Clinical trial results:
A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Study to Assess the Efficacy and Safety of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients with Cytomegalovirus (CMV) Infections that are Refractory or Resistant to Treatment with Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir

Summary

EudraCT number	2015-004725-13
Trial protocol	DE GB BE ES FR AT HR IT DK
Global end of trial date	17 August 2020

Results information

Result version number	v1 (current)
This version publication date	25 August 2021
First version publication date	25 August 2021

Trial information

Trial identification

Sponsor protocol code	SHP620-303

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02931539
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Shire
Sponsor organisation address	300 Shire Way, Lexington, United States, MA 02421
Public contact	Study Director, Shire, ClinicalTransparency@takeda.com
Scientific contact	Study Director, Shire, ClinicalTransparency@takeda.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	17 August 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 August 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to compare the efficacy of maribavir to Investigator-assigned Anti-CMV Treatment (IAT) (control) in CMV viremia clearance at the end of Study Week 8 in transplant recipients who were refractory or resistant to prior anti-CMV treatment.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and in compliance with all applicable industry regulations, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guideline E6 (1996), European Union (EU) Directive 2001/20/EC, as well as all applicable national and local laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 191
Country: Number of subjects enrolled	Canada: 14
Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Singapore: 3
Country: Number of subjects enrolled	Belgium: 31
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 49
Country: Number of subjects enrolled	Germany: 20
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	Croatia: 2
Worldwide total number of subjects	352
EEA total number of subjects	122

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)	282
From 65 to 84 years	70
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 94 sites in North America, Europe, and Asia Pacific between 22 December 2016 (first subject first visit) and 17 August 2020 (last subject last visit).

Pre-assignment

Screening details:

Subjects with CMV infections were randomized into 2 treatment groups: IAT and Maribavir 400mg. Subjects randomized to IAT arm, were considered eligible for entry into Maribavir rescue arm at Week 3 if met the criteria for worsening of CMV infection based on medical monitor review. As planned, combined data has been reported for IAT control group.

Period 1

Period 1 title	Period 1: Treatment Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Investigator-assigned Anti-CMV Treatment (IAT)

Arm description:

Subjects received 1 or 2 of the 4 anti-CMV agents from the following: ganciclovir, valganciclovir, foscarnet, or cidofovir based on the investigator's discretion for the 8 week treatment period.

Arm type	Active comparator
Investigational medicinal product name	Ganciclovir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received ganciclovir intravenously based on the the investigator's discretion for the 8 week treatment period.

Investigational medicinal product name	Valganciclovir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received valganciclovir orally based on the the investigator's discretion for the 8 week treatment period.

Investigational medicinal product name	Foscarnet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received foscarnet intravenously based on investigator's discretion for the 8 week treatment period.

Investigational medicinal product name	Cidofovir
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received cidofovir intravenously based on the investigator's discretion for the 8 week treatment period.

Arm title	Maribavir 400 mg

Arm description:

Subjects received maribavir 400 milligram (mg) (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Arm type	Experimental
Investigational medicinal product name	Maribavir
Investigational medicinal product code	SHP620
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Number of subjects in period 1	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg
Started	117	235
Treated Subjects	116	234
Completed	58	199
Not completed	59	36
Adverse event, serious fatal	8	24
Consent withdrawn by subject	16	8
Adverse event, non-fatal	5	1
Subjects transitioned into maribavir rescue arm	22	-
Investigator discretion	1	1
Lost to follow-up	1	2
Protocol deviation	6	-

Period 2

Period 2 title	Period 2: Maribavir Rescue Therapy
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Maribavir Rescue Arm

Arm description:

Subjects with clear evidence of virologic failure (not just intolerance) after a minimum of 3 weeks of therapy with IAT entered maribavir rescue arm and received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Arm type	Experimental
Investigational medicinal product name	Maribavir
Investigational medicinal product code	SHP620
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Number of subjects in period 2[1]	Maribavir Rescue Arm
Started	22
Completed	20
Not completed	2
Sponsor decision	2

Notes:

[1] - 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 subjects who completed the treatment phase entered the Maribavir Rescue Therapy. No subjects from the Maribavir 400 mg entered the Maribavir Rescue Therapy.

Baseline characteristics

Reporting groups	
Reporting group title	Investigator-assigned Anti-CMV Treatment (IAT)
Reporting group description:	
Subjects received 1 or 2 of the 4 anti-CMV agents from the following: ganciclovir, valganciclovir, foscarnet, or cidofovir based on the investigator's discretion for the 8 week treatment period.	
Reporting group title	Maribavir 400 mg
Reporting group description:	
Subjects received maribavir 400 milligram (mg) (2*200 mg tablets), orally, twice daily for the 8 week treatment period.	

Reporting group values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg	Total
Number of subjects	117	235	352
Age categorical Units:			
Age Continuous Units: years			
arithmetic mean	51.5	53.8	
standard deviation	± 12.80	± 13.39	-
Sex: Female, Male Units: subjects			
Female	52	87	139
Male	65	148	213
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	7	14	21
Not Hispanic or Latino	95	198	293
Unknown or Not Reported	15	23	38
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	7	9	16
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	18	29	47
White	87	179	266
More than one race	0	0	0
Unknown or Not Reported	5	18	23

End points

End points reporting groups

Reporting group title	Investigator-assigned Anti-CMV Treatment (IAT)
Reporting group description:	
Subjects received 1 or 2 of the 4 anti-CMV agents from the following: ganciclovir, valganciclovir, foscarnet, or cidofovir based on the investigator's discretion for the 8 week treatment period.	
Reporting group title	Maribavir 400 mg
Reporting group description:	
Subjects received maribavir 400 milligram (mg) (2*200 mg tablets), orally, twice daily for the 8 week treatment period.	
Reporting group title	Maribavir Rescue Arm
Reporting group description:	
Subjects with clear evidence of virologic failure (not just intolerance) after a minimum of 3 weeks of therapy with IAT entered maribavir rescue arm and received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.	

