



Clinical trial results:
Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial - EXTended Criteria Donors (BENEFIT-EXT)
Summary

EudraCT number	2004-002974-48
Trial protocol	GB HU AT BE SE DE CZ IT ES PT
Global end of trial date	30 September 2014

Results information

Result version number	v1 (current)
This version publication date	28 December 2016
First version publication date	28 December 2016

Trial information

Trial identification

Sponsor protocol code	IM103-027
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00114777
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb International Corporation
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb International Corporation, clinical.trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb International Corporation, clinical.trials@bms.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	30 September 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the effects of belatacept, relative to cyclosporin A, on the following:

1. Subject and graft survival by 12 months
2. Measured glomerular filtration (GFR) rate <60 mL/min/1.73 m² at Month 12 or a decrease in measured GFR ≥ 10 mL/min/1.73 m² from Month 3 to Month 12.

Assess the long term safety and tolerability of belatacept in subjects who have received a kidney transplant, completed the Short Term (36 months of treatment in the main study) and remain on study therapy for up to an additional 48 months.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy:

All subjects received induction with basiliximab and a background maintenance immunosuppressive regimen of mycophenolate mofetil and corticosteroids.

Evidence for comparator: -

Actual start date of recruitment	10 March 2005
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	48 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czech Republic: 12
Country: Number of subjects enrolled	France: 106
Country: Number of subjects enrolled	Germany: 49
Country: Number of subjects enrolled	Hungary: 5
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Norway: 9
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	South Africa: 1
Country: Number of subjects enrolled	Spain: 55
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	United Kingdom: 3

Country: Number of subjects enrolled	United States: 139
Country: Number of subjects enrolled	Argentina: 64
Country: Number of subjects enrolled	Austria: 10
Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Brazil: 95
Country: Number of subjects enrolled	Canada: 13
Country: Number of subjects enrolled	Chile: 1
Worldwide total number of subjects	595
EEA total number of subjects	280

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)	416
From 65 to 84 years	179
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled at 79 sites; 28 in the United States, 9 in France, 6 in Brazil, 5 each in Germany, Argentina, and Spain, 4 in Canada, 3 in Italy, 2 each in Hungary, Austria, and Poland, 1 each in Belgium, Chile, Czech Republic, Norway, South Africa, Sweden, UK, and Australia.

Pre-assignment

Screening details:

A total of 595 subjects were enrolled; 578 were randomized: 13 subjects no longer met study criteria; 3 discontinued on sponsor's discretion; and 1 discontinued due to "other" reason.

Period 1

Period 1 title	Randomization to Month 36
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Blinding implementation details:

During the first 36 months, study drugs (belatacept or cyclosporine A) were administered in an open-label fashion. The assigned dose regimen (MI or LI) of the belatacept-treated subjects was blinded both to the subjects and study personnel up to Month 36.

Arms

Are arms mutually exclusive?	Yes
Arm title	Belatacept MI (Period 1)

Arm description:

Subjects in more intensive (MI) regimen received belatacept 10 mg/kg intravenous solution on Days 1 and 5 during the first week, and then every other week through 3 months (Weeks 2, 4, 8, and 12) and then every 4 weeks through 6 months (Weeks 16, 20 and 24), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Arm type	Experimental
Investigational medicinal product name	Belatacept
Investigational medicinal product code	BMS-224818
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Belatacept 10-mg/kg intravenous solution over 30 minutes on Days 1 and 5 during the first week, and then every other week through 3 months (Weeks 2, 4, 8, and 12) and then every 4 weeks through 6 months (Weeks 16, 20 and 24), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for 36 months.

Arm title	Belatacept LI (Period 1)
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Arm description:

Subjects in less intensive (LI) regimen received belatacept, 10 mg/kg intravenously on Day 1 and Day 5 during the first week, and then every other week for 4 weeks (Weeks 2 and 4), and then every 4 weeks for 2 months (Weeks 8 and 12), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Arm type	Experimental
Investigational medicinal product name	Belatacept
Investigational medicinal product code	BMS-224818
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Belatacept 10-mg/kg intravenous solution for over 30 minutes on n Day 1 and Day 5 during the first week, and then every other week for [4] weeks (Weeks 2 and 4), and then every 4 weeks for 2 months (Weeks 8 and 12), followed by a maintenance dose of belatacept, 5 mg/kg i.v. every 4 weeks thereafter for 36 months.

Arm title	Cyclosporin A (Period 1)
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Arm description:

Subjects received an initial daily dose of 4 -10 mg/kg cyclosporin A capsules orally, in 2 divided doses, adjusted thereafter to maintain serum concentrations of 150-300 ng/mL during the first month. Subsequently, doses were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 36 months.

Arm type	Experimental
Investigational medicinal product name	Cyclosporin A
Investigational medicinal product code	
Other name	Neoral®
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Cyclosporine was initially administered at a daily dose of 4-10 mg/kg, orally as capsules. The dose was then adjusted to maintain trough whole blood concentrations of 150-300 ng/mL during the first month. Subsequently, doses were adjusted to maintain a predefined range of trough whole blood concentrations of 100-250 ng/mL for up to 36 months.

Number of subjects in period 1^[1]	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)
Started	184	175	184
Received treatment	183	174	179
Completed	109	114	100
Not completed	75	61	84
Consent withdrawn by subject	3	4	5
Adverse event, non-fatal	34	35	44
Poor/non-Compliance	-	-	1
Death	10	4	3
Subject no longer meet study criteria	-	-	2
Other reasons	9	3	12
Lack of efficacy	19	15	17

Notes:

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

Justification: The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial as of the 595 subjects enrolled only 578 subjects randomized and 543 were transplanted into the study. The 17 subjects which were not randomized for the following reasons: 13 no longer met study criteria, 3 discontinued on sponsor's discretion, and 1 discontinued for "other", a non-specified reason.

Period 2

Period 2 title	Long-Term Extension to Month 84
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

The long-term extension was conducted as a fully open-label clinical study.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Belatacept MI (Period 2)
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Arm description:

Subjects in more intensive (MI) regimen during long term extension continued to receive belatacept at a maintenance dose of 5 mg/kg intravenously every 4 weeks for up to 84 months.

Arm type	Experimental
Investigational medicinal product name	Belatacept
Investigational medicinal product code	BMS-224818
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Belatacept 5 mg/kg intravenous solution over 30 minutes every 4 weeks for up to 84 months.

Arm title	Belatacept LI (Period 2)
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Arm description:

Subjects in less intensive (LI) regimen during long term extension continued to receive belatacept at a maintenance dose of 5 mg/kg intravenously every 4 weeks for up to 84 months.

Arm type	Experimental
Investigational medicinal product name	Belatacept
Investigational medicinal product code	BMS-224818
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Belatacept 5 mg/kg intravenous solution over 30 minutes every 4 weeks for up to 84 months.

Arm title	Cyclosporin A (Period 2)
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Arm description:

Subjects during the long-term extension continued to receive doses that were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 84 months.

Arm type	Experimental
Investigational medicinal product name	Cyclosporin A
Investigational medicinal product code	
Other name	Neoral®
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Cyclosporine A doses were adjusted to maintain a predefined range of trough whole blood concentrations of 100-250 ng/mL for up to 84 months.

Number of subjects in period 2^[2]	Belatacept MI (Period 2)	Belatacept LI (Period 2)	Cyclosporin A (Period 2)
Started	104	113	87
Completed	74	84	57
Not completed	30	29	30
Consent withdrawn by subject	2	1	6
Adverse event, non-fatal	15	14	7
Poor/non-Compliance	1	1	3
Death	8	13	7
Subject no longer met study criteria	1	-	-
Other reasons	2	-	3
Lost to follow-up	-	-	2
Subject no longer meets study criteria	-	-	1
Lack of efficacy	1	-	1

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants chose to enter long-term extension phase.

Baseline characteristics

Reporting groups

Reporting group title	Belatacept MI (Period 1)
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Reporting group description:

Subjects in more intensive (MI) regimen received belatacept 10 mg/kg intravenous solution on Days 1 and 5 during the first week, and then every other week through 3 months (Weeks 2, 4, 8, and 12) and then every 4 weeks through 6 months (Weeks 16, 20 and 24), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Reporting group title	Belatacept LI (Period 1)
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Reporting group description:

Subjects in less intensive (LI) regimen received belatacept, 10 mg/kg intravenously on Day 1 and Day 5 during the first week, and then every other week for 4 weeks (Weeks 2 and 4), and then every 4 weeks for 2 months (Weeks 8 and 12), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Reporting group title	Cyclosporin A (Period 1)
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Reporting group description:

Subjects received an initial daily dose of 4 -10 mg/kg cyclosporin A capsules orally, in 2 divided doses, adjusted thereafter to maintain serum concentrations of 150-300 ng/mL during the first month. Subsequently, doses were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 36 months.

Reporting group values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)
Number of subjects	184	175	184
Age categorical Units: Subjects			
18 years to 45 years	32	35	34
46 years to 65 years	100	97	108
more than 65 years	52	43	42
Age continuous Units: years			
arithmetic mean	56.7	56.1	55.7
standard deviation	± 12.6	± 12.4	± 12.2
Gender categorical Units: Subjects			
Female	65	46	68
Male	119	129	116

Reporting group values	Total		
Number of subjects	543		
Age categorical Units: Subjects			
18 years to 45 years	101		
46 years to 65 years	305		
more than 65 years	137		
Age continuous Units: years			
arithmetic mean	-		
standard deviation	-		

Gender categorical			
Units: Subjects			
Female	179		
Male	364		

End points

End points reporting groups

Reporting group title	Belatacept MI (Period 1)
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Reporting group description:

Subjects in more intensive (MI) regimen received belatacept 10 mg/kg intravenous solution on Days 1 and 5 during the first week, and then every other week through 3 months (Weeks 2, 4, 8, and 12) and then every 4 weeks through 6 months (Weeks 16, 20 and 24), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Reporting group title	Belatacept LI (Period 1)
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Reporting group description:

Subjects in less intensive (LI) regimen received belatacept, 10 mg/kg intravenously on Day 1 and Day 5 during the first week, and then every other week for 4 weeks (Weeks 2 and 4), and then every 4 weeks for 2 months (Weeks 8 and 12), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 36 months.

Reporting group title	Cyclosporin A (Period 1)
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Reporting group description:

Subjects received an initial daily dose of 4 -10 mg/kg cyclosporin A capsules orally, in 2 divided doses, adjusted thereafter to maintain serum concentrations of 150-300 ng/mL during the first month. Subsequently, doses were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 36 months.

Reporting group title	Belatacept MI (Period 2)
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Reporting group description:

Subjects in more intensive (MI) regimen during long term extension continued to receive belatacept at a maintenance dose of 5 mg/kg intravenously every 4 weeks for up to 84 months.

Reporting group title	Belatacept LI (Period 2)
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Reporting group description:

Subjects in less intensive (LI) regimen during long term extension continued to receive belatacept at a maintenance dose of 5 mg/kg intravenously every 4 weeks for up to 84 months.

Reporting group title	Cyclosporin A (Period 2)
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Reporting group description:

Subjects during the long-term extension continued to receive doses that were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 84 months.

Subject analysis set title	Belatacept MI (Periods 1&2)
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Intent-to-treat (ITT) Population

Subject analysis set title	Belatacept LI (Periods 1&2)
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

intent-to-treat (ITT) population

Subject analysis set title	Cyclosporin A (Periods 1&2)
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Intent-to-Treat (ITT) population

Primary: Percentage of Subjects Who Survived With a Graft at 12 Months Post-Transplant

End point title	Percentage of Subjects Who Survived With a Graft at 12 Months Post-Transplant
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End point description:

Subject and graft survival at 12 months was summarized within each treatment group. Graft loss was defined as either functional loss or physical loss (nephrectomy). Functional loss will be defined as a sustained level of serum creatinine ≥ 6.0 mg/dL (530 μ mol/L) as determined by central laboratory for \geq

4 weeks or 56 or more consecutive days of dialysis. The analysis was performed in the Intent-to-Treat population which includes all the subjects who are randomized into the study and received a transplant. Patients whose death or graft loss status was missing at Month 12 were imputed to have experienced death or graft loss if one or more of the criteria pre-specified in the statistical analysis plan for the study were met.

End point type	Primary
End point timeframe:	Month 12 post-transplant

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of Subjects				
number (confidence interval 95%)	85.9 (80.8 to 90.9)	88 (83.2 to 92.8)	84.8 (79.6 to 90)	

Statistical analyses

Statistical analysis title	Subject and Graft Survival of Belatacept MI
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Statistical analysis description:

The treatment differences between each belatacept MI treatment group and cyclosporine group was tested at the 0.027 significance level for subject and graft survival (based on 10% non-inferiority margin).

Comparison groups	Belatacept MI (Period 1) v Cyclosporin A (Period 1)
Number of subjects included in analysis	368
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Treatment Difference
Point estimate	1.1
Confidence interval	
level	Other: 97.3 %
sides	2-sided
lower limit	-7.2
upper limit	9.4

Statistical analysis title	Subject and Graft Survival of Belatacept LI
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Statistical analysis description:

The treatment differences between each belatacept LI treatment group and cyclosporine group was tested at the 0.027 significance level for subject and graft survival (based on 10% non-inferiority margin).

Comparison groups	Cyclosporin A (Period 1) v Belatacept LI (Period 1)
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Number of subjects included in analysis	359
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Treatment Difference
Point estimate	3.2
Confidence interval	
level	Other: 97.3 %
sides	2-sided
lower limit	-5
upper limit	11.4

Primary: Percentage of Subjects with a Measured Glomerular Filtration Rate (GFR) <60 mL/min per 1.73 m² at Month 12 or a Decrease in Measured GFR ≥10 mL/min per 1.73 m² from Month 3 to Month 12

End point title	Percentage of Subjects with a Measured Glomerular Filtration Rate (GFR) <60 mL/min per 1.73 m ² at Month 12 or a Decrease in Measured GFR ≥10 mL/min per 1.73 m ² from Month 3 to Month 12
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End point description:

GFR was assessed using a true measure of glomerular filtration via non-radiolabeled iothalamate clearance test using a validated procedure. The analysis was performed in the Intent-to-Treat population. Missing measured GFR assessments were imputed as having a GFR of zero.

End point type	Primary
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End point timeframe:

From Month 3 to Month 12

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of subjects				
number (not applicable)				
Measured GFR <60 mL/min/1.73 m ² at month 12	55.7	62.1	67.4	
GFR of ≥ 10 mL/min/1.73 m ² from months 3-12	17.6	27.2	24.7	

Statistical analyses

Statistical analysis title	Measured GFR of Belatacept MI
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Statistical analysis description:

A continuity-corrected chi-square test (at the significance level 0.027) was performed to assess the effect of each belatacept regimen on renal function compared with CsA. 2-sided 97.3% CIs were generated for the difference in the percentage of subjects meeting the composite renal function endpoint between belatacept MI regimen and cyclosporine.

Comparison groups	Belatacept MI (Period 1) v Cyclosporin A (Period 1)
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Number of subjects included in analysis	368
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0018
Method	Chi-squared
Parameter estimate	Percentage Difference
Point estimate	-14.4
Confidence interval	
level	Other: 97.3 %
sides	2-sided
lower limit	-24
upper limit	-4.7

Statistical analysis title	Measured GFR of Belatacept LI
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Statistical analysis description:

A continuity-corrected chi-square test (at the significance level 0.027) was performed to assess the effect of each belatacept regimen on renal function compared with CsA. 2-sided 97.3% CIs were generated for the difference in the Percentage of subjects meeting the composite renal function endpoint between belatacept LI regimen and cyclosporine.

Comparison groups	Cyclosporin A (Period 1) v Belatacept LI (Period 1)
Number of subjects included in analysis	359
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0616
Method	Chi-squared
Parameter estimate	Percentage Difference
Point estimate	-8.5
Confidence interval	
level	Other: 97.3 %
sides	2-sided
lower limit	-18
upper limit	0.9

Secondary: Measured Glomerular Filtration Rate (GFR) by Month 12 and 24

End point title	Measured Glomerular Filtration Rate (GFR) by Month 12 and 24
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End point description:

GFR was assessed using a true measure of glomerular filtration via a non-radiolabeled iothalamate clearance test using a validated procedure. The analysis was performed in the Intent-to-Treat population. Missing measured GFR assessments were imputed to a GFR of zero. Here, 'n' signifies the number of evaluable subjects for the reporting arm at the given time point.

End point type	Secondary
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End point timeframe:

Month 12, and 24

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: mL/min/1.73 m ²				
arithmetic mean (standard deviation)				
Month 12	52.1 (± 21.9)	49.5 (± 25.4)	45.2 (± 21.1)	
Month 24	51.5 (± 22.9)	49.7 (± 23.67)	45 (± 27.18)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Chronic Allograft Nephropathy (CAN) at Month 12

End point title	Percentage of Subjects with Chronic Allograft Nephropathy (CAN) at Month 12
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End point description:

Biopsy-proven CAN was determined by a blinded central histopathologist using the Banff 97 working classification of kidney transplant pathology. Onset of CAN was determined by the biopsy date when it was observed. Subjects were considered as having CAN at 12 months if: CAN observed in a biopsy either prior to 12 months (including baseline biopsy) or first post 12 months biopsy; Subject had graft loss during the first year post transplant; no biopsy available post 12 months and CAN not observed in biopsies prior to 12 months; no biopsy available either prior to or post 12 months; and the measured glomerular filtration rate from Month 3 to Month 12 decreases at least 10 mL/min/1.73m². All other subjects with missing 12 month biopsy were considered having no CAN observed at 12 months. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 12

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of Subjects				
number (confidence interval 95%)	44.8 (37.6 to 52)	46 (38.6 to 53.4)	51.6 (44.4 to 58.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Survived With a Graft at 24 and 36 Months Post-Transplant

End point title	Percentage of Subjects Who Survived With a Graft at 24 and 36 Months Post-Transplant
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End point description:

Subject and graft survival at 24 and 36 months was summarized within each treatment group. Graft loss was defined as either functional loss or physical loss (nephrectomy). Functional loss was defined as a sustained level of serum creatinine \geq 6.0 mg/dL (530 μ mol/L) as determined by central laboratory for \geq 4 weeks or 56 or more consecutive days of dialysis. The analysis was performed in the Intent-to-Treat population which includes all the subjects who were randomized into the study and received a transplant.

End point type	Secondary
End point timeframe:	Month 24 and 36 post-transplant

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 24	82.6 (77.1 to 88.1)	84 (78.6 to 89.4)	82.6 (77.1 to 88.1)	
Month 36	80.4 (74.7 to 86.2)	82.3 (76.6 to 87.9)	79.9 (74.1 to 85.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated Glomerular Filtration Rate (GFR) at 6, 12, 24, 36 and 84 Months

End point title	Calculated Glomerular Filtration Rate (GFR) at 6, 12, 24, 36 and 84 Months
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End point description:

GFR was assessed using a true measure of glomerular filtration via non-radiolabeled iothalamate clearance test using a validated procedure. The analysis was performed in the Intent-to-Treat population. Missing measured GFR assessments were imputed as a GFR of zero. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
End point timeframe:	Month 6, 12, 24, 36 and 84

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: mL/min/1.73 m ²				
arithmetic mean (standard deviation)				
Month 6 (n = 161,152,153)	43.6 (\pm 21.67)	43.4 (\pm 18.57)	35.5 (\pm 20.51)	
Month 12 (n = 159,154,154)	44.4 (\pm 22.78)	44.8 (\pm 21.57)	36.5 (\pm 21.08)	

Month 24 (n = 152,158,154)	44.4 (± 26.72)	42.8 (± 24.07)	34.9 (± 21.59)	
Month 36 (n = 152,154,143)	42.7 (± 27.59)	42.2 (± 25.2)	31.5 (± 22.13)	
Month 84 (n = 69,79,51)	57.6 (± 18.58)	59.1 (± 18.85)	44.6 (± 17.37)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Calculated GFR from Month 3 to 12, 24, 36 and 84

End point title	Change in Calculated GFR from Month 3 to 12, 24, 36 and 84
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End point description:

GFR was assessed using a true measure of glomerular filtration via non-radiolabeled iothalamate clearance test using a validated procedure. The analysis was performed in the Intent-to-Treat population. Missing measured GFR assessments were imputed to a GFR of zero. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36 and 84

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: mL/min/1.73 m ²				
arithmetic mean (standard deviation)				
Month 12 (n = 159,154,154)	-0.7 (± 17.96)	-0.6 (± 15.39)	-1.1 (± 12.48)	
Month 24 (n = 146,154,149)	-1.4 (± 17.68)	-1.6 (± 18.7)	-3.6 (± 15.37)	
Month 36 (n = 146,150,139)	-2.9 (± 23.7)	-2.1 (± 20.92)	-6.1 (± 17.39)	
Month 84 (n = 67,76,49)	7.5 (± 17.48)	10.4 (± 17.54)	-4 (± 17.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Anti-Hypertensive Medications Used to Control Hypertension at 12, 24 and 36 Months

End point title	Number of Subjects with Anti-Hypertensive Medications Used to Control Hypertension at 12, 24 and 36 Months
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End point description:

Subjects were determined to have hypertension at a particular time point if standardized SBP ≥ 130 mm Hg or standardized DBP ≥ 80 mm Hg or subject had received an antihypertensive medication(s) for hypertension. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Number of subjects				
1-2 Medications (Month 12) (n=184,175,184)	82	79	76	
≥ 3 Medications (Month 12) (n=184,175,184)	76	66	93	
1-2 Medications (Month 24) (n=177,170,179)	80	79	71	
≥ 3 Medications (Month 24) (n=177,170,179)	78	65	89	
1-2 Medications (Month 36) (n=151,145,143)	65	67	51	
≥ 3 Medications (Month 36) (n=151,145,143)	70	60	79	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Used Anti-Hypertensive Medications to Control Hypertension at Month 12, 24 and 36

End point title	Percentage of Subjects Who Used Anti-Hypertensive Medications to Control Hypertension at Month 12, 24 and 36
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End point description:

Subjects were determined to have hypertension at a particular time point if standardized SBP \geq 130 mm Hg or standardized DBP \geq 80 mm Hg or subject had received an antihypertensive medication(s) for hypertension. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of subject number (confidence interval 95%)				
Month 12 (n = 184,175,184)	87 (82.09 to 91.82)	83.4 (77.92 to 88.94)	87 (82.09 to 91.82)	
Month 24 (n = 177,170,179)	89.3 (84.71 to 93.83)	84.7 (79.3 to 90.12)	89.4 (84.87 to 93.9)	
Month 36 (n = 151,145,143)	89.4 (84.49 to 94.31)	87.6 (82.22 to 92.25)	90.9 (86.2 to 95.62)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with New Onset Diabetes Mellitus (NODM) at 12, 24 and 36 Months

End point title	Percentage of Subjects with New Onset Diabetes Mellitus (NODM) at 12, 24 and 36 Months
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End point description:

NODM was defined as subject who did not have diabetes prior to randomization. Subjects were determined for NODM if the subject received an antidiabetic medication for a duration of at least 30 days, or at least two fasting plasma glucose (FPG) tests indicate that FPG is ≥ 126 mg/dL (7.0 mmol/L). The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of subjects				
number (not applicable)				
12 Month	2.3	5.1	9.3	
24 Month	3	7.4	9.3	
36 Month	5.3	9.6	9.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Systolic and Diastolic Blood Pressure at 12, 24 and 36 Months

End point title	Systolic and Diastolic Blood Pressure at 12, 24 and 36 Months
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End point description:

Subjects were determined to have hypertension at a particular time point if standardized SBP ≥ 130 mm Hg or standardized DBP ≥ 80 mm Hg or subject had received an antihypertensive medication(s) for hypertension. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: mmHg				
arithmetic mean (standard deviation)				
Diastolic BP (Month 12) (n=184,175,184)	77.8 (± 13.83)	78.3 (± 10.62)	81.8 (± 11.68)	
Systolic BP (Month 12) (n=184,175,184)	141.4 (± 21.29)	140.9 (± 21.09)	149.5 (± 19.81)	
Diastolic BP (Month 24) (n=120,129,120)	78.2 (± 13.28)	77 (± 11.18)	81.7 (± 11.47)	
Systolic BP (Month 24) (n=120,129,120)	138.8 (± 24.31)	136.7 (± 20.96)	146.8 (± 21.11)	
Diastolic BP (Month 36) (n=112,119,108)	75.4 (± 11.55)	75.2 (± 10.85)	77.2 (± 11.79)	
Systolic BP (Month 36) (n=112,119,108)	134.9 (± 19.54)	134.7 (± 21.59)	140.7 (± 21.19)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Framingham Risk Score from Baseline to Month 12, 24 and 36

End point title	Mean Framingham Risk Score from Baseline to Month 12, 24 and 36
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End point description:

The risk score utilized data from the Framingham Heart Study to estimate 10-year risk for 'hard' coronary heart disease (myocardial infarction and coronary death). The risk factors included were age, gender, total cholesterol, HDL cholesterol, SBP, diabetes, treatment for hypertension, and any cigarette use in the prior month. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Score on a scale				
arithmetic mean (standard deviation)				
Month 12	5.3 (± 4.11)	4.5 (± 4.02)	6 (± 3.98)	
Month 24	5 (± 4.25)	4.6 (± 4.23)	6.2 (± 4.07)	
Month 36	5.2 (± 4.18)	4.9 (± 3.84)	5.8 (± 4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Using Lipid-Lowering Therapy at 12, 24, and 36 Months

End point title	Percentage of Subjects Using Lipid-Lowering Therapy at 12, 24, and 36 Months
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End point description:

Dyslipidemia was defined as triglyceride \geq 500 mg/dL [5.65 mmol/L], low-density lipoprotein (LDL) \geq 100 mg/dL [2.59 mmol/L], and elevated non-high density lipoprotein (HDL) \geq 130 mg/dL [3.36 mmol/L]. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 12 (n = 184,175,184)	43.5 (36.3 to 50.6)	40 (32.7 to 47.3)	46.2 (39 to 53.2)	
Month 24 (n = 184,175,184)	47.8 (40.6 to 55)	42.3 (35 to 49.6)	51.1 (43.9 to 58.3)	
Month 36 (n = 151,145,143)	52.3 (44.4 to 60.3)	45.5 (37.4 to 53.6)	60.8 (52.8 to 68.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Total Cholesterol, Non-HDL, LDL and HDL Cholesterol and Triglyceride at 12, 24 and 36 Months

End point title	Change in Total Cholesterol, Non-HDL, LDL and HDL Cholesterol and Triglyceride at 12, 24 and 36 Months
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End point description:

Dyslipidemia was defined as triglyceride \geq 500 mg/dL [5.65 mmol/L], low-density lipoprotein (LDL) \geq 100 mg/dL [2.59 mmol/L], and elevated non-high density lipoprotein (HDL) \geq 130 mg/dL [3.36 mmol/L]. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: mg/dL				
arithmetic mean (standard deviation)				
Non-HDL (Month 12) (n = 184,175,184)	134.5 (± 45.04)	134.2 (± 40.69)	153.4 (± 46.69)	
Total Cholesterol (Month 12) (n = 184,175,184)	183.7 (± 47.72)	184.1 (± 45.51)	201.3 (± 49.49)	
Triglyceride (Month 12) (n = 184,175,184)	171.9 (± 129.76)	153.2 (± 69.92)	213.8 (± 113.12)	
HDL (Month 12) (n = 184,175,184)	49.2 (± 13.73)	49.8 (± 15.85)	47.9 (± 14.76)	
LDL (Month 12) (n = 184,175,184)	104 (± 39.33)	102.4 (± 36.63)	107.8 (± 40.08)	
Non-HDL (Month 24) (n = 119,128,111)	126.1 (± 45.45)	129.8 (± 37.89)	148.7 (± 60.46)	
Total Cholesterol (Month 24) (n = 119,128,111)	175.6 (± 47.99)	178 (± 41.9)	195.7 (± 61.46)	
Triglyceride (Month 24) (n = 98,104,93)	152 (± 108.97)	147 (± 69.45)	208.2 (± 135.19)	
HDL (Month 24) (n = 119,128,111)	49.5 (± 16.27)	48.2 (± 14.41)	47 (± 17.77)	
LDL (Month 24) (n = 97,104,93)	96.9 (± 33.46)	101.4 (± 36.64)	108.6 (± 40.8)	
Non-HDL (Month 36) (n = 111,117,97)	132.6 (± 41.86)	132.2 (± 46.81)	139.1 (± 49.68)	
Total Cholesterol (Month 36) (n = 111,117,98)	181 (± 43.84)	181.9 (± 49.16)	196.7 (± 127.35)	
Triglyceride (Month 36) (n = 80,88,78)	160.7 (± 98.56)	154.3 (± 76.58)	181.3 (± 108.32)	
HDL (Month 36) (n = 111,117,97)	48.9 (± 14.82)	49.6 (± 16.24)	47 (± 14.28)	
LDL (Month 36) (n = 79,88,77)	103.1 (± 32.59)	106 (± 37.29)	102.3 (± 47.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Have an Acute Rejection by Month 6, 12, 24, 36 and 84

End point title	Percentage of Subjects Who Have an Acute Rejection by Month 6, 12, 24, 36 and 84
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End point description:

Acute rejection was defined as central biopsy proven rejection that was either clinically suspected by protocol defined reasons or clinically suspected by other reasons and treated. Clinically suspected acute rejection was defined as an unexplained rise of serum creatinine \geq 25% from baseline creatinine or an unexplained decreased urine output or fever and graft tenderness or serum creatinine that remains elevated within 14 days post-transplantation and clinical suspicion of acute rejection exists. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 6, 12, 24, 36 and 84

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6	17.4 (11.9 to 22.9)	16.6 (11.1 to 22.1)	13.6 (8.6 to 18.5)	
Month 12	17.4 (11.9 to 22.9)	17.7 (12.1 to 23.4)	14.1 (9.1 to 19.2)	
Month 24	17.4 (11.9 to 22.9)	18.3 (12.6 to 24)	15.2 (10 to 20.4)	
Month 36	17.9 (12.4 to 23.5)	18.9 (13.1 to 24.7)	15.8 (10.5 to 21.1)	
Month 84	19 (13.4 to 24.7)	19.4 (13.6 to 25.3)	15.8 (10.5 to 21.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Using Lymphocyte Depleting Therapy and Steroid-Resistant for Acute Rejection by Month 6, 12, 24, and 36

End point title	Number of Subjects Using Lymphocyte Depleting Therapy and Steroid-Resistant for Acute Rejection by Month 6, 12, 24, and 36
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End point description:

Acute rejection was defined as central biopsy proven rejection that was either clinically suspected by protocol defined reasons or clinically suspected by other reasons and treated. Lymphocyte-depletion therapy for treatment of an episode of acute was defined as subject treated with therapy and provided not treated with steroids earlier while steroid resistant acute rejection was defined as subjects initially treated with steroids alone for suspected acute rejection for at least 2 days and then followed by the start of lymphocyte-depletion therapy. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 6, 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Number of subjects				
number (not applicable)				
Only corticosteroid treated (Month 6)	14	16	9	
Corticosteroid resistant (Month 6)	2	2	2	

Lymphocyte-depleting treated (Month 6)	13	5	4	
Only corticosteroid treated (Month 12)	14	16	10	
Corticosteroid resistant (Month 12)	2	2	2	
Lymphocyte-depleting treated (Month 12)	13	5	4	
Only corticosteroid treated (Month 24)	13	19	11	
Corticosteroid resistant (Month 24)	2	1	2	
Lymphocyte-depleting treated (Month 24)	14	7	4	
Only corticosteroid treated (Month 36)	13	19	11	
Corticosteroid resistant (Month 36)	2	1	2	
Lymphocyte-depleting treated (Month 36)	14	7	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Based on Severity of Acute Rejection Based on Banff Grade Level by Months 6, 12, 24, 36 and 84.

End point title	Number of Subjects Based on Severity of Acute Rejection Based on Banff Grade Level by Months 6, 12, 24, 36 and 84.
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End point description:

Acute rejection was defined as central biopsy proven rejection that was either clinically suspected by protocol defined reasons or clinically suspected by other reasons and treated. Clinically suspected acute rejection was defined as an unexplained rise of serum creatinine \geq 25% from baseline creatinine or an unexplained decreased urine output or fever and graft tenderness or serum creatinine that remains elevated within 14 days post-transplantation and clinical suspicion of acute rejection exists. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Month 6, 12, 24, 36 and 84

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: Subjects				
Mild acute (IA) (Month 6)	0	4	2	
Mild acute (IB) (Month 6)	6	2	2	
Moderate acute (IIA) (Month 6)	11	15	16	
Moderate acute (IB) (Month 6)	15	8	5	
Severe acute (III) (Month 6)	0	0	0	
Mild acute (IA) (Month 12)	0	4	2	
Mild acute (IB) (Month 12)	6	2	2	
Moderate acute (IIA) (Month 12)	11	17	17	
Moderate acute (IB) (Month 12)	15	8	5	
Severe acute (III) (Month 12)	0	0	0	
Mild acute (IA) (Month 24)	0	4	2	
Mild acute (IB) (Month 24)	6	2	3	

Moderate acute (IIA) (Month 24)	10	17	18	
Moderate acute (IB) (Month 24)	16	9	5	
Severe acute (III) (Month 24)	0	0	0	
Mild acute (IA) (Month 36)	0	4	2	
Mild acute (IB) (Month 36)	6	2	4	
Moderate acute (IIA) (Month 36)	10	18	18	
Moderate acute (IB) (Month 36)	16	9	5	
Severe acute (III) (Month 36)	1	0	0	
Mild acute (IA) (Month 84)	0	4	2	
Mild acute (1B) (Month 84)	6	3	4	
Moderate acute (IIA) (Month 84)	12	18	18	
Moderate acute (IIB) (Month 84)	16	9	5	
Severe acute (III) (Month 84)	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Changes in Mental Component and Physical Component Health-Related Quality of Life (SF-36) from Baseline to Months 12, 24 and 36

End point title	Mean Changes in Mental Component and Physical Component Health-Related Quality of Life (SF-36) from Baseline to Months 12, 24 and 36
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End point description:

The SF-36 was used to measure health-related quality of life (QoL). Individual subscale scores (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) and 2 summary scores (physical component score and mental component score) were calculated. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Month 12, 24, 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Score on a scale				
arithmetic mean (standard deviation)				
Physical functioning (Month 12) (n=148, 153, 155)	44.7 (± 10.56)	46 (± 11.01)	44 (± 10.64)	
Role-physical (Month 12) (n=148, 153, 156)	43.6 (± 11.24)	43.9 (± 11.45)	42.3 (± 10.86)	
Bodily pain (Month 12) (n=148, 153, 154)	52.5 (± 10.81)	49.9 (± 12)	48.3 (± 11.23)	
General health (Month 12) (n=148, 154, 156)	47.6 (± 9.55)	46.9 (± 9.87)	46 (± 9.92)	
Vitality (Month 12) (n=147, 152, 156)	53.5 (± 9.9)	53.3 (± 11.54)	51.9 (± 10.63)	
Social functioning (Month 12) (n=148, 153, 156)	48.7 (± 9.8)	47 (± 11.22)	45.4 (± 11.53)	

Role-emotional (Month 12) (n=148, 152, 154)	44.1 (± 12.38)	43.5 (± 13.68)	44.1 (± 12.27)
Mental health (Month 12) (n=147, 151, 156)	50.1 (± 10.56)	49.1 (± 12.43)	49.1 (± 11.29)
Physical functioning (Month 24) (n=145, 151, 153)	43.9 (± 10.77)	46 (± 10.2)	43.1 (± 11.47)
Role-physical (Month 24) (n=145, 150, 151)	43.4 (± 11.17)	43.9 (± 10.58)	42.1 (± 10.76)
Bodily pain (Month 24) (n=144, 152, 152)	51.4 (± 11.09)	49.2 (± 11.45)	47.2 (± 11.87)
General health (Month 24) (n=147, 152, 154)	46.8 (± 9.37)	46.5 (± 10.1)	44.6 (± 10.49)
Vitality (Month 24) (n=145, 150, 153)	53.3 (± 9.8)	52.9 (± 11.31)	50.5 (± 11.07)
Social functioning (Month 24) (n=146, 152, 153)	47.2 (± 10.87)	48.7 (± 9.35)	45.7 (± 11.5)
Role-emotional (Month 24) (n=144, 148, 147)	44.5 (± 12.38)	44.3 (± 12.43)	43.6 (± 12.37)
Mental health (Month 24) (n=145, 150, 153)	50.1 (± 10.59)	49.3 (± 11.81)	48.2 (± 11.5)
Physical functioning (Month 36) (n=144, 151, 153)	43.8 (± 11.66)	45.5 (± 10.84)	43 (± 11.77)
Role-physical (Month 36) (n=144, 148, 152)	43.9 (± 11)	43.5 (± 11.08)	41.9 (± 11.15)
Bodily pain (Month 36) (n=143, 151, 153)	51.1 (± 11.19)	49.5 (± 11.76)	46.9 (± 11.16)
General health (Month 36) (n=147, 152, 154)	46.3 (± 9.96)	45.4 (± 10.5)	43.6 (± 10.51)
Vitality (Month 36) (n=144, 149, 153)	53.5 (± 10.07)	52.3 (± 11.94)	50.5 (± 11.26)
Social functioning (Month 36) (n=146, 152, 154)	46.9 (± 10.64)	48.3 (± 10.1)	45.1 (± 11.57)
Role-emotional (Month 36) (n=144, 146, 148)	44.2 (± 12.74)	43.5 (± 12.73)	43.1 (± 12.96)
Mental health (Month 36) (n=144, 149, 153)	50.8 (± 9.35)	48.1 (± 12.31)	47.7 (± 11.19)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Clinically Significant Changes in Vital Signs up to 36 Months

End point title	Number of Subjects with Clinically Significant Changes in Vital Signs up to 36 Months
End point description: Subjects with abnormal blood pressure, body weight and body temperature outside the defined normal range were graded as clinically significant vital signs by the investigator. The analysis was performed in the Intent-to-Treat population.	
End point type	Secondary
End point timeframe: Baseline up to Month 36	

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Subjects				
Heart rate	0	0	0	
Body temperature	0	0	0	
Body weight	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Laboratory Test Abnormalities up to 36 Months

End point title	Number of Subjects with Laboratory Test Abnormalities up to 36 Months
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End point description:

Subjects with laboratory values outside the defined normal range were graded as clinically significant laboratory abnormalities by the investigator. Subjects were analysed for Alkaline phosphatase (ALP), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Hemoglobin, Platelet Count, Leukocytes, Bilirubin, Creatinine, Calcium, Bicarbonate, Potassium, Magnesium, Sodium, Phosphorus, Albumin, Uric Acid and Protein. Laboratory abnormalities were assessed according to the Common Terminology Criteria for Adverse Events (CTCAE) version 3. The analysis was performed in the Intent-to-Treat population. Here 'n' signifies those subjects evaluable for this measure at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline up to Month 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Subjects				
Hemoglobin (Low) (n=177,172,181)	25	24	16	
Platelet Count (Low) (n=177,172,181)	2	1	2	
Leukocytes (Low) (n=177,172,181)	10	5	8	
ALP (High) (n=177,172,182)	1	1	0	
ALT (High) (n=177,172,181)	4	2	4	
AST (High) (n=177,172,181)	1	1	0	
Bilirubin, Total (High) (n=177,172,182)	0	2	1	
Creatinine (High) (n=177,172,182)	125	117	128	
Calcium, Total (Low) (n=177,172,182)	19	14	10	
Calcium, Total (High) (n=177,172,182)	2	2	1	
Bicarbonate (Low) (n=176,171,181)	2	1	2	
Bicarbonate (High) (n=176,171,181)	0	0	0	
Potassium, Serum (Low) (n=177,172,181)	6	3	9	
Potassium, Serum (High) (n=177,172,181)	8	6	11	

Magnesium, Serum (Low) (n=177,172,181)	6	3	1	
Magnesium, Serum (High) (n=177,172,181)	6	4	9	
Sodium, Serum (Low) (n=177,172,182)	18	16	23	
Sodium, Serum (High) (n=177,172,182)	0	0	1	
Phosphorus (Low) (n=177,172,182)	66	58	44	
Albumin (Low) (n=177,172,182)	2	4	1	
Uric Acid (High) (n=177,172,182)	31	34	60	
Protein, Urine (High) (n=173,168,177)	44	37	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), Related AEs and SAEs, AEs Leading to Discontinuation and Who Died up to Month 36

End point title	Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), Related AEs and SAEs, AEs Leading to Discontinuation and Who Died up to Month 36
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End point description:

AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. Serious adverse events are any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Baseline up to Month 36

End point values	Belatacept MI (Period 1)	Belatacept LI (Period 1)	Cyclosporin A (Period 1)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	184	175	184	
Units: Subjects				
AEs	182	174	184	
SAEs	149	139	146	
AEs leading to Discontinuation	34	36	44	
SAEs leading to Discontinuation	31	31	28	
Related AEs	115	106	141	
Related SAEs	60	51	58	
Deaths	22	15	17	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), Related AEs and SAEs, AEs Leading to Discontinuation and Who Died up to Month 84

End point title	Number of Subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), Related AEs and SAEs, AEs Leading to Discontinuation and Who Died up to Month 84
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End point description:

AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. Serious adverse events are any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards. The analysis was performed in the Intent-to-Treat population.

End point type	Secondary
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End point timeframe:

Baseline up to Month 84

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: Subjects				
AEs	104	113	87	
SAEs	94	104	73	
AEs leading to Discontinuation	14	14	7	
SAEs leading to Discontinuation	10	13	7	
Deaths	14	21	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Graft Loss or Death to Month 84

End point title	Percentage of Subjects with Graft Loss or Death to Month 84
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End point description:

Subject and graft survival at 84 months was summarized within each treatment group. The analyses was performed in the Intent-to-Treat population which includes all subjects who are randomized into the study and received a transplant.

End point type	Secondary
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End point timeframe:

Randomization to date of death, up to 84 months

End point values	Belatacept MI (Periods 1&2)	Belatacept LI (Periods 1&2)	Cyclosporin A (Periods 1&2)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	175	184	
Units: Percentage of Subjects				
number (not applicable)				
Graft Loss or Death	29.3	30.9	28.3	
Graft Loss	11.4	13.1	15.8	
Death	20.1	21.1	15.8	
Death with Functioning Graft	17.9	17.7	12.5	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to 56 days after the last dose of the study drug

Adverse event reporting additional description:

On treatment-period

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	13.0
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Reporting groups

Reporting group title	Belatacept MI
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Reporting group description:

Subjects in more intensive (MI) regimen received belatacept 10 mg/kg intravenous solution on Day 1 and 5 during the first week, and then every other week through 3 months (Weeks 2, 4, 8, and 12) and then every 4 weeks through 6 months (Weeks 16, 20 and 24), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 84 months.

Reporting group title	Belatacept LI
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Reporting group description:

Subjects in less intensive (LI) regimen received belatacept, 10 mg/kg intravenously on Day 1 and Day 5 during the first week, and then every other week for 4 weeks (Weeks 2 and 4), and then every 4 weeks for 2 months (Weeks 8 and 12), followed by a maintenance dose of belatacept, 5 mg/kg intravenously every 4 weeks thereafter for up to 84 months.

Reporting group title	Cyclosporin A
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Reporting group description:

Subjects received an initial daily dose of 4 -10 mg/kg cyclosporine capsules orally, in 2 divided doses, adjusted thereafter to maintain serum concentrations of 150-300 ng/mL. Subsequent doses were adjusted to maintain a predefined range of trough serum concentrations of 100-250 ng/mL for up to 84 months.

Serious adverse events	Belatacept MI	Belatacept LI	Cyclosporin A
Total subjects affected by serious adverse events			
subjects affected / exposed	162 / 183 (88.52%)	157 / 177 (88.70%)	152 / 179 (84.92%)
number of deaths (all causes)	35	35	29
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	9 / 183 (4.92%)	6 / 177 (3.39%)	12 / 179 (6.70%)
occurrences causally related to treatment / all	8 / 16	10 / 11	7 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			

subjects affected / exposed	8 / 183 (4.37%)	6 / 177 (3.39%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	7 / 14	6 / 8	13 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	2 / 183 (1.09%)	4 / 177 (2.26%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	4 / 183 (2.19%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kaposi's sarcoma			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 1	1 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Squamous cell carcinoma			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	2 / 3	0 / 0	2 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Central nervous system lymphoma			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 183 (0.00%)	3 / 177 (1.69%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 1
Adenocarcinoma of colon			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Renal cell carcinoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cholangiocarcinoma			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Epiglottic carcinoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hepatic cancer			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Laryngeal cancer			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Lung cancer metastatic			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Lymphoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Malignant pleural effusion			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Non-small cell lung cancer			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Pituitary tumour benign			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural mesothelioma malignant			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Plasma cell myeloma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Prostatic adenoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Rectal adenocarcinoma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Skin cancer			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Lymphocele			
subjects affected / exposed	2 / 183 (1.09%)	5 / 177 (2.82%)	11 / 179 (6.15%)
occurrences causally related to treatment / all	1 / 3	3 / 7	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	7 / 183 (3.83%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 7	0 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	2 / 183 (1.09%)	5 / 177 (2.82%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	4 / 183 (2.19%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	2 / 183 (1.09%)	3 / 177 (1.69%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	1 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 183 (0.00%)	3 / 177 (1.69%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Thrombophlebitis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			

subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Aneurysm ruptured			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angiopathy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic dissection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic stenosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Arterial haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Arterial occlusive disease			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Arterial stenosis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Haemorrhagic infarction			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lymphoedema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Shock			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Thrombophlebitis superficial			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stenosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous stenosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	17 / 183 (9.29%)	10 / 177 (5.65%)	12 / 179 (6.70%)
occurrences causally related to treatment / all	2 / 19	3 / 16	4 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	5 / 183 (2.73%)	3 / 177 (1.69%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Adverse drug reaction			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Haemorrhagic cyst			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi -organ failure			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oedema			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Asthenia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cyst			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Device malfunction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Drug intolerance			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Extravasation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Fatigue			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Non-cardiac chest pain			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Oedema peripheral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired hydrocele			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Priapism			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Prostatism			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Rectocele			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Scrotal oedema			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Testicular swelling			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine malposition			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 183 (1.09%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	5 / 179 (2.79%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pulmonary oedema			
subjects affected / exposed	3 / 183 (1.64%)	3 / 177 (1.69%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 3	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	0 / 179 (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
Respiratory failure			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea exertional			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Interstitial lung disease			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Acute pulmonary oedema			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Aspiration			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Asthma			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Bronchial secretion retention			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumopathy			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hiccups			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal disorder			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Orthopnoea			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal oedema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Vocal cord disorder			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute psychosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Completed suicide			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Suicide attempt			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Investigations			
Blood creatinine increased			
subjects affected / exposed	14 / 183 (7.65%)	11 / 177 (6.21%)	17 / 179 (9.50%)
occurrences causally related to treatment / all	2 / 14	1 / 14	6 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
White blood cell count decreased			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Antibody test positive			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose abnormal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcus test positive			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia test positive			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Liver function test abnormal			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Pancreatic enzymes increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Platelet count decreased			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Polyomavirus test positive			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
White blood cells urine positive			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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			
Transplant dysfunction			
subjects affected / exposed	9 / 183 (4.92%)	6 / 177 (3.39%)	11 / 179 (6.15%)
occurrences causally related to treatment / all	0 / 9	1 / 6	3 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complications of transplanted kidney			
subjects affected / exposed	3 / 183 (1.64%)	8 / 177 (4.52%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	1 / 4	2 / 10	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Graft loss			
subjects affected / exposed	4 / 183 (2.19%)	7 / 177 (3.95%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	3 / 4	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic allograft nephropathy			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	5 / 179 (2.79%)
occurrences causally related to treatment / all	1 / 3	1 / 1	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	1 / 183 (0.55%)	5 / 177 (2.82%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 183 (0.00%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal haematoma			
subjects affected / exposed	2 / 183 (1.09%)	3 / 177 (1.69%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft thrombosis			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound evisceration			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	2 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			

subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula aneurysm			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula thrombosis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 183 (0.00%)	3 / 177 (1.69%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural urine leak			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal transplant failure			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shunt occlusion			

subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft complication			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (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
Fall			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dose administered			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (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
Meniscus injury			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seroma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Anaemia postoperative			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic complication			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic haemorrhage			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula occlusion			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation complication			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Complications of transplant surgery			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Foot fracture			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Head injury			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Hip fracture			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Humerus fracture			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site complication			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Incision site haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Joint dislocation			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Kidney rupture			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Perinephric collection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 complication			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 haemorrhage			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 ileus			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Procedural complication			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous haematoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Ulna fracture			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Wound			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	9 / 183 (4.92%)	11 / 177 (6.21%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 11	1 / 14	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	10 / 183 (5.46%)	5 / 177 (2.82%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	1 / 15	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Myocardial infarction			
subjects affected / exposed	7 / 183 (3.83%)	3 / 177 (1.69%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Cardiac failure			
subjects affected / exposed	3 / 183 (1.64%)	3 / 177 (1.69%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2

Acute myocardial infarction			
subjects affected / exposed	2 / 183 (1.09%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Acute coronary syndrome			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Arrhythmia			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Atrioventricular block			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Mitral valve stenosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Aortic valve disease			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Aortic valve stenosis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Arrhythmia supraventricular			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Atrial flutter			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 tachycardia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cardiovascular disorder			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Intracardiac thrombus			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Left ventricular dysfunction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Myocardial ischaemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Pericarditis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Supraventricular tachyarrhythmia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Tachyarrhythmia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Ventricular extrasystoles			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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			
Cerebrovascular accident			
subjects affected / exposed	6 / 183 (3.28%)	1 / 177 (0.56%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 6	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Convulsion			

subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Haemorrhage intracranial			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Neurotoxicity			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain mass			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Carpal tunnel syndrome			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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 syndrome			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cerebral haematoma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cerebral ischaemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cognitive disorder			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Dementia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Dizziness			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Encephalitis toxic			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Guillain-Barre syndrome			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Mononeuropathy			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Optic neuritis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	11 / 183 (6.01%)	9 / 177 (5.08%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	1 / 11	2 / 9	4 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	8 / 183 (4.37%)	2 / 177 (1.13%)	5 / 179 (2.79%)
occurrences causally related to treatment / all	3 / 9	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	3 / 183 (1.64%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agranulocytosis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Febrile neutropenia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Granulocytopenia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Haemolysis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Leukocytosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Eye disorders			
Cataract			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Eyelid ptosis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Macular fibrosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular oedema			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Retinal detachment			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Uveitis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 impairment			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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 disorders			
Diarrhoea			
subjects affected / exposed	18 / 183 (9.84%)	14 / 177 (7.91%)	10 / 179 (5.59%)
occurrences causally related to treatment / all	1 / 20	5 / 16	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	2 / 183 (1.09%)	3 / 177 (1.69%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastritis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastric ulcer			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine obstruction			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial eventration			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Gastroduodenal ulcer			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Large intestine polyp			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (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
Abdominal discomfort			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 lower			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 upper			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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 wall haematoma			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Aphthous stomatitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Diverticulum			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Duodenal perforation			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Dyspepsia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Enterocolitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Erosive oesophagitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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 ulcer			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Gingival hyperplasia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hiatus hernia			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Ileus paralytic			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Impaired gastric emptying			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Intestinal fistula			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Intestinal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Intestinal perforation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Large intestine perforation			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Malabsorption			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Oral disorder			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Peritoneal disorder			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Volvulus			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cholecystitis			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cholecystitis chronic			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cholestasis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder perforation			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hepatic cyst			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hepatic mass			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hepatic steatosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Hepatitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Skin and subcutaneous tissue disorders			
Skin ulcer			

subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Angioedema			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blister			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Diabetic bullosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Dry gangrene			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Rash			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure acute			

subjects affected / exposed	7 / 183 (3.83%)	12 / 177 (6.78%)	11 / 179 (6.15%)
occurrences causally related to treatment / all	1 / 17	1 / 12	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	2 / 183 (1.09%)	5 / 177 (2.82%)	7 / 179 (3.91%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	2 / 183 (1.09%)	3 / 177 (1.69%)	9 / 179 (5.03%)
occurrences causally related to treatment / all	1 / 2	1 / 3	2 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric stenosis			
subjects affected / exposed	4 / 183 (2.19%)	3 / 177 (1.69%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 9	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	4 / 183 (2.19%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	4 / 183 (2.19%)	3 / 177 (1.69%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 4	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	6 / 183 (3.28%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary fistula			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive uropathy			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery thrombosis			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder prolapse			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Urinary tract obstruction			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Azotaemia			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neck sclerosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Bladder obstruction			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Diabetic nephropathy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hypertonic bladder			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Microalbuminuria			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Nephritis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric effusion			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postrenal failure			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Prerenal failure			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Pyelocaliectasis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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 artery dissection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst haemorrhage			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure chronic			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular atrophy			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteral necrosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Ureteric dilatation			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Ureteric fistula			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Ureteric obstruction			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Urethral disorder			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Urethral obstruction			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Urine abnormality			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesical fistula			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Endocrine disorders			
Adrenal mass			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism tertiary			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hyperthyroidism			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthralgia			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Osteonecrosis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Bursitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastasis recti abdominis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Dupuytren's contracture			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Fistula			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hypercreatinaemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Intervertebral disc disorder			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Joint effusion			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Mobility decreased			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Myopathy			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post transplant distal limb syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Tenosynovitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	25 / 183 (13.66%)	28 / 177 (15.82%)	26 / 179 (14.53%)
occurrences causally related to treatment / all	8 / 39	6 / 36	9 / 47
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			

subjects affected / exposed	18 / 183 (9.84%)	16 / 177 (9.04%)	13 / 179 (7.26%)
occurrences causally related to treatment / all	17 / 29	10 / 18	4 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	15 / 183 (8.20%)	14 / 177 (7.91%)	11 / 179 (6.15%)
occurrences causally related to treatment / all	6 / 21	8 / 20	4 / 13
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Sepsis			
subjects affected / exposed	8 / 183 (4.37%)	10 / 177 (5.65%)	15 / 179 (8.38%)
occurrences causally related to treatment / all	1 / 10	2 / 10	4 / 16
deaths causally related to treatment / all	0 / 4	0 / 3	2 / 4
Pyelonephritis			
subjects affected / exposed	12 / 183 (6.56%)	6 / 177 (3.39%)	14 / 179 (7.82%)
occurrences causally related to treatment / all	4 / 17	3 / 6	2 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastroenteritis			
subjects affected / exposed	8 / 183 (4.37%)	6 / 177 (3.39%)	8 / 179 (4.47%)
occurrences causally related to treatment / all	1 / 8	2 / 6	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	6 / 183 (3.28%)	7 / 177 (3.95%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	2 / 8	1 / 7	3 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Herpes zoster			
subjects affected / exposed	8 / 183 (4.37%)	3 / 177 (1.69%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	3 / 8	1 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	4 / 183 (2.19%)	1 / 177 (0.56%)	7 / 179 (3.91%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 2	1 / 5
Bacteraemia			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	5 / 179 (2.79%)
occurrences causally related to treatment / all	2 / 3	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	3 / 183 (1.64%)	3 / 177 (1.69%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 3	0 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	5 / 183 (2.73%)	4 / 177 (2.26%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	2 / 5	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	5 / 179 (2.79%)
occurrences causally related to treatment / all	0 / 3	0 / 1	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	3 / 183 (1.64%)	3 / 177 (1.69%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	3 / 4	2 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	4 / 183 (2.19%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	4 / 183 (2.19%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 5	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	3 / 183 (1.64%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	2 / 3	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	3 / 183 (1.64%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 2	2 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	2 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	3 / 183 (1.64%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 183 (0.55%)	4 / 177 (2.26%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Device related infection			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cyst infection			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyomavirus-associated nephropathy			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 3	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Wound infection			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptococcosis			
subjects affected / exposed	1 / 183 (0.55%)	3 / 177 (1.69%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	3 / 179 (1.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis cryptococcal			
subjects affected / exposed	2 / 183 (1.09%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	3 / 183 (1.64%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	0 / 179 (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
Appendicitis			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 1	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst infection			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant abscess			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gangrene			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Endocarditis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			

subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Erysipelas			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Hepatitis B			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected lymphocele			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Necrotising fasciitis			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strongyloidiasis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 183 (0.00%)	2 / 177 (1.13%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess rupture			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Anal abscess			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Appendicitis perforated			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
BK virus infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Bacterial infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial prostatitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cerebral aspergillosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cerebral fungal infection			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Chorioretinitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Cystitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis bacterial			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cytomegalovirus chorioretinitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cytomegalovirus gastritis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus gastroenteritis			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus gastrointestinal infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cytomegalovirus hepatitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Cytomegalovirus syndrome			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Diarrhoea infectious			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated cytomegaloviral infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Empysematous cystitis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Encephalomyelitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Herpes zoster disseminated			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human polyomavirus infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Infected cyst			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Infection			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint tuberculosis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Kidney infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Leishmaniasis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Lobar pneumonia			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Lung infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Lymphangitis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Mycoplasma infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Nasopharyngitis			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Oral candidiasis			

subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Oral fungal infection			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Pneumonia cryptococcal			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pseudomonas infection			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purulent discharge			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Sinusitis bacterial			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Tooth abscess			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Tuberculosis			

subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis of eye			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Tuberculosis laryngitis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Varicella			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	7 / 183 (3.83%)	10 / 177 (5.65%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	1 / 7	2 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	3 / 183 (1.64%)	4 / 177 (2.26%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	2 / 183 (1.09%)	3 / 177 (1.69%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	1 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	2 / 183 (1.09%)	1 / 177 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			

subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 183 (0.55%)	2 / 177 (1.13%)	0 / 179 (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
Hypokalaemia			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 183 (1.09%)	0 / 177 (0.00%)	0 / 179 (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
Hypovolaemia			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	0 / 179 (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
Metabolic acidosis			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cachexia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Electrolyte imbalance			
subjects affected / exposed	1 / 183 (0.55%)	0 / 177 (0.00%)	0 / 179 (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
Hypercreatininaemia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Hypomagnesaemia			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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
Iron deficiency			

subjects affected / exposed	0 / 183 (0.00%)	0 / 177 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 183 (0.00%)	1 / 177 (0.56%)	0 / 179 (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

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

Non-serious adverse events	Belatacept MI	Belatacept LI	Cyclosporin A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	177 / 183 (96.72%)	171 / 177 (96.61%)	179 / 179 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	11 / 183 (6.01%)	6 / 177 (3.39%)	11 / 179 (6.15%)
occurrences (all)	23	7	22
Vascular disorders			
Hypertension			
subjects affected / exposed	63 / 183 (34.43%)	63 / 177 (35.59%)	80 / 179 (44.69%)
occurrences (all)	131	170	190
Hypotension			
subjects affected / exposed	38 / 183 (20.77%)	52 / 177 (29.38%)	29 / 179 (16.20%)
occurrences (all)	69	86	54
Haematoma			
subjects affected / exposed	16 / 183 (8.74%)	16 / 177 (9.04%)	18 / 179 (10.06%)
occurrences (all)	27	22	23
Lymphocele			
subjects affected / exposed	9 / 183 (4.92%)	7 / 177 (3.95%)	15 / 179 (8.38%)
occurrences (all)	18	20	42
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	92 / 183 (50.27%)	81 / 177 (45.76%)	96 / 179 (53.63%)
occurrences (all)	295	269	412
Pyrexia			

subjects affected / exposed occurrences (all)	56 / 183 (30.60%) 98	64 / 177 (36.16%) 107	52 / 179 (29.05%) 112
Oedema subjects affected / exposed occurrences (all)	26 / 183 (14.21%) 65	23 / 177 (12.99%) 68	30 / 179 (16.76%) 51
Chest pain subjects affected / exposed occurrences (all)	22 / 183 (12.02%) 34	24 / 177 (13.56%) 42	24 / 179 (13.41%) 46
Fatigue subjects affected / exposed occurrences (all)	26 / 183 (14.21%) 41	22 / 177 (12.43%) 44	19 / 179 (10.61%) 39
Asthenia subjects affected / exposed occurrences (all)	23 / 183 (12.57%) 42	17 / 177 (9.60%) 35	23 / 179 (12.85%) 53
Pain subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 29	13 / 177 (7.34%) 15	14 / 179 (7.82%) 31
Peripheral swelling subjects affected / exposed occurrences (all)	10 / 183 (5.46%) 24	14 / 177 (7.91%) 31	12 / 179 (6.70%) 23
Chills subjects affected / exposed occurrences (all)	9 / 183 (4.92%) 11	6 / 177 (3.39%) 8	9 / 179 (5.03%) 10
Reproductive system and breast disorders Erectile dysfunction subjects affected / exposed occurrences (all)	12 / 183 (6.56%) 18	9 / 177 (5.08%) 14	5 / 179 (2.79%) 6
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	53 / 183 (28.96%) 155	56 / 177 (31.64%) 138	41 / 179 (22.91%) 103
Dyspnoea subjects affected / exposed occurrences (all)	33 / 183 (18.03%) 67	40 / 177 (22.60%) 90	37 / 179 (20.67%) 85
Oropharyngeal pain			

subjects affected / exposed occurrences (all)	16 / 183 (8.74%) 26	9 / 177 (5.08%) 17	11 / 179 (6.15%) 13
Dyspnoea exertional subjects affected / exposed occurrences (all)	15 / 183 (8.20%) 27	10 / 177 (5.65%) 20	8 / 179 (4.47%) 22
Productive cough subjects affected / exposed occurrences (all)	9 / 183 (4.92%) 18	18 / 177 (10.17%) 36	6 / 179 (3.35%) 12
Nasal congestion subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 7	1 / 177 (0.56%) 1	9 / 179 (5.03%) 12
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	37 / 183 (20.22%) 92	31 / 177 (17.51%) 56	39 / 179 (21.79%) 77
Anxiety subjects affected / exposed occurrences (all)	27 / 183 (14.75%) 55	20 / 177 (11.30%) 33	30 / 179 (16.76%) 48
Depression subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 22	16 / 177 (9.04%) 43	18 / 179 (10.06%) 30
Investigations			
Blood creatinine increased subjects affected / exposed occurrences (all)	29 / 183 (15.85%) 63	29 / 177 (16.38%) 71	31 / 179 (17.32%) 71
Weight decreased subjects affected / exposed occurrences (all)	17 / 183 (9.29%) 32	21 / 177 (11.86%) 45	13 / 179 (7.26%) 20
Weight increased subjects affected / exposed occurrences (all)	15 / 183 (8.20%) 30	13 / 177 (7.34%) 24	11 / 179 (6.15%) 18
C-reactive protein increased subjects affected / exposed occurrences (all)	12 / 183 (6.56%) 30	14 / 177 (7.91%) 36	11 / 179 (6.15%) 22
Blood pressure increased			

subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 12	5 / 177 (2.82%) 8	10 / 179 (5.59%) 16
Injury, poisoning and procedural complications			
Transplant dysfunction			
subjects affected / exposed	65 / 183 (35.52%)	64 / 177 (36.16%)	85 / 179 (47.49%)
occurrences (all)	129	117	176
Procedural pain			
subjects affected / exposed	36 / 183 (19.67%)	38 / 177 (21.47%)	37 / 179 (20.67%)
occurrences (all)	74	59	62
Incision site pain			
subjects affected / exposed	26 / 183 (14.21%)	22 / 177 (12.43%)	36 / 179 (20.11%)
occurrences (all)	52	43	71
Complications of transplanted kidney			
subjects affected / exposed	10 / 183 (5.46%)	20 / 177 (11.30%)	17 / 179 (9.50%)
occurrences (all)	14	39	42
Chronic allograft nephropathy			
subjects affected / exposed	14 / 183 (7.65%)	9 / 177 (5.08%)	22 / 179 (12.29%)
occurrences (all)	21	11	23
Fall			
subjects affected / exposed	16 / 183 (8.74%)	8 / 177 (4.52%)	11 / 179 (6.15%)
occurrences (all)	23	12	18
Contusion			
subjects affected / exposed	8 / 183 (4.37%)	11 / 177 (6.21%)	4 / 179 (2.23%)
occurrences (all)	21	19	13
Arteriovenous fistula thrombosis			
subjects affected / exposed	4 / 183 (2.19%)	7 / 177 (3.95%)	9 / 179 (5.03%)
occurrences (all)	5	10	14
Toxicity to various agents			
subjects affected / exposed	1 / 183 (0.55%)	1 / 177 (0.56%)	18 / 179 (10.06%)
occurrences (all)	1	1	27
Ligament sprain			
subjects affected / exposed	8 / 183 (4.37%)	1 / 177 (0.56%)	10 / 179 (5.59%)
occurrences (all)	14	2	16
Wound dehiscence			

subjects affected / exposed occurrences (all)	3 / 183 (1.64%) 14	5 / 177 (2.82%) 14	10 / 179 (5.59%) 17
Wound complication subjects affected / exposed occurrences (all)	3 / 183 (1.64%) 4	5 / 177 (2.82%) 9	9 / 179 (5.03%) 14
Post procedural discharge subjects affected / exposed occurrences (all)	1 / 183 (0.55%) 1	2 / 177 (1.13%) 2	9 / 179 (5.03%) 15
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	14 / 183 (7.65%) 17	22 / 177 (12.43%) 47	12 / 179 (6.70%) 24
Atrial fibrillation subjects affected / exposed occurrences (all)	16 / 183 (8.74%) 27	11 / 177 (6.21%) 28	12 / 179 (6.70%) 21
Bradycardia subjects affected / exposed occurrences (all)	10 / 183 (5.46%) 13	7 / 177 (3.95%) 14	12 / 179 (6.70%) 18
Angina pectoris subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 7	8 / 177 (4.52%) 10	12 / 179 (6.70%) 15
Sinus bradycardia subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 9	4 / 177 (2.26%) 6	9 / 179 (5.03%) 11
Left ventricular hypertrophy subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 7	9 / 177 (5.08%) 12	6 / 179 (3.35%) 11
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	37 / 183 (20.22%) 95	41 / 177 (23.16%) 108	47 / 179 (26.26%) 110
Tremor subjects affected / exposed occurrences (all)	17 / 183 (9.29%) 29	21 / 177 (11.86%) 38	31 / 179 (17.32%) 56
Dizziness			

subjects affected / exposed occurrences (all)	26 / 183 (14.21%) 47	18 / 177 (10.17%) 32	18 / 179 (10.06%) 33
Paraesthesia subjects affected / exposed occurrences (all)	11 / 183 (6.01%) 17	13 / 177 (7.34%) 23	16 / 179 (8.94%) 37
Sciatica subjects affected / exposed occurrences (all)	7 / 183 (3.83%) 10	11 / 177 (6.21%) 22	8 / 179 (4.47%) 11
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	98 / 183 (53.55%) 286	93 / 177 (52.54%) 281	103 / 179 (57.54%) 270
Leukopenia subjects affected / exposed occurrences (all)	51 / 183 (27.87%) 135	40 / 177 (22.60%) 86	48 / 179 (26.82%) 126
Thrombocytopenia subjects affected / exposed occurrences (all)	24 / 183 (13.11%) 48	13 / 177 (7.34%) 29	11 / 179 (6.15%) 30
Leukocytosis subjects affected / exposed occurrences (all)	15 / 183 (8.20%) 32	12 / 177 (6.78%) 14	9 / 179 (5.03%) 18
Neutropenia subjects affected / exposed occurrences (all)	12 / 183 (6.56%) 20	10 / 177 (5.65%) 21	12 / 179 (6.70%) 27
Lymphopenia subjects affected / exposed occurrences (all)	10 / 183 (5.46%) 23	12 / 177 (6.78%) 20	8 / 179 (4.47%) 15
Polycythaemia subjects affected / exposed occurrences (all)	4 / 183 (2.19%) 15	10 / 177 (5.65%) 17	7 / 179 (3.91%) 15
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 7	14 / 177 (7.91%) 19	8 / 179 (4.47%) 13
Eye disorders			

Cataract			
subjects affected / exposed	20 / 183 (10.93%)	13 / 177 (7.34%)	16 / 179 (8.94%)
occurrences (all)	27	21	34
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	103 / 183 (56.28%)	94 / 177 (53.11%)	74 / 179 (41.34%)
occurrences (all)	358	304	196
Constipation			
subjects affected / exposed	61 / 183 (33.33%)	63 / 177 (35.59%)	79 / 179 (44.13%)
occurrences (all)	149	132	177
Nausea			
subjects affected / exposed	54 / 183 (29.51%)	49 / 177 (27.68%)	52 / 179 (29.05%)
occurrences (all)	113	95	98
Vomiting			
subjects affected / exposed	37 / 183 (20.22%)	51 / 177 (28.81%)	44 / 179 (24.58%)
occurrences (all)	64	87	88
Abdominal pain			
subjects affected / exposed	30 / 183 (16.39%)	39 / 177 (22.03%)	33 / 179 (18.44%)
occurrences (all)	55	75	66
Abdominal pain upper			
subjects affected / exposed	21 / 183 (11.48%)	25 / 177 (14.12%)	27 / 179 (15.08%)
occurrences (all)	37	43	55
Dyspepsia			
subjects affected / exposed	22 / 183 (12.02%)	16 / 177 (9.04%)	20 / 179 (11.17%)
occurrences (all)	38	29	29
Abdominal distension			
subjects affected / exposed	13 / 183 (7.10%)	13 / 177 (7.34%)	19 / 179 (10.61%)
occurrences (all)	25	20	34
Haemorrhoids			
subjects affected / exposed	16 / 183 (8.74%)	13 / 177 (7.34%)	8 / 179 (4.47%)
occurrences (all)	31	30	12
Aphthous stomatitis			
subjects affected / exposed	10 / 183 (5.46%)	13 / 177 (7.34%)	4 / 179 (2.23%)
occurrences (all)	31	33	6
Gastrooesophageal reflux disease			

subjects affected / exposed occurrences (all)	9 / 183 (4.92%) 9	9 / 177 (5.08%) 12	9 / 179 (5.03%) 12
Gastritis subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 15	7 / 177 (3.95%) 19	9 / 179 (5.03%) 12
Flatulence subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 13	5 / 177 (2.82%) 9	10 / 179 (5.59%) 17
Gingival hypertrophy subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	1 / 177 (0.56%) 1	9 / 179 (5.03%) 22
Gingival hyperplasia subjects affected / exposed occurrences (all)	0 / 183 (0.00%) 0	0 / 177 (0.00%) 0	9 / 179 (5.03%) 20
Skin and subcutaneous tissue disorders			
Skin lesion subjects affected / exposed occurrences (all)	18 / 183 (9.84%) 35	15 / 177 (8.47%) 28	11 / 179 (6.15%) 18
Acne subjects affected / exposed occurrences (all)	7 / 183 (3.83%) 16	12 / 177 (6.78%) 24	15 / 179 (8.38%) 34
Pruritus subjects affected / exposed occurrences (all)	16 / 183 (8.74%) 26	8 / 177 (4.52%) 9	6 / 179 (3.35%) 10
Ecchymosis subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 30	4 / 177 (2.26%) 8	9 / 179 (5.03%) 15
Hyperkeratosis subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 16	9 / 177 (5.08%) 15	5 / 179 (2.79%) 9
Renal and urinary disorders			
Haematuria subjects affected / exposed occurrences (all)	41 / 183 (22.40%) 88	39 / 177 (22.03%) 89	36 / 179 (20.11%) 69
Proteinuria			

subjects affected / exposed occurrences (all)	40 / 183 (21.86%) 89	36 / 177 (20.34%) 90	29 / 179 (16.20%) 75
Renal tubular necrosis subjects affected / exposed occurrences (all)	17 / 183 (9.29%) 29	21 / 177 (11.86%) 34	30 / 179 (16.76%) 78
Dysuria subjects affected / exposed occurrences (all)	25 / 183 (13.66%) 53	23 / 177 (12.99%) 36	16 / 179 (8.94%) 26
Renal impairment subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 25	13 / 177 (7.34%) 25	19 / 179 (10.61%) 41
Leukocyturia subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 53	14 / 177 (7.91%) 41	12 / 179 (6.70%) 58
Hydronephrosis subjects affected / exposed occurrences (all)	9 / 183 (4.92%) 11	2 / 177 (1.13%) 3	11 / 179 (6.15%) 18
Urinary retention subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 8	6 / 177 (3.39%) 8	11 / 179 (6.15%) 23
Renal failure acute subjects affected / exposed occurrences (all)	4 / 183 (2.19%) 4	7 / 177 (3.95%) 11	9 / 179 (5.03%) 12
Endocrine disorders			
Hyperparathyroidism subjects affected / exposed occurrences (all)	7 / 183 (3.83%) 10	5 / 177 (2.82%) 5	12 / 179 (6.70%) 17
Cushingoid subjects affected / exposed occurrences (all)	6 / 183 (3.28%) 8	7 / 177 (3.95%) 11	9 / 179 (5.03%) 13
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	41 / 183 (22.40%) 100	44 / 177 (24.86%) 98	39 / 179 (21.79%) 81
Pain in extremity			

subjects affected / exposed occurrences (all)	35 / 183 (19.13%) 78	34 / 177 (19.21%) 69	42 / 179 (23.46%) 116
Arthralgia subjects affected / exposed occurrences (all)	33 / 183 (18.03%) 76	43 / 177 (24.29%) 97	34 / 179 (18.99%) 77
Muscle spasms subjects affected / exposed occurrences (all)	17 / 183 (9.29%) 28	17 / 177 (9.60%) 38	19 / 179 (10.61%) 34
Musculoskeletal pain subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 22	15 / 177 (8.47%) 34	10 / 179 (5.59%) 14
Myalgia subjects affected / exposed occurrences (all)	11 / 183 (6.01%) 19	9 / 177 (5.08%) 13	17 / 179 (9.50%) 26
Osteoporosis subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 17	7 / 177 (3.95%) 18	5 / 179 (2.79%) 5
Osteopenia subjects affected / exposed occurrences (all)	10 / 183 (5.46%) 12	7 / 177 (3.95%) 7	6 / 179 (3.35%) 12
Neck pain subjects affected / exposed occurrences (all)	5 / 183 (2.73%) 6	5 / 177 (2.82%) 7	9 / 179 (5.03%) 13
Muscular weakness subjects affected / exposed occurrences (all)	4 / 183 (2.19%) 7	4 / 177 (2.26%) 6	10 / 179 (5.59%) 14
Infections and infestations			
Urinary tract infection subjects affected / exposed occurrences (all)	79 / 183 (43.17%) 364	76 / 177 (42.94%) 293	86 / 179 (48.04%) 347
Nasopharyngitis subjects affected / exposed occurrences (all)	45 / 183 (24.59%) 135	44 / 177 (24.86%) 139	38 / 179 (21.23%) 99
Bronchitis subjects affected / exposed occurrences (all)	37 / 183 (20.22%) 83	36 / 177 (20.34%) 84	25 / 179 (13.97%) 57

Cytomegalovirus infection subjects affected / exposed occurrences (all)	22 / 183 (12.02%) 82	18 / 177 (10.17%) 64	17 / 179 (9.50%) 41
Upper respiratory tract infection subjects affected / exposed occurrences (all)	35 / 183 (19.13%) 108	29 / 177 (16.38%) 96	23 / 179 (12.85%) 81
Sinusitis subjects affected / exposed occurrences (all)	19 / 183 (10.38%) 48	23 / 177 (12.99%) 51	20 / 179 (11.17%) 58
Herpes zoster subjects affected / exposed occurrences (all)	21 / 183 (11.48%) 47	17 / 177 (9.60%) 34	13 / 179 (7.26%) 21
Influenza subjects affected / exposed occurrences (all)	17 / 183 (9.29%) 30	16 / 177 (9.04%) 38	18 / 179 (10.06%) 29
Gastroenteritis subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 13	18 / 177 (10.17%) 26	22 / 179 (12.29%) 29
Oral candidiasis subjects affected / exposed occurrences (all)	14 / 183 (7.65%) 31	10 / 177 (5.65%) 27	13 / 179 (7.26%) 22
Oral herpes subjects affected / exposed occurrences (all)	13 / 183 (7.10%) 34	14 / 177 (7.91%) 26	9 / 179 (5.03%) 18
Pneumonia subjects affected / exposed occurrences (all)	7 / 183 (3.83%) 9	15 / 177 (8.47%) 21	11 / 179 (6.15%) 18
Conjunctivitis subjects affected / exposed occurrences (all)	15 / 183 (8.20%) 25	9 / 177 (5.08%) 17	7 / 179 (3.91%) 11
Rhinitis subjects affected / exposed occurrences (all)	11 / 183 (6.01%) 14	8 / 177 (4.52%) 12	11 / 179 (6.15%) 18
Escherichia urinary tract infection subjects affected / exposed occurrences (all)	9 / 183 (4.92%) 47	6 / 177 (3.39%) 11	13 / 179 (7.26%) 25

Onychomycosis subjects affected / exposed occurrences (all)	14 / 183 (7.65%) 33	6 / 177 (3.39%) 9	8 / 179 (4.47%) 14
Fungal skin infection subjects affected / exposed occurrences (all)	8 / 183 (4.37%) 19	9 / 177 (5.08%) 16	8 / 179 (4.47%) 14
Respiratory tract infection subjects affected / exposed occurrences (all)	6 / 183 (3.28%) 11	13 / 177 (7.34%) 31	6 / 179 (3.35%) 12
Tinea versicolour subjects affected / exposed occurrences (all)	2 / 183 (1.09%) 4	3 / 177 (1.69%) 6	9 / 179 (5.03%) 23
Metabolism and nutrition disorders			
Dyslipidaemia subjects affected / exposed occurrences (all)	34 / 183 (18.58%) 110	29 / 177 (16.38%) 69	41 / 179 (22.91%) 124
Hyperkalaemia subjects affected / exposed occurrences (all)	43 / 183 (23.50%) 81	47 / 177 (26.55%) 77	44 / 179 (24.58%) 90
Hypokalaemia subjects affected / exposed occurrences (all)	47 / 183 (25.68%) 104	40 / 177 (22.60%) 88	40 / 179 (22.35%) 102
Hyperglycaemia subjects affected / exposed occurrences (all)	35 / 183 (19.13%) 76	29 / 177 (16.38%) 81	37 / 179 (20.67%) 80
Hypocalcaemia subjects affected / exposed occurrences (all)	35 / 183 (19.13%) 61	37 / 177 (20.90%) 68	22 / 179 (12.29%) 43
Hypophosphataemia subjects affected / exposed occurrences (all)	35 / 183 (19.13%) 70	34 / 177 (19.21%) 60	22 / 179 (12.29%) 56
Hypercholesterolaemia subjects affected / exposed occurrences (all)	21 / 183 (11.48%) 76	20 / 177 (11.30%) 45	23 / 179 (12.85%) 61
Hyperuricaemia			

subjects affected / exposed	16 / 183 (8.74%)	16 / 177 (9.04%)	31 / 179 (17.32%)
occurrences (all)	30	58	73
Hypercalcaemia			
subjects affected / exposed	24 / 183 (13.11%)	16 / 177 (9.04%)	22 / 179 (12.29%)
occurrences (all)	45	27	49
Hypomagnesaemia			
subjects affected / exposed	21 / 183 (11.48%)	14 / 177 (7.91%)	26 / 179 (14.53%)
occurrences (all)	44	20	52
Diabetes mellitus			
subjects affected / exposed	14 / 183 (7.65%)	18 / 177 (10.17%)	19 / 179 (10.61%)
occurrences (all)	27	35	38
Decreased appetite			
subjects affected / exposed	15 / 183 (8.20%)	16 / 177 (9.04%)	17 / 179 (9.50%)
occurrences (all)	27	27	29
Metabolic acidosis			
subjects affected / exposed	15 / 183 (8.20%)	16 / 177 (9.04%)	16 / 179 (8.94%)
occurrences (all)	21	32	25
Hyperphosphataemia			
subjects affected / exposed	16 / 183 (8.74%)	15 / 177 (8.47%)	15 / 179 (8.38%)
occurrences (all)	32	25	29
Acidosis			
subjects affected / exposed	16 / 183 (8.74%)	14 / 177 (7.91%)	15 / 179 (8.38%)
occurrences (all)	33	37	25
Hyponatraemia			
subjects affected / exposed	15 / 183 (8.20%)	13 / 177 (7.34%)	12 / 179 (6.70%)
occurrences (all)	29	24	21
Hyperlipidaemia			
subjects affected / exposed	13 / 183 (7.10%)	13 / 177 (7.34%)	13 / 179 (7.26%)
occurrences (all)	31	20	21
Hypoglycaemia			
subjects affected / exposed	10 / 183 (5.46%)	12 / 177 (6.78%)	13 / 179 (7.26%)
occurrences (all)	13	26	30
Gout			
subjects affected / exposed	3 / 183 (1.64%)	11 / 177 (6.21%)	7 / 179 (3.91%)
occurrences (all)	6	38	10
Dehydration			

subjects affected / exposed	13 / 183 (7.10%)	10 / 177 (5.65%)	8 / 179 (4.47%)
occurrences (all)	18	17	12
Hypertriglyceridaemia			
subjects affected / exposed	1 / 183 (0.55%)	5 / 177 (2.82%)	16 / 179 (8.94%)
occurrences (all)	4	8	41
Fluid overload			
subjects affected / exposed	11 / 183 (6.01%)	5 / 177 (2.82%)	5 / 179 (2.79%)
occurrences (all)	14	9	8

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 February 2005	Post-transplant steroid tapering schedule was included, exclusion criteria for tuberculosis and mammogram requirements was modified.
16 February 2006	Month 24 Glomerular Filtration Rate (GFR) test and sample collection for Angiotensin II Type I (AT-1) receptor antibodies was added, administration of the first belatacept infusion on call to the operating room was permitted. Withholding only the morning dose Cyclosporine A prior to the GFR test Safety monitoring was initiated upon randomization prior to transplant.
29 October 2007	Long-term extension phase, extending the study two years was added, in-line filter manufacturer and specification details were added, serious adverse events reporting contact information and mailing addresses were updated.
13 February 2009	Surveillance measures for post-transplant lymphoproliferative disorder, safety data from the phase 3 studies, revised risk/benefit assessment, serious breach definition and reporting requirements were added. AT-1 receptor antibody sample collection and ICON Medical Monitor were removed.
18 October 2010	Added immunogenicity assessments after discontinuation.
10 February 2011	Updated benefit/risk assessment, added procedures to monitor and better understand post-transplant lymphoproliferative disorder (PTLD) and progressive multifocal leukoencephalopathy (PML), added monitoring guidelines for drug induced liver toxicity (DILI).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported