 213 (7.98%)	20 / 212 (9.43%)	17 / 211 (8.06%)
occurrences (all)	21	21	28
Vitreous detachment			
subjects affected / exposed	7 / 213 (3.29%)	11 / 212 (5.19%)	8 / 211 (3.79%)
occurrences (all)	7	12	8
Vitreous floaters			
subjects affected / exposed	17 / 213 (7.98%)	19 / 212 (8.96%)	2 / 211 (0.95%)
occurrences (all)	20	25	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pegcetacoplan Monthly: Ocular Fellow Eye	Pegcetacoplan EOM: Ocular Fellow Eye	Sham Pooled: Ocular Fellow Eye
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 213 (32.39%)	56 / 212 (26.42%)	65 / 211 (30.81%)

Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	3 / 213 (1.41%)	9 / 212 (4.25%)	4 / 211 (1.90%)
occurrences (all)	3	10	5
Cataract			
subjects affected / exposed	7 / 213 (3.29%)	6 / 212 (2.83%)	12 / 211 (5.69%)
occurrences (all)	7	6	12
Conjunctival haemorrhage			
subjects affected / exposed	2 / 213 (0.94%)	3 / 212 (1.42%)	3 / 211 (1.42%)
occurrences (all)	2	3	4
Dry eye			
subjects affected / exposed	13 / 213 (6.10%)	13 / 212 (6.13%)	5 / 211 (2.37%)
occurrences (all)	13	14	6
Eye pain			
subjects affected / exposed	4 / 213 (1.88%)	1 / 212 (0.47%)	2 / 211 (0.95%)
occurrences (all)	4	1	2
Low luminance best-corrected visual acuity decreased			
subjects affected / exposed	10 / 213 (4.69%)	6 / 212 (2.83%)	11 / 211 (5.21%)
occurrences (all)	14	7	13
Neovascular age-related macular degeneration			
subjects affected / exposed	9 / 213 (4.23%)	5 / 212 (2.36%)	11 / 211 (5.21%)
occurrences (all)	9	5	12
Punctate keratitis			

subjects affected / exposed	9 / 213 (4.23%)	4 / 212 (1.89%)	1 / 211 (0.47%)
occurrences (all)	9	4	1
Retinal haemorrhage			
subjects affected / exposed	10 / 213 (4.69%)	5 / 212 (2.36%)	11 / 211 (5.21%)
occurrences (all)	15	5	13
Visual acuity reduced			
subjects affected / exposed	13 / 213 (6.10%)	11 / 212 (5.19%)	19 / 211 (9.00%)
occurrences (all)	15	13	25
Vitreous detachment			
subjects affected / exposed	4 / 213 (1.88%)	3 / 212 (1.42%)	5 / 211 (2.37%)
occurrences (all)	4	3	5
Vitreous floaters			
subjects affected / exposed	2 / 213 (0.94%)	5 / 212 (2.36%)	3 / 211 (1.42%)
occurrences (all)	3	5	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pegcetacoplan Monthly: Non-ocular	Pegcetacoplan EOM: Non-ocular	Sham Pooled: Non-ocular
Total subjects affected by non-serious adverse events			
subjects affected / exposed	86 / 213 (40.38%)	72 / 212 (33.96%)	67 / 211 (31.75%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	16 / 213 (7.51%)	16 / 212 (7.55%)	9 / 211 (4.27%)
occurrences (all)	17	18	10

Vascular disorders			
Hypertension			
subjects affected / exposed	20 / 213 (9.39%)	16 / 212 (7.55%)	17 / 211 (8.06%)
occurrences (all)	20	16	17
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 213 (5.63%)	4 / 212 (1.89%)	9 / 211 (4.27%)
occurrences (all)	15	4	9
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Low luminance best-corrected visual acuity decreased			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0

Visual acuity reduced			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 213 (0.00%)	0 / 212 (0.00%)	0 / 211 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	15 / 213 (7.04%)	12 / 212 (5.66%)	7 / 211 (3.32%)
occurrences (all)	21	15	7
Infections and infestations			
COVID-19			
subjects affected / exposed	15 / 213 (7.04%)	11 / 212 (5.19%)	10 / 211 (4.74%)
occurrences (all)	16	11	10
Nasopharyngitis			
subjects affected / exposed	10 / 213 (4.69%)	5 / 212 (2.36%)	12 / 211 (5.69%)
occurrences (all)	11	5	14
Urinary tract infection			
subjects affected / exposed	23 / 213 (10.80%)	20 / 212 (9.43%)	22 / 211 (10.43%)
occurrences (all)	26	22	31

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 May 2018	Study objectives were expanded to describe the endpoints. Added that exploratory objectives utilizing digital applications would be conducted in select sites/countries only as these applications would be utilized according to local regulation. Clarified that to participate in the study, subjects must be diagnosed with GA of the macula secondary to AMD in the study eye. Added that if both eyes had the same visual acuity score, the right eye would be selected as the study eye. The inclusion criterion for microperimetry was incorporated to the main list of inclusion criteria as all subjects in this study would now be participating in this portion. “Endothelial cell count” was removed as an assessment that was provided to the reading center for objective assessment of subject eligibility. The optical coherence tomography angiography (OCT-A) (selected sites only) was added as an assessment that was provided to the reading center for objective assessment of subject eligibility. The OCT-A was added as a monitoring assessment for select sites to confirm the diagnosis of new active choroidal neovascularization (CNV). Protocol updated to specify that microperimetry should be conducted on both eyes. Amended to clarify that the study staff performing visual acuity should be masked to the treatment assignment only; the protocol had previously stated that staff should also be blinded to the study eye.
08 August 2018	Exclusion criteria were modified for clarity and to exclude subjects with history of IVT injection in either eye. The following exclusion criterion was added "Prior participation in another interventional clinical study for GA in either eye including investigational oral medication and placebo". Noted that the National Eye Institute 25-Item Visual Function Questionnaire distance activity and near activity subscale score endpoints would be conducted in select countries as these subscales were not available in all languages. Masking language was modified to indicate that the Principal Investigator was required to remain masked to subjects’ treatment assignments, while the treating physician and any associated support staff involved in study drug administration would be unmasked. Guidance on the treatment of new exudation related to active CNV in the study eye and/or fellow eye was modified to clarify that the reading center would provide a report to indicate whether or not there was evidence of active, exudative AMD, and the investigator would then determine if anti-vascular endothelial growth factor (VEGF) treatment should be initiated. Clarified that either ranibizumab or aflibercept should be selected as the anti-VEGF therapy, and that the unmasked physician should administer anti-VEGF treatment if the treatment was administered on the same day as pegcetacoplan. Any treatments of therapies administered to the fellow eye within 5 years of screening should be recorded as a concomitant medication. Clarified that: In the event that a subject was suspected to have new active CNV in the study eye and/or the fellow eye, an spectral domain optical coherence tomography and fluorescein angiography using the protocol specified procedures should be performed and sent to the reading center to confirm the diagnosis.
14 February 2019	The Pharmacokinetic and complement profile assessments were removed from this study. Updated to include the following statement: In recent studies conducted with APL-2 IVT from a single manufacturer, events of transient moderate and severe intraocular inflammation have been observed. The treatment administration section was revised to allow study treatment administration to occur on a day separate from the assessment visit. The procedure for sham injection was further described. Through the study procedures section it had also been noted that endothelial cell count assessment was for “select sites only.” This had been previously noted in the schedule of events but not consistently in the body of the protocol. In addition, FAF and near-infrared reflectance were no longer “study eye only”. The following assessments were removed as they would no longer be conducted at the screening visit: Low-luminance BCVA; Endothelial cell count; and OCT-A. The following assessments were added at Day 1: Endothelial cell count; and OCT-A (select sites).

27 April 2020	An appendix was added to include information related to COVID-19–related changes to the study. Rescreening procedure: If a subject was deemed a screen failure for not being able to meet the original screening window (Day −28 to Day −1 [±2 days]) due to COVID-19 related restrictions, a rescreening visit was allowed. Extended study drug administration windows. Temporary changes to masking rules: Every masked individual who performed study drug administration and/or postinjection assessment (all unmasked assessment) as a temporary measure, was permanently considered an unmasked individual and was not able to perform masked assessments once these exemptions were lifted. Minimum schedules of assessments: Minimum assessment tables were temporarily implemented to reduce the time required for each study visit and eliminate non-study drug administration visits.
12 August 2020	Added the descriptor "maximum" when referencing reading speed. Removed the 6-month follow-up period and updated the study length from 30 months to 24 months and made it a 30- or 60-day follow-up period based on treatment group because that length of time is deemed sufficient to evaluate the safety of pegcetacoplan based on its half-life in the vitreous. Additionally, there was an option for subjects to enroll in a separate extension study (APL2-GA-305 study) during which longer-term safety and efficacy will be collected. Inclusion criterion was updated from "Reliability test ratio must be <=20%" to "Fixation losses must be <=20%" on the basis of regulatory feedback provided to the microperimetry device manufacturer.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
24 September 2018	This study was temporarily paused in September 2018 after 1 subject had an serious AE of severe acute endophthalmitis in the study eye. A thorough investigation concluded that this event was caused by an impurity in the polyethylene glycol diol starting material that had been introduced during the manufacturing process. The manufacturing process was modified to eliminate the impurity and additional process controls implemented to ensure its level remained below the limit of quantitation. Pegcetacoplan was then introduced in a small safety study (APL2-103 study) to evaluate the safety of new lots of drug product in subjects with low vision. APL2-304 study was restarted in March 2019 after no events of intraocular inflammation were observed once the drug product without the impurity was tested in APL2-103 study.	04 March 2019

Notes:

Limitations and caveats

None reported