Primary: Percentage of Subjects who Achieved Confirmed Clearance of Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (CMV Viremia Clearance) at end of Week 8

End point title	Percentage of Subjects who Achieved Confirmed Clearance of Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (CMV Viremia Clearance) at end of Week 8
End point description:	
Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration less than (<) lower limit of quantification (LLOQ) that is, <137 International Units per milliliter (IU/mL) when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV Test in 2 consecutive postbaseline samples, separated by at least 5 days. Percentage of subjects with confirmed CMV viremia clearance at end of study Week 8 regardless of whether either study-assigned treatment was discontinued before the end of the stipulated 8 weeks of therapy, and could not have received alternative anti-CMV treatment were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.	
End point type	Primary
End point timeframe:	
Week 8	

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	23.9	55.7		

Statistical analyses

Statistical analysis title	Difference in percentage of responders
Comparison groups	Investigator-assigned Anti-CMV Treatment (IAT) v Maribavir 400 mg
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage of responders
Point estimate	32.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.8
upper limit	42.74

Secondary: Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control at end of Week 8, Followed by Maintenance of Treatment Effect at Week 16

End point title	Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control at end of Week 8, Followed by Maintenance of Treatment Effect at Week 16

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is, <137IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive postbaseline samples, separated by at least 5 days. CMV infection symptom control was defined as resolution or improvement of tissue invasive CMV disease or CMV syndrome for subjects symptomatic at baseline, or maintaining no symptoms of tissue invasive CMV disease or CMV syndrome for subjects asymptomatic at baseline. Percentage of subjects who achieved confirmed CMV viremia clearance and CMV infection symptom control at end of Week 8, followed by maintenance of treatment effect at Week 16. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Up to Week 16

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	10.3	18.7		

Statistical analyses

Statistical analysis title	Difference in percentage of responders
Comparison groups	Investigator-assigned Anti-CMV Treatment (IAT) v Maribavir 400 mg
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage of responders
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.02
upper limit	16.88

Secondary: Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance After Receiving 8 Weeks of Study-assigned Treatment

End point title	Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance After Receiving 8 Weeks of Study-assigned Treatment

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is, <137IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive postbaseline samples, separated by at least 5 days. Percentage of subjects who achieved confirmed CMV viremia clearance after receiving 8 weeks study-assigned treatment at end of Week 8, and maintained this effect through 12, 16 and 20 were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

At Week 8 through Weeks 12, 16 and 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)				
At Week 8	18.8	54.9		
At Week 12	5.1	22.6		
At Week 16	5.1	18.7		
At Week 20	4.3	18.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control After Receiving 8 Weeks of Study-assigned Treatment Through Weeks 12, 16 and 20

End point title	Percentage of Subjects who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control After Receiving 8 Weeks of Study-assigned Treatment Through Weeks 12, 16 and 20

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is, <137IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive postbaseline samples, separated by at least 5 days. CMV infection symptom control was defined as resolution or improvement of tissue invasive CMV disease or CMV syndrome for subjects symptomatic at baseline, or maintaining no symptoms of tissue invasive CMV disease or CMV syndrome for subjects asymptomatic at baseline. Percentage of subjects who achieved confirmed CMV viremia clearance and CMV infection control after receiving 8 weeks study-assigned treatment at end of Week 8, and maintained this effect through 12, 16 and 20 were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

At Week 8 through Weeks 12, 16 and 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)				
At Week 8	18.8	54.9		
At Week 12	5.1	22.6		
At Week 16	5.1	18.7		
At Week 20	4.3	18.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Maintained CMV Viremia Clearance and CMV Infection Symptom Control at the End of Study Week 8 Through Weeks 12 and 20 Regardless of Whether Either Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point title	Percentage of Subjects who Maintained CMV Viremia Clearance and CMV Infection Symptom Control at the End of Study Week 8 Through Weeks 12 and 20 Regardless of Whether Either Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is,

<137IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive postbaseline samples, separated by at least 5 days. CMV infection symptom control was defined as resolution or improvement of tissue invasive CMV disease or CMV syndrome for subjects symptomatic at baseline or maintaining no symptoms of tissue invasive CMV disease or CMV syndrome for subjects asymptomatic at baseline. Percentage of subjects who maintained CMV viremia clearance and CMV infection symptom control at the end of study Week 8 through Weeks 12 and 20 regardless of whether either study-assigned treatment was discontinued before 8 weeks of therapy were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Weeks 8, 12 and 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)				
At Week 8	23.9	55.7		
At Week 12	10.3	22.6		
At Week 20	9.4	18.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Recurrence of CMV Viremia During the First 8 Weeks of Study Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point title	Percentage of Subjects With Recurrence of CMV Viremia During the First 8 Weeks of Study Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration greater than or equal to (>=) LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance, regardless of whether either study-assigned treatment was discontinued before the end of the stipulated 8 weeks of therapy. Percentage of subjects with recurrence of CMV viremia during the first 8 weeks of study regardless of whether study-assigned treatment was discontinued before 8 weeks of therapy were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

At Week 8

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	12.3	17.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Recurrence of CMV Viremia During the 12 Weeks Follow-up Period Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point title	Percentage of Subjects With Recurrence of CMV Viremia During the 12 Weeks Follow-up Period Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance, regardless of whether either study-assigned treatment was discontinued before the end of the stipulated 8 weeks of therapy. Percentage of subjects with recurrence of CMV viremia during the 12 weeks follow-up period regardless of whether study-assigned treatment was discontinued before 8 weeks of therapy were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

End of Week 8 up to Week 20 (12 weeks follow up period)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	21.5	38.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Recurrence of CMV Viremia at any Time on Study Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point title	Percentage of Subjects With Recurrence of CMV Viremia at any Time on Study Regardless of Whether Study-assigned Treatment was Discontinued Before 8 Weeks of Therapy

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance, regardless of whether either study-assigned treatment was discontinued before the end of the stipulated 8 weeks of therapy. Percentage of subjects with recurrence of CMV viremia during at any time on study regardless of whether study-assigned treatment was discontinued before 8 weeks of therapy were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Baseline up to Week 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	33.8	56.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the First 8 Weeks of the Treatment

End point title	Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the First 8 Weeks of the Treatment

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance. Percentage of subjects with recurrence of CMV viremia during the first 8 Weeks of the treatment who completed 8 weeks of study-assigned treatment was reported. Percentage of subjects with recurrence of CMV viremia during the first 8 Weeks of the treatment who completed 8 weeks of study-assigned treatment were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study. Here "number of subjects analyzed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

Baseline up to Week 8

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	183		
Units: percentage of subjects				
number (not applicable)	9.7	15.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the 12 Weeks of Follow-up Period

End point title	Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the 12 Weeks of Follow-up Period

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance. Percentage of subjects who completed 8 weeks of study-assigned treatment with recurrence of CMV viremia during the 12 weeks of follow-up period were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study. Here "number of subjects analysed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

End of Week 8 up to Week 20 (12 weeks follow-up period)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	183		
Units: percentage of subjects				
number (not applicable)	35.5	40.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the 20 Weeks of Study

End point title	Percentage of Subjects who Completed 8 Weeks of Study-assigned Treatment With Recurrence of CMV Viremia During the 20 Weeks of Study

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance. Percentage of subjects who completed 8 weeks of study-assigned treatment with recurrence of CMV viremia during the 20 weeks of study were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study. Here "number of subjects analysed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

Baseline up to Week 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	183		
Units: percentage of subjects				
number (not applicable)	45.2	56.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Recurrence of CMV Viremia While on Study-assigned Treatment

End point title	Percentage of Subjects With Recurrence of CMV Viremia While on Study-assigned Treatment

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance. Percentage of subjects with recurrence of CMV viremia during study-assigned treatment period was reported. Percentage of subjects with recurrence of CMV viremia while on study-assigned treatment period were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Baseline up to termination of study treatment (up to Week 8)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	4.6	15.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Recurrence of CMV Viremia While off Study-assigned Treatment During Follow-up Period

End point title	Percentage of Subjects With Recurrence of CMV Viremia While off Study-assigned Treatment During Follow-up Period

End point description:

Recurrence of CMV viremia was defined as plasma CMV DNA concentration >=LLOQ when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive plasma samples at least 5 days apart, after achieving confirmed viremia clearance. Percentage of subjects with recurrence of CMV viremia while off study-assigned treatment during follow-up period were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Termination of study treatment (Week 8) up to the End of the Study (Week 20)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: percentage of subjects				
number (not applicable)	29.2	40.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who had Maribavir CMV Resistance at Baseline

End point title	Number of Subjects who had Maribavir CMV Resistance at Baseline

End point description:

Resistance-associated amino acid substitutions (RASs) to maribavir are known to generally map to the pUL97 and pUL27 genes. Genotyping was performed to identify RASs mapping to the pUL97 and pUL27 genes. Number of subjects who had maribavir CMV resistance at baseline was reported. The combination of maribavir resistance set (MRS) and non-MRS set (MRS+non-MRS) included all subjects in modified randomized set who had been randomized in the study and who had taken any dose of study-assigned treatment with evaluable CMV genotypic data at baseline with or without pre-existing known maribavir RASs in pUL97 and/or pUL27. Here "number of subjects analysed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

At Baseline

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir Rescue Arm	Maribavir 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	100	17	214	
Units: subjects				
RASs associated with pUL97 only	3	1	0	
RASs associated with pUL27 only	0	0	1	
RASs associated with pUL97 and pUL27	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who had Post-baseline Resistance to Maribavir

End point title	Number of Subjects who had Post-baseline Resistance to Maribavir

End point description:

Resistance-associated amino acid substitutions (RASs) to maribavir are known to generally map to the pUL97 and pUL27 genes. Genotyping was performed to identify RASs mapping to the pUL97 and pUL27 genes. Number of subjects who had postbaseline resistance to maribavir was reported. The combination of maribavir resistance set (MRS) and non-MRS set (MRS+non-MRS) included all subjects in modified randomized set who had been randomized in the study and who had taken any dose of study-assigned treatment with evaluable CMV genotypic data at baseline with or without pre-existing known maribavir RASs in pUL97 and/or pUL27. Here "number of subjects analysed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

After first dose of study drug up to Week 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir Rescue Arm	Maribavir 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	100	17	214	
Units: subjects				
RASs associated with pUL97 only	0	4	45	
RASs associated with pUL27 only	0	0	0	
RASs associated with pUL97 and pUL27	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With All-cause Mortality by the End of the Study

End point title	Number of Subjects With All-cause Mortality by the End of the Study

End point description:

All-cause mortality was analysed by the end of study regardless of the use of rescue treatment or alternative anti-CMV treatment. Number of subjects who died during the entire study period were reported. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

From enrollment up to end of study (approximately 44 months)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: subjects	13	27		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to all Cause Mortality

End point title	Time to all Cause Mortality

End point description:

The time to all-cause mortality by the end of the study participation in days was calculated. Subjects who were alive at the last study follow-up (regardless of use of rescue or alternative anti-CMV treatment), withdrew from study or were lost to follow-up were censored at the date of last contact. The randomized set consisted of all subjects who had signed informed consent and had begun some study procedures and were randomized to the study.

End point type	Secondary

End point timeframe:

Baseline up to Week 20

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	235		
Units: days				
median (full range (min-max))	73.0 (13.0 to	55.0 (3.0 to		

186.0)	182.0)

Statistical analyses

Statistical analysis title	Time to Death
Comparison groups	Investigator-assigned Anti-CMV Treatment (IAT) v Maribavir 400 mg
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.647
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.549
upper limit	2.357

Secondary: Percentage of Subjects who Achieved Confirmed Clearance of Plasma CMV DNA (CMV Viremia Clearance) at end of Week 8 After Starting Maribavir Rescue Treatment

End point title	Percentage of Subjects who Achieved Confirmed Clearance of Plasma CMV DNA (CMV Viremia Clearance) at end of Week 8 After Starting Maribavir Rescue Treatment

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is, <137 IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV Test in 2 consecutive postbaseline samples, separated by at least 5 days, regardless of whether the rescue treatment was discontinued before the end of the stipulated 8 weeks of therapy. Percentage of subjects who achieved confirmed CMV viremia clearance at end of Week 8 after starting maribavir rescue treatment were reported. The rescue set consisted of all subjects who entered the rescue arm and received any dose of maribavir as rescue therapy. As planned, this end point was assessed only in maribavir rescue arm.

End point type	Secondary

End point timeframe:

From start of maribavir rescue treatment through 8 weeks

End point values	Maribavir Rescue Arm			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: percentage of subjects				
number (confidence interval 95%)	50.0 (28.22 to 71.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Receiving Maribavir Rescue Treatment who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control at Week 8 With Maintenance of Effect Through Week 16

End point title	Percentage of Subjects Receiving Maribavir Rescue Treatment who Achieved Confirmed CMV Viremia Clearance and CMV Infection Symptom Control at Week 8 With Maintenance of Effect Through Week 16

End point description:

Confirmed CMV viremia clearance was defined as plasma CMV DNA concentration <LLOQ that is, <137 IU/mL when assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test in 2 consecutive postbaseline samples, separated by at least 5 days. CMV infection symptom control was defined as resolution or improvement of tissue invasive CMV disease or CMV syndrome for subjects symptomatic at baseline, or maintaining no symptoms of tissue invasive CMV disease or CMV syndrome for subjects asymptomatic at baseline. Percentage of subjects receiving maribavir rescue treatment who achieved confirmed CMV viremia clearance and CMV infection symptom control at Week 8 with maintenance of effect through Week 16 were reported. The rescue set consisted of all subjects who entered the rescue arm and received any dose of maribavir as rescue therapy. As planned, this end point was assessed only in maribavir rescue arm.

End point type	Secondary

End point timeframe:

Up to Week 16

End point values	Maribavir Rescue Arm			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: percentage of subjects				
number (confidence interval 95%)				
At Week 16	27.3 (10.73 to 50.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-emergent Adverse Events (TEAEs) and Serious TEAEs During the On-treatment Observation Period

End point title	Number of Subjects with Treatment-emergent Adverse Events (TEAEs) and Serious TEAEs During the On-treatment Observation Period

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. Serious AE was any untoward medical occurrence (whether considered to be related to study-assigned treatment or not) that at any dose resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, resulted in a congenital abnormality/birth defect, or was an important medical event. TEAEs was defined as any adverse events (classified by preferred term) that had a start date on or after the first dose of study treatment or that had a start date before the date of first dose of study treatment, but increased in severity after the first dose of study treatment. The safety set consisted of all subjects who had taken any dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline up to 7 days or 21 days (if cidofovir used) after the last dose of study treatment (up to Week 8)

End point values	Investigator-assigned Anti-CMV Treatment (IAT)	Maribavir Rescue Arm	Maribavir 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	22	234	
Units: subjects				
TEAEs	106	22	228	
Serious TEAEs	43	11	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Predose Concentration (Cmin) of Maribavir

End point title	Predose Concentration (Cmin) of Maribavir[1]

End point description:

Cmin of maribavir was reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. Here "number of subjects analysed" were subjects who were evaluable for this end point.

End point type	Secondary

End point timeframe:

Predose at Week 1, 4 and 8

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	208		
Units: micrograms per milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Cmin at Week 1 (n =20, 208)	8.57 (± 6.28)	8.77 (± 7.88)		

Cmin at Week 4 (n =16, 177)	5.75 (± 3.99)	7.59 (± 7.05)		
Cmin at Week 8 (n =18, 168)	5.65 (± 4.47)	7.19 (± 6.41)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration Time Curve Over the 12-hour Dosing Interval at Steady State (AUC0-tau) of Marivabir for Adolescent Subjects

End point title	Area Under the Concentration Time Curve Over the 12-hour Dosing Interval at Steady State (AUC0-tau) of Marivabir for Adolescent Subjects[2]

End point description:

AUC0-tau of maribavir for adolescent subjects was planned to be reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. This end point was planned to be analysed only in adolescent subjects. Data was not collected and analysed as adolescent subjects were not enrolled in this study.

End point type	Secondary

End point timeframe:

Week 1: Pre-morning dose and 1, 2, 3, 4, 6, 8 and 12 hours post morning dose, Week 4: Pre-morning dose, and Week 8: Pre-morning dose and 2-4 hour post morning dose

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	0[4]		
Units: hour*microgram per milliliter (h*mcg/mL)				
arithmetic mean (standard deviation)	()	()		

Notes:

[3] - No subject was analysed, as none of the adolescents subject were enrolled.

[4] - No subject was analysed, as none of the adolescents subject were enrolled.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Plasma Concentration (Cmax) of Maribavir for Adolescent Subjects

End point title	Maximum Plasma Concentration (Cmax) of Maribavir for Adolescent Subjects[5]

End point description:

Cmax of maribavir for adolescent subjects was planned to be reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. This end point was planned to be analysed only in adolescent subjects. Data was not collected and analysed as adolescent subjects were not enrolled in this study.

End point type	Secondary

End point timeframe:

Week 1: Pre-morning dose and 1, 2, 3, 4, 6, 8 and 12 hours post morning dose

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: micrograms per milliliter (mcg/mL)				
arithmetic mean (standard deviation)	()	()		

Notes:

[6] - No subject was analysed, as none of the adolescents subject were enrolled.

[7] - No subject was analysed, as none of the adolescents subject were enrolled.

Statistical analyses

No statistical analyses for this end point

Secondary: Time When Maximum Concentration is Observed (Tmax) of Maribavir for Adolescent Subjects

End point title	Time When Maximum Concentration is Observed (Tmax) of Maribavir for Adolescent Subjects[8]

End point description:

Tmax of maribavir for adolescent subjects was planned to be reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. This end point was planned to be analysed only in adolescent subjects. Data was not collected and analysed as adolescent subjects were not enrolled in this study.

End point type	Secondary

End point timeframe:

Week 1: Pre-morning dose and 1, 2, 3, 4, 6, 8 and 12 hours post morning dose

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[9]	0[10]		
Units: hours				
median (full range (min-max))	(to)	(to)		

Notes:

[9] - No subject was analysed, as none of the adolescents subject were enrolled.

[10] - No subject was analysed, as none of the adolescents subject were enrolled.

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Oral Clearance (CL/F) of Maribavir for Adolescent Subjects

End point title	Apparent Oral Clearance (CL/F) of Maribavir for Adolescent Subjects[11]

End point description:

Apparent oral clearance (CL/F) of maribavir for adolescent subjects was planned to be reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. This end point was planned to be analysed only in adolescent subjects. Data was not collected and analysed as adolescent subjects were not enrolled in this study.

End point type	Secondary

End point timeframe:

Week 1: Pre-morning dose and 1, 2, 3, 4, 6, 8 and 12 hours post morning dose

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: liter per hour (L/h)				
median (standard deviation)	()	()		

Notes:

[12] - No subject was analysed, as none of the adolescents subject were enrolled.

[13] - No subject was analysed, as none of the adolescents subject were enrolled.

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution (Vz/F) of Maribavir for Adolescent Subjects

End point title	Apparent Volume of Distribution (Vz/F) of Maribavir for Adolescent Subjects[14]

End point description:

Apparent volume of distribution (Vz/F) of maribavir for adolescent subjects was planned to be reported. The pharmacokinetic set consisted of all subjects who had taken any dose of study treatment and who had plasma samples drawn and tested for maribavir concentrations. This end point was planned to be analysed only in adolescent subjects. Data was not collected and analysed as adolescent subjects were not enrolled in this study.

End point type	Secondary

End point timeframe:

Week 1: Pre-morning dose and 1, 2, 3, 4, 6, 8 and 12 hours post morning dose

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Maribavir Rescue Arm	Maribavir 400 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[15]	0[16]		
Units: liter (L)				
arithmetic mean (standard deviation)	()	()		

Notes:

[15] - No subject was analysed, as none of the adolescents subject were enrolled.

[16] - No subject was analysed, as none of the adolescents subject were enrolled.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to end of study (approximately 44 months)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	IAT: Ganciclovir/ Valganciclovir

Reporting group description:

Subjects received ganciclovir intravenously or valganciclovir orally based on the the investigator's discretion for the 8 week treatment period.

Reporting group title	IAT: Foscarnet

Reporting group description:

Subjects received foscarnet intravenously based on investigator's discretion for the 8 week treatment period.

Reporting group title	IAT: Cidofovir

Reporting group description:

Subjects received cidofovir intravenously based on the investigator's discretion for the 8 week treatment period.

Reporting group title	IAT: Foscarnet + Ganciclovir/ Valganciclovir

Reporting group description:

Subjects received foscarnet intravenously in combination with ganciclovir intravenously or valganciclovir orally based on investigator's discretion for the 8 week treatment period.

Reporting group title	Maribavir 400 mg

Reporting group description:

Subjects received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Reporting group title	Maribavir Rescue Arm

Reporting group description:

Subjects with clear evidence of virologic failure (not just intolerance) after a minimum of 3 weeds of therapy with IAT entered maribavir rescue arm and received maribavir 400 mg (2*200 mg tablets), orally, twice daily for the 8 week treatment period.

Serious adverse events	IAT: Ganciclovir/ Valganciclovir	IAT: Foscarnet	IAT: Cidofovir
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 56 (58.93%)	26 / 47 (55.32%)	3 / 6 (50.00%)
number of deaths (all causes)	6	7	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia recurrent			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Leukaemia recurrent			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma recurrent			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post transplant lymphoproliferative disorder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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 interaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 56 (1.79%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Treatment failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in liver			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant rejection			
subjects affected / exposed	2 / 56 (3.57%)	1 / 47 (2.13%)	0 / 6 (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
Graft versus host disease			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 transplant failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 56 (0.00%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Acute respiratory failure			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (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
Dyspnoea			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Pleural effusion			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Pneumonia aspiration			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device breakage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
General physical condition abnormal			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral load increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Incorrect dose administered			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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 pneumothorax			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skin laceration			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Paraesthesia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Ischaemic stroke			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	4 / 56 (7.14%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 47 (0.00%)	0 / 6 (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
Pancytopenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Glaucoma			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Iridocyclitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Haematochezia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 56 (1.79%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal perforation			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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-induced liver injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 56 (0.00%)	6 / 47 (12.77%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematuria			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (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
Renal impairment			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Nephrotic syndrome			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 artery stenosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc compression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BK virus infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus chorioretinitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 colitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	3 / 56 (5.36%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus mucocutaneous ulcer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 47 (0.00%)	0 / 6 (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
Device related infection			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis cytomegalovirus			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (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
Encephalitis viral			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia cryptococcal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (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
Pneumonia haemophilus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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 zoster virus infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral toxoplasmosis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Clostridium colitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 enterocolitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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
Cytomegalovirus gastroenteritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 gastrointestinal infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal skin infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			

subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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 tract infection viral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic arthritis staphylococcal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis fungal			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
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 osteomyelitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (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
Urosepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis hyperchloraemic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IAT: Foscarnet + Ganciclovir/ Valganciclovir	Maribavir 400 mg	Maribavir Rescue Arm
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)	131 / 234 (55.98%)	14 / 22 (63.64%)
number of deaths (all causes)	0	27	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia recurrent			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Leukaemia recurrent			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Diffuse large B-cell lymphoma recurrent			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Post transplant lymphoproliferative disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Venous thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Disease progression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug interaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
General physical health deterioration			

subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	6 / 234 (2.56%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Treatment failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in liver			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Transplant rejection			
subjects affected / exposed	1 / 7 (14.29%)	2 / 234 (0.85%)	0 / 22 (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
Graft versus host disease			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 transplant failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Pleural effusion			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Pneumomediastinum			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device breakage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
General physical condition abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Viral load increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Injury, poisoning and procedural complications			
Incorrect dose administered			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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

Skin laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 infarction			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Nervous system disorders			
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Epilepsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Thrombotic microangiopathy			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Glaucoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridocyclitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 7 (0.00%)	8 / 234 (3.42%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 angiodysplasia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Ileal perforation			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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-induced liver injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Biliary colic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 acute			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	13 / 234 (5.56%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	3 / 14	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Nephrolithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Nephrotic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Vesicoureteric reflux			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Intervertebral disc compression			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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			
Arthritis bacterial			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Aspergillus infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 chorioretinitis			
subjects affected / exposed	0 / 7 (0.00%)	5 / 234 (2.14%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	9 / 234 (3.85%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	1 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 7 (0.00%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus mucocutaneous ulcer			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 syndrome			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 7 (0.00%)	12 / 234 (5.13%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	2 / 13	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Device related sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Encephalitis cytomegalovirus			
subjects affected / exposed	0 / 7 (0.00%)	5 / 234 (2.14%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Encephalitis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Erysipelas			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Escherichia sepsis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Gastroenteritis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
H1N1 influenza			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Osteomyelitis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cryptococcal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Pneumonia haemophilus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Adenovirus infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Bacterial infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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 toxoplasmosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Cytomegalovirus gastrointestinal infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Febrile infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Fungal skin infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	0 / 22 (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
Pneumonia fungal			

subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Salmonellosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Septic arthritis staphylococcal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Sinusitis fungal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal osteomyelitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Stenotrophomonas infection			

subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Failure to thrive			

subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (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
Acidosis hyperchloraemic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (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	IAT: Ganciclovir/ Valganciclovir	IAT: Foscarnet	IAT: Cidofovir
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 56 (96.43%)	43 / 47 (91.49%)	5 / 6 (83.33%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 56 (3.57%)	6 / 47 (12.77%)	0 / 6 (0.00%)
occurrences (all)	2	7	0
Hypotension			

subjects affected / exposed	4 / 56 (7.14%)	2 / 47 (4.26%)	1 / 6 (16.67%)
occurrences (all)	4	2	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	10 / 56 (17.86%)	5 / 47 (10.64%)	0 / 6 (0.00%)
occurrences (all)	10	5	0
Oedema peripheral			
subjects affected / exposed	5 / 56 (8.93%)	7 / 47 (14.89%)	0 / 6 (0.00%)
occurrences (all)	7	10	0
Pyrexia			
subjects affected / exposed	12 / 56 (21.43%)	10 / 47 (21.28%)	2 / 6 (33.33%)
occurrences (all)	15	11	2
Chills			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Gait disturbance			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Temperature intolerance			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 56 (5.36%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
Device related thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	1 / 56 (1.79%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	3 / 56 (5.36%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Transplant rejection			

subjects affected / exposed	0 / 56 (0.00%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 56 (12.50%)	4 / 47 (8.51%)	1 / 6 (16.67%)
occurrences (all)	7	4	1
Dyspnoea			
subjects affected / exposed	4 / 56 (7.14%)	4 / 47 (8.51%)	0 / 6 (0.00%)
occurrences (all)	5	4	0
Epistaxis			
subjects affected / exposed	5 / 56 (8.93%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	5	3	0
Nasal congestion			
subjects affected / exposed	2 / 56 (3.57%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 56 (3.57%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Insomnia			
subjects affected / exposed	2 / 56 (3.57%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
Investigations			
Blood creatinine increased			
subjects affected / exposed	4 / 56 (7.14%)	4 / 47 (8.51%)	0 / 6 (0.00%)
occurrences (all)	4	5	0
Immunosuppressant drug level increased			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			

subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Blood phosphorus decreased			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Clostridium test positive			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Liver function test increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Platelet count decreased			
subjects affected / exposed	4 / 56 (7.14%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	5	4	0
White blood cell count decreased			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Alanine aminotransferase increased			
subjects affected / exposed	3 / 56 (5.36%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 56 (5.36%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Blood urea increased			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	2 / 56 (3.57%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
Weight decreased			
subjects affected / exposed	2 / 56 (3.57%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	3 / 56 (5.36%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 56 (12.50%)	2 / 47 (4.26%)	1 / 6 (16.67%)
occurrences (all)	7	2	1
Dysgeusia			
subjects affected / exposed	4 / 56 (7.14%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	1
Headache			
subjects affected / exposed	9 / 56 (16.07%)	9 / 47 (19.15%)	0 / 6 (0.00%)
occurrences (all)	11	10	0
Taste disorder			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Aura			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 56 (1.79%)	5 / 47 (10.64%)	0 / 6 (0.00%)
occurrences (all)	1	6	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	4 / 56 (7.14%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	7 / 56 (12.50%)	10 / 47 (21.28%)	1 / 6 (16.67%)
occurrences (all)	8	12	2
Leukopenia			
subjects affected / exposed	7 / 56 (12.50%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	8	2	0
Neutropenia			
subjects affected / exposed	19 / 56 (33.93%)	8 / 47 (17.02%)	0 / 6 (0.00%)
occurrences (all)	41	17	0
Thrombocytopenia			
subjects affected / exposed	7 / 56 (12.50%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	8	2	0
Lymphadenopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Chorioretinopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pterygium			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			

subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 56 (7.14%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Abdominal pain upper			
subjects affected / exposed	6 / 56 (10.71%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	8	1	0
Constipation			
subjects affected / exposed	7 / 56 (12.50%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	7	3	0
Diarrhoea			
subjects affected / exposed	16 / 56 (28.57%)	10 / 47 (21.28%)	1 / 6 (16.67%)
occurrences (all)	18	15	2
Nausea			
subjects affected / exposed	12 / 56 (21.43%)	16 / 47 (34.04%)	2 / 6 (33.33%)
occurrences (all)	17	19	2
Vomiting			
subjects affected / exposed	13 / 56 (23.21%)	9 / 47 (19.15%)	1 / 6 (16.67%)
occurrences (all)	16	10	1
Abdominal pain lower			
subjects affected / exposed	0 / 56 (0.00%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Dry mouth			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Odynophagia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Appendix disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Nail disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 56 (5.36%)	7 / 47 (14.89%)	0 / 6 (0.00%)
occurrences (all)	3	9	0
Dysuria			
subjects affected / exposed	2 / 56 (3.57%)	4 / 47 (8.51%)	0 / 6 (0.00%)
occurrences (all)	2	4	0
Micturition urgency			
subjects affected / exposed	0 / 56 (0.00%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Pollakiuria			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 56 (0.00%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Renal failure			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Renal impairment			
subjects affected / exposed	0 / 56 (0.00%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 56 (5.36%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
Pain in extremity			
subjects affected / exposed	6 / 56 (10.71%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	6	1	0
Muscle spasms			
subjects affected / exposed	1 / 56 (1.79%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
Myalgia			
subjects affected / exposed	1 / 56 (1.79%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Back pain			
subjects affected / exposed	2 / 56 (3.57%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Osteopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cytomegalovirus viraemia			
subjects affected / exposed	5 / 56 (8.93%)	3 / 47 (6.38%)	0 / 6 (0.00%)
occurrences (all)	5	3	0
BK virus infection			
subjects affected / exposed	1 / 56 (1.79%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Conjunctivitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			

subjects affected / exposed	4 / 56 (7.14%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	5	2	0
Influenza			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	4 / 56 (7.14%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Urinary tract infection			
subjects affected / exposed	4 / 56 (7.14%)	4 / 47 (8.51%)	0 / 6 (0.00%)
occurrences (all)	4	4	0
Cytomegalovirus infection			
subjects affected / exposed	3 / 56 (5.36%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 56 (3.57%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	3 / 56 (5.36%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Oral herpes			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Systemic bacterial infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 47 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Varicella zoster virus infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 47 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rhinovirus infection			
subjects affected / exposed	2 / 56 (3.57%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	7 / 56 (12.50%)	4 / 47 (8.51%)	1 / 6 (16.67%)
occurrences (all)	7	4	1
Hypokalaemia			
subjects affected / exposed	3 / 56 (5.36%)	8 / 47 (17.02%)	0 / 6 (0.00%)
occurrences (all)	4	12	0
Hypomagnesaemia			
subjects affected / exposed	5 / 56 (8.93%)	9 / 47 (19.15%)	1 / 6 (16.67%)
occurrences (all)	7	10	1
Hypocalcaemia			
subjects affected / exposed	2 / 56 (3.57%)	5 / 47 (10.64%)	0 / 6 (0.00%)
occurrences (all)	2	5	0
Hypophosphataemia			
subjects affected / exposed	3 / 56 (5.36%)	6 / 47 (12.77%)	0 / 6 (0.00%)
occurrences (all)	3	10	0
Fluid overload			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 47 (2.13%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	3 / 56 (5.36%)	2 / 47 (4.26%)	0 / 6 (0.00%)
occurrences (all)	3	3	0

Non-serious adverse events	IAT: Foscarnet + Ganciclovir/ Valganciclovir	Maribavir 400 mg	Maribavir Rescue Arm
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	229 / 234 (97.86%)	22 / 22 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	15 / 234 (6.41%)	1 / 22 (4.55%)
occurrences (all)	1	15	2
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	11 / 234 (4.70%)	1 / 22 (4.55%)
occurrences (all)	0	13	1
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	36 / 234 (15.38%)	3 / 22 (13.64%)
occurrences (all)	1	38	3
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	26 / 234 (11.11%)	3 / 22 (13.64%)
occurrences (all)	2	27	3
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	32 / 234 (13.68%)	5 / 22 (22.73%)
occurrences (all)	0	48	6
Chills			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Gait disturbance			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Temperature intolerance			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	17 / 234 (7.26%)	0 / 22 (0.00%)
occurrences (all)	0	20	0
Device related thrombosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	0 / 7 (0.00%)	6 / 234 (2.56%)	0 / 22 (0.00%)
occurrences (all)	0	6	0
Transplant rejection			
subjects affected / exposed	0 / 7 (0.00%)	8 / 234 (3.42%)	0 / 22 (0.00%)
occurrences (all)	0	9	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 7 (14.29%)	22 / 234 (9.40%)	5 / 22 (22.73%)
occurrences (all)	1	28	5
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	23 / 234 (9.83%)	0 / 22 (0.00%)
occurrences (all)	0	24	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	1 / 22 (4.55%)
occurrences (all)	0	6	1
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	8	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	1 / 22 (4.55%)
occurrences (all)	1	7	1
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	1 / 22 (4.55%)
occurrences (all)	0	4	1
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 7 (14.29%)	18 / 234 (7.69%)	1 / 22 (4.55%)
occurrences (all)	1	19	1
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 7 (0.00%)	21 / 234 (8.97%)	0 / 22 (0.00%)
occurrences (all)	0	23	0
Blood calcium decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Blood phosphorus decreased			

subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Clostridium test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	5 / 234 (2.14%)	1 / 22 (4.55%)
occurrences (all)	0	6	1
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	2 / 22 (9.09%)
occurrences (all)	0	2	2
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	0	7	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Blood urea increased			
subjects affected / exposed	1 / 7 (14.29%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences (all)	1	4	0
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	5 / 234 (2.14%)	1 / 22 (4.55%)
occurrences (all)	0	5	1
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	8 / 234 (3.42%)	0 / 22 (0.00%)
occurrences (all)	0	12	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 7 (0.00%)	9 / 234 (3.85%)	0 / 22 (0.00%)
occurrences (all)	0	9	0
Cardiac disorders			

Atrial flutter			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 7 (28.57%)	20 / 234 (8.55%)	1 / 22 (4.55%)
occurrences (all)	3	23	1
Dysgeusia			
subjects affected / exposed	1 / 7 (14.29%)	88 / 234 (37.61%)	1 / 22 (4.55%)
occurrences (all)	1	95	1
Headache			
subjects affected / exposed	3 / 7 (42.86%)	30 / 234 (12.82%)	2 / 22 (9.09%)
occurrences (all)	3	34	3
Taste disorder			
subjects affected / exposed	0 / 7 (0.00%)	21 / 234 (8.97%)	0 / 22 (0.00%)
occurrences (all)	0	21	0
Aura			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	6 / 234 (2.56%)	1 / 22 (4.55%)
occurrences (all)	1	6	1
Peroneal nerve palsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 7 (14.29%)	2 / 234 (0.85%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Tremor			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	1 / 22 (4.55%)
occurrences (all)	1	7	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	31 / 234 (13.25%)	3 / 22 (13.64%)
occurrences (all)	1	36	3
Leukopenia			

subjects affected / exposed	1 / 7 (14.29%)	12 / 234 (5.13%)	4 / 22 (18.18%)
occurrences (all)	1	15	4
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	38 / 234 (16.24%)	7 / 22 (31.82%)
occurrences (all)	2	92	13
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	18 / 234 (7.69%)	1 / 22 (4.55%)
occurrences (all)	0	19	1
Lymphadenopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 7 (14.29%)	2 / 234 (0.85%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Chorioretinopathy			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	8	0
Pterygium			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	3 / 7 (42.86%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences (all)	4	4	0
Periorbital oedema			
subjects affected / exposed	2 / 7 (28.57%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	2 / 7 (28.57%)	22 / 234 (9.40%)	1 / 22 (4.55%)
occurrences (all)	2	26	1
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)	9 / 234 (3.85%)	1 / 22 (4.55%)
occurrences (all)	1	9	1
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	14 / 234 (5.98%)	3 / 22 (13.64%)
occurrences (all)	2	14	4
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	67 / 234 (28.63%)	10 / 22 (45.45%)
occurrences (all)	4	92	13
Nausea			
subjects affected / exposed	2 / 7 (28.57%)	67 / 234 (28.63%)	5 / 22 (22.73%)
occurrences (all)	4	88	6
Vomiting			
subjects affected / exposed	2 / 7 (28.57%)	46 / 234 (19.66%)	2 / 22 (9.09%)
occurrences (all)	2	69	3
Abdominal pain lower			
subjects affected / exposed	1 / 7 (14.29%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	1 / 7 (14.29%)	10 / 234 (4.27%)	0 / 22 (0.00%)
occurrences (all)	1	11	0
Odynophagia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	9	0
Appendix disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Cholestasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 7 (0.00%)	3 / 234 (1.28%)	1 / 22 (4.55%)
occurrences (all)	0	4	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	26 / 234 (11.11%)	1 / 22 (4.55%)
occurrences (all)	0	33	1
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	6 / 234 (2.56%)	1 / 22 (4.55%)
occurrences (all)	0	7	1
Micturition urgency			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Pollakiuria			
subjects affected / exposed	1 / 7 (14.29%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences (all)	2	4	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	2 / 234 (0.85%)	2 / 22 (9.09%)
occurrences (all)	0	2	2
Renal failure			
subjects affected / exposed	2 / 7 (28.57%)	3 / 234 (1.28%)	2 / 22 (9.09%)
occurrences (all)	2	3	2
Renal impairment			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	1 / 7 (14.29%)	1 / 234 (0.43%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Thyroiditis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	16 / 234 (6.84%)	0 / 22 (0.00%)
occurrences (all)	0	17	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	8 / 234 (3.42%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
Muscle spasms			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	7	0
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 234 (1.28%)	0 / 22 (0.00%)
occurrences (all)	1	3	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	17 / 234 (7.26%)	1 / 22 (4.55%)
occurrences (all)	0	22	1
Osteopenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Cytomegalovirus viraemia			
subjects affected / exposed	2 / 7 (28.57%)	32 / 234 (13.68%)	0 / 22 (0.00%)
occurrences (all)	2	33	0
BK virus infection			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	8	0
Conjunctivitis			
subjects affected / exposed	1 / 7 (14.29%)	2 / 234 (0.85%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Cytomegalovirus infection reactivation			

subjects affected / exposed	0 / 7 (0.00%)	25 / 234 (10.68%)	0 / 22 (0.00%)
occurrences (all)	0	30	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	1 / 234 (0.43%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	13 / 234 (5.56%)	0 / 22 (0.00%)
occurrences (all)	1	16	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	12 / 234 (5.13%)	0 / 22 (0.00%)
occurrences (all)	0	13	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	13 / 234 (5.56%)	0 / 22 (0.00%)
occurrences (all)	0	15	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	12 / 234 (5.13%)	0 / 22 (0.00%)
occurrences (all)	0	16	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	7 / 234 (2.99%)	1 / 22 (4.55%)
occurrences (all)	0	8	1
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	9 / 234 (3.85%)	0 / 22 (0.00%)
occurrences (all)	0	10	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	12 / 234 (5.13%)	0 / 22 (0.00%)
occurrences (all)	0	12	0
Systemic bacterial infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Varicella zoster virus infection			
subjects affected / exposed	1 / 7 (14.29%)	2 / 234 (0.85%)	0 / 22 (0.00%)
occurrences (all)	1	6	0
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	7 / 234 (2.99%)	3 / 22 (13.64%)
occurrences (all)	0	9	3
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	1 / 7 (14.29%)	23 / 234 (9.83%)	3 / 22 (13.64%)
occurrences (all)	1	25	3
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	13 / 234 (5.56%)	2 / 22 (9.09%)
occurrences (all)	1	16	2
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	14 / 234 (5.98%)	4 / 22 (18.18%)
occurrences (all)	0	17	4
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 234 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 234 (1.71%)	2 / 22 (9.09%)
occurrences (all)	0	4	2
Fluid overload			
subjects affected / exposed	1 / 7 (14.29%)	4 / 234 (1.71%)	0 / 22 (0.00%)
occurrences (all)	1	4	0
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	7 / 234 (2.99%)	0 / 22 (0.00%)
occurrences (all)	1	7	0
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	10 / 234 (4.27%)	1 / 22 (4.55%)
occurrences (all)	0	11	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 July 2016	Protocol Amendment 1: Removal of the restriction to utilize only a single commercially available anti-CMV treatment for 8 weeks of the study for the subjects in the IAT arm. Subjects could also continue on prior therapy if this was the treatment option selected by the investigator. Addition of assessment of "invasive bacterial and fungal infection" to the list of safety endpoints since it was one of the AESIs in the study population. Update to the table for prior medications/procedures/diagnostic interventions.
01 December 2016	Protocol Amendment 2: Modification of Inclusion Criterion 10 to only allow enrollment of subjects who were able to swallow tablets. Inclusion of cutoff levels for CMV DNA concentration in whole blood for evaluating eligibility at screening. Emphasis on potent inducers of cytochrome P450 (CYP) 3A4 and/or P-gp and caution for concomitant use of potent inhibitors of CYP 3A4, in alignment with the guidance to the investigators provided in the maribavir Investigator Brochure (IB). Caution and recommendation for careful monitoring of concentration levels of concomitant medications that were substrates of CYP 2C19 and P-gp both after initiation of maribavir (when substrate levels may increase) and after discontinuation of maribavir (when substrate levels may decrease), in alignment with the guidance to the investigators provided in the maribavir IB. Specified that since intolerance to assigned treatment alone did not qualify a subject for the rescue arm, such subjects would not be considered nonresponders for the purpose of primary analysis. The same would be applicable for subjects that might be discontinued from maribavir due to intolerance. Creation of a list of definitions relevant for analyses for easy access and convenience.
01 March 2017	Protocol Amendment 3: Modified primary, key secondary, and secondary objectives and corresponding endpoints to include subjects who had discontinued study treatment early and met the criteria of confirmed CMV viremia clearance as responders in the primary efficacy analysis. Added an intensive PK sampling schedule at Visit 3/Week 1 for adolescent subjects (>=12 to <18 years of age). Modified Inclusion Criterion 5 to indicate that the investigator was to be willing to treat the subject with at least 1 of the available anti-CMV drugs. Note: Combination therapy with foscarnet and cidofovir were not permitted in the IAT arm due to the potential for serious nephrotoxicity. Clarified Inclusion Criterion 9 to indicate that urine-based pregnancy tests may have been performed per institutional requirements (in addition to protocol-required serum β-HCG testing); however, they were not sufficient for eligibility determination. Modified Inclusion Criterion 10 to allow subjects the option to receive tablets crushed and/or dispersed in water via a nasogastric or orogastric tube. Clarified in Exclusion Criterion 13 that subjects who had received an unapproved agent or device within 30 days before initiation of study treatment would not be eligible.

26 March 2018	Protocol Amendment 4: Modified AE collection period to indicate that collection of nonserious AEs that were not related to study-assigned treatment would be restricted to 30 days after the last dose of study-assigned treatment. Amended Exclusion Criterion 6 regarding subjects who had tissue-invasive CMV disease with CNS involvement to indicate that such CNS involvement includes the retina (example, CMV retinitis). Modified the reporting requirements for prior therapeutic or diagnostic interventions performed prior to study enrollment. Clarified procedure requirements for subjects moving from investigator-assigned treatment to rescue arm to indicate that procedures did not need to be repeated when the end-of-treatment visit was performed on the same day as rescue arm entry. Clarified that study treatment could be interrupted for up to 7 consecutive days, or up to 2 study treatment interruptions for a total of up to 7 days. Clarified language regarding sample size calculation, removing anticipated treatment discontinuation rate for foscarnet-treated subjects. Clarified restrictions regarding re-screening of subjects who had previously screen failed. Limited hepatitis testing requirements at screening to antibody testing. Added GVHD assessment criteria forms from cited publications in the appendices. Added letermovir to list of prohibited medications during study, and washout instructions for letermovir use prior to study entry.
11 July 2018	Protocol Amendment 5: Added a study visit at Day 4 (+/-1) for subjects who were taking a narrow therapeutic index immunosuppressive agent (that is, tacrolimus, cyclosporine, everolimus, sirolimus) at baseline to align the protocol with a recent recommendation from the DMC. Added a visit for subjects not taking a narrow therapeutic index immunosuppressive agent at baseline who began therapy during the course of the treatment period (4 days after starting the immunosuppressive agent), and subjects in the IAT arm who entered the maribavir rescue arm (4 days after starting maribavir) to align the protocol with a recent recommendation from the DMC. Updated definition of symptomatic CMV infection to include both tissue-invasive CMV disease and CMV syndrome throughout the protocol.
07 December 2018	Protocol Amendment 6: Specified that any subject not tested for HIV within 3 months prior to screening had to be tested during screening by a local laboratory and must have a negative HIV test result available before randomization. Removed Hematopoietic Cell Transplant Comorbidity Index from assessments, and deleted corresponding appendix describing the tool. Specified KPS and Lansky scales were retained as the only assessment tools for evaluation of comorbidity status. Reduced minimum washout period prior to the first dose of study treatment for letermovir from 14 days to 3 days. For subjects who failed to attain CMV viremia clearance, a Visit 18/Week 20 (previously only Visit 16/Week 16) CMV DNA assessment result above the predefined cut off to necessitate CMV genotyping was added. Identified specific dated Summary of Medicinal Product Characteristics as reference safety information for investigator-assigned treatments. Removed requirement of duplicate SAE and pregnancy reporting to PPD/CRO and Medical Monitors, removed corresponding erroneous contacts, updated name of Shire Global Drug Safety Department, and removed individual names of medical contacts at PPD. Clarified that a product quality complaint from any site had to be directed to a single central e-mail address.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported