Clinical trial results:
A Phase 2, Randomized, Dose-Ranging Study to Assess the Safety And Anti-Cytomegalovirus (CMV) Activity of Maribavir Versus Valganciclovir for Treatment of CMV Infections in Transplant Recipients Who Do Not Have CMV Organ Disease

Summary

EudraCT number	2010-024247-32
Trial protocol	BE DE FR AT ES GB
Global end of trial date	25 July 2014

Results information

Result version number	v1
This version publication date	28 August 2018
First version publication date	01 July 2015

Trial information

Trial identification

Sponsor protocol code	1263-203

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Shire Development LLC (formerly ViroPharma Incorporated)
Sponsor organisation address	725 Chesterbrook Boulevard, Wayne, Pennsylvania, United States, 19087
Public contact	Clinical Study Manager, Viropharma , 0032 23007811, Katrien.Danneels@viropharma.com
Scientific contact	Clinical Study Manager, Viropharma , 0032 23007811, Katrien.Danneels@viropharma.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	11 March 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 July 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of different doses of maribavir versus valganciclovir, administered orally for up to 12 weeks, for treatment of Cytomegalovirus (CMV) infections in recipients of stem cell or solid organ transplants who do not have CMV organ disease.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation of Good Clinical Practice, the principles of the Declaration of Helsinki, as well as other applicable local ethical and legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 May 2012
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	France: 12
Country: Number of subjects enrolled	Germany: 27
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	Austria: 10
Country: Number of subjects enrolled	Belgium: 67
Country: Number of subjects enrolled	Spain: 26
Worldwide total number of subjects	159
EEA total number of subjects	159

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)	124
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects who had neither CMV organ disease nor CMV infection that was genotypically resistant to other anti-CMV drugs and documented CMV infection in blood or plasma, with a screening value of >= 1,000 to <= 100,000 DNA copies/mL as determined by quantitative polymerase chain reaction (PCR) or comparable quantitative CMV assay type were recruited.

Pre-assignment

Screening details:

Of the 174 subjects screened to participate in the study, 13 were screen failures. Therefore, 161 were randomized.

Period 1

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

Blinding implementation details:

Regarding subjects who received maribavir; subjects, investigators, and study staff knew that they were receiving maribavir, but were blinded to dose strength and an unblinded, independent statistician from the Sponsor’s biostatistics contract research organization (CRO) provided the data monitoring committee (DMC) with unblinded data reports for their review.

Arms

Are arms mutually exclusive?	Yes
Arm title	Maribavir 400 mg

Arm description:

Maribavir 400 milligrams (mg) tablet orally twice a day (BID) up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Maribavir
Investigational medicinal product code	VP 41263, SHP620
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Maribavir 400 mg tablet orally BID up to 12 weeks.

Arm title	Maribavir 800 mg

Arm description:

Maribavir 800 mg tablet orally BID up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Maribavir
Investigational medicinal product code	VP 41263, SHP620
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Maribavir 800 mg tablet orally BID up to 12 weeks.

Arm title	Maribavir 1200 mg

Arm description:

Maribavir 1200 mg tablet orally BID up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Maribavir
Investigational medicinal product code	VP 41263, SHP620
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Maribavir 1200 mg tablet orally BID up to 12 weeks.

Arm title	Valganciclovir 900 mg

Arm description:

Valganciclovir 900 mg tablet orally BID for 3 weeks, thereafter once daily (QD) up to 9 weeks.

Arm type	Experimental
Investigational medicinal product name	Valganciclovir
Investigational medicinal product code	
Other name	Valcyte®, Roche
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Valganciclovir 900 mg tablet orally BID for 3 weeks, thereafter QD up to 9 weeks.

Number of subjects in period 1	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg
Started	40	40	39
Completed	36	36	34
Not completed	4	4	5
Physician decision	1	-	-
Consent withdrawn by subject	-	3	2
Death	1	1	3
Lost to follow-up	2	-	-

Number of subjects in period 1	Valganciclovir 900 mg
Started	40
Completed	34
Not completed	6
Physician decision	-
Consent withdrawn by subject	3
Death	3
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Maribavir 400 mg
Reporting group description:	
Maribavir 400 milligrams (mg) tablet orally twice a day (BID) up to 12 weeks.	
Reporting group title	Maribavir 800 mg
Reporting group description:	
Maribavir 800 mg tablet orally BID up to 12 weeks.	
Reporting group title	Maribavir 1200 mg
Reporting group description:	
Maribavir 1200 mg tablet orally BID up to 12 weeks.	
Reporting group title	Valganciclovir 900 mg
Reporting group description:	
Valganciclovir 900 mg tablet orally BID for 3 weeks, thereafter once daily (QD) up to 9 weeks.	

Reporting group values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg
Number of subjects	40	40	39
Age categorical Units: Subjects			
18 to 44 years	11	7	5
45 to 64 years	16	26	26
65 to 75 years	12	7	8
greater than (>) 75 years	1	0	0
Age continuous Units: years			
arithmetic mean	53	54.4	55.9
standard deviation	± 14.18	± 12.72	± 10.69
Gender categorical Units: Subjects			
Female	18	13	17
Male	22	27	22

Reporting group values	Valganciclovir 900 mg	Total	
Number of subjects	40	159	
Age categorical Units: Subjects			
18 to 44 years	9	32	
45 to 64 years	24	92	
65 to 75 years	6	33	
greater than (>) 75 years	1	2	
Age continuous Units: years			
arithmetic mean	54.5		
standard deviation	± 12.36	-	
Gender categorical Units: Subjects			
Female	13	61	

Male	27	98	

End points

End points reporting groups

Reporting group title	Maribavir 400 mg
Reporting group description: Maribavir 400 milligrams (mg) tablet orally twice a day (BID) up to 12 weeks.	
Reporting group title	Maribavir 800 mg
Reporting group description: Maribavir 800 mg tablet orally BID up to 12 weeks.	
Reporting group title	Maribavir 1200 mg
Reporting group description: Maribavir 1200 mg tablet orally BID up to 12 weeks.	
Reporting group title	Valganciclovir 900 mg
Reporting group description: Valganciclovir 900 mg tablet orally BID for 3 weeks, thereafter once daily (QD) up to 9 weeks.	
Subject analysis set title	Maribavir All Doses
Subject analysis set type	Sub-group analysis
Subject analysis set description: Maribavir (N= 119) 400 or 800 or 1200 mg tablet orally BID for 12 weeks.	

Primary: Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 3 Weeks

End point title	Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 3 Weeks
End point description: Plasma CMV DNA was assayed using polymerase chain reaction (PCR) testing, this method was linear over the range 200-100,000 viral copies per milliliter (copies/mL) with a lower limit of quantification (LLOQ) of 200 copies/mL and any results below this LLOQ are referred to as undetectable. Confirmed undetectable plasma CMV DNA (central laboratory) was defined as 2 consecutive post-baseline, on-treatment undetectable results (<200 copies/mL) separated by at least 5 days. Intent-to-treat Safety (ITT-S) Population included all subjects who were randomized and received at least one dose of study drug.	
End point type	Primary
End point timeframe: Within 3 Weeks	

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects	26	23	23	22

End point values	Maribavir All Doses			
Subject group type	Subject analysis set			
Number of subjects analysed	119			
Units: subjects	72			

Statistical analyses

Statistical analysis title	Maribavir 400 mg
Comparison groups	Maribavir 400 mg v Valganciclovir 900 mg
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2775
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	5.08

Statistical analysis title	Maribavir 800 mg
Comparison groups	Maribavir 800 mg v Valganciclovir 900 mg
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7218
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	3.22

Statistical analysis title	Maribavir 1200 mg
Comparison groups	Maribavir 1200 mg v Valganciclovir 900 mg

Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6437
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	3.53

Statistical analysis title	Maribavir All Doses
Comparison groups	Valganciclovir 900 mg v Maribavir All Doses
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0822
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	4.96

Primary: Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 weeks

End point title	Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 weeks

End point description:

Plasma CMV DNA was assayed using PCR testing, this method was linear over the range 200-100,000 viral copies/mL with a LLOQ of 200 copies/mL and any results below this LLOQ are referred to as undetectable. Confirmed undetectable plasma CMV DNA (central laboratory) was defined as 2 consecutive post-baseline, on-treatment undetectable results (<200 copies/mL) separated by at least 5 days. Censored observations included subjects who did not meet the criteria for confirmed undetectable plasma CMV DNA within 6 weeks and subjects who discontinued the study for any reason prior to achieving undetectable plasma CMV DNA. ITT-S population.

End point type	Primary

End point timeframe:

Within 6 weeks

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects				
Subjects with event	31	33	28	26
Subjects censored, discontinued	1	1	2	2
Subjects censored, ongoing	7	6	8	11

End point values	Maribavir All Doses			
Subject group type	Subject analysis set			
Number of subjects analysed	119			
Units: subjects				
Subjects with event	92			
Subjects censored, discontinued	4			
Subjects censored, ongoing	21			

Statistical analyses

Statistical analysis title	Maribavir 400 mg
Comparison groups	Maribavir 400 mg v Valganciclovir 900 mg
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1712
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	6.3

Statistical analysis title	Maribavir 800 mg
Comparison groups	Maribavir 800 mg v Valganciclovir 900 mg
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0633
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	9.35

Statistical analysis title	Maribavir 1200 mg
Comparison groups	Maribavir 1200 mg v Valganciclovir 900 mg
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4528
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	4.16

Statistical analysis title	Maribavir All Doses
Comparison groups	Valganciclovir 900 mg v Maribavir All Doses
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0822
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	4.96

Secondary: Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up (Week 1, 4, 8, 12)

End point title	Number Of Subjects With Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up (Week 1, 4, 8, 12)

End point description:

Plasma CMV DNA was assayed using PCR testing, this method was linear over the range 200-100,000

viral copies/mL with a LLOQ of 200 copies/mL and any results below this LLOQ are referred to as undetectable. Confirmed undetectable plasma CMV DNA (central laboratory) was defined as 2 consecutive post-baseline, on-treatment undetectable results (<200 copies/mL) separated by at least 5 days. Observed and last observation carried forward (LOCF) data were presented. ITT-S population.

End point type	Secondary

End point timeframe:

Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up (Week 1, 4, 8, 12)

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects				
Baseline	4	4	2	4
Week 1 (observed)	10	10	11	17
Week 1 (LOCF)	0	0	0	0
Week 2 (observed)	22	14	20	19
Week 2 (LOCF)	0	0	1	2
Week 3 (observed)	25	24	22	19
Week 3 (LOCF)	3	1	4	6
Week 4 (observed)	27	27	25	24
Week 4 (LOCF)	6	4	6	7
Week 5 (observed)	23	25	21	19
Week 5 (LOCF)	11	9	10	13
Week 6 (observed)	23	23	22	17
Week 6 (LOCF)	11	10	10	15
Week 8 (observed)	16	12	17	16
Week 8 (LOCF)	17	20	14	17
Week 10 (observed)	13	8	14	11
Week 10 (LOCF)	18	24	17	21
Week 12 (observed)	11	7	14	12
Week 12 (LOCF)	20	25	17	21
Follow-up Week 1 (observed)	27	25	25	23
Follow-up Week 1 (LOCF)	3	1	5	2
Follow-up Week 4 (observed)	25	21	23	22
Follow-up Week 4 (LOCF)	2	1	4	2
Follow-up Week 8 (observed)	26	27	27	21
Follow-up Week 8 (LOCF)	3	3	6	4
Follow-up Week 12 (observed)	27	29	27	24
Follow-up Week 12 (LOCF)	4	4	4	4

End point values	Maribavir All Doses			
Subject group type	Subject analysis set			
Number of subjects analysed	119			
Units: subjects				
Baseline	10			
Week 1 (observed)	31			

Week 1 (LOCF)	0			
Week 2 (observed)	56			
Week 2 (LOCF)	1			
Week 3 (observed)	71			
Week 3 (LOCF)	8			
Week 4 (observed)	79			
Week 4 (LOCF)	16			
Week 5 (observed)	69			
Week 5 (LOCF)	30			
Week 6 (observed)	68			
Week 6 (LOCF)	31			
Week 8 (observed)	45			
Week 8 (LOCF)	51			
Week 10 (observed)	35			
Week 10 (LOCF)	59			
Week 12 (observed)	32			
Week 12 (LOCF)	62			
Follow-up Week 1 (observed)	77			
Follow-up Week 1 (LOCF)	9			
Follow-up Week 4 (observed)	69			
Follow-up Week 4 (LOCF)	7			
Follow-up Week 8 (observed)	80			
Follow-up Week 8 (LOCF)	12			
Follow-up Week 12 (observed)	83			
Follow-up Week 12 (LOCF)	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number Of Subjects With Undetectable Blood/Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up (Week 1, 4, 8, 12)

End point title	Number Of Subjects With Undetectable Blood/Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up (Week 1, 4, 8, 12)

End point description:

Plasma CMV DNA was assayed using PCR testing, this method was linear over the range 200-100,000 viral copies/mL with a LLOQ of 200 copies/mL and any results below this LLOQ are referred to as undetectable. Observed and LOCF data were presented. ITT-S population.

End point type	Secondary

End point timeframe:

Baseline, Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up Week (1, 4, 8, 12)

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects				
Baseline	4	4	2	4
Week 1 (observed)	10	10	11	17
Week 1 (LOCF)	0	0	0	0
Week 2 (observed)	22	14	20	20
Week 2 (LOCF)	0	0	1	2
Week 3 (observed)	25	24	22	19
Week 3 (LOCF)	3	1	4	6
Week 4 (observed)	28	27	25	24
Week 4 (LOCF)	5	4	6	7
Week 5 (observed)	24	27	21	20
Week 5 (LOCF)	10	7	10	12
Week 6 (observed)	23	23	22	17
Week 6 (LOCF)	11	10	10	15
Week 8 (observed)	17	13	18	16
Week 8 (LOCF)	16	19	13	17
Week 10 (observed)	13	8	14	11
Week 10 (LOCF)	18	24	17	21
Week 12 (observed)	11	7	14	12
Week 12 (LOCF)	20	25	17	21
Follow-up Week 1 (observed)	27	25	26	24
Follow-up Week 1 (LOCF)	3	0	4	1
Follow-up Week 4 (observed)	25	22	23	22
Follow-up Week 4 (LOCF)	1	0	4	2
Follow-up Week 8 (observed)	27	28	28	23
Follow-up Week 8 (LOCF)	2	2	4	2
Follow-up Week 12 (observed)	27	29	27	25
Follow-up Week 12 (LOCF)	4	4	4	4

End point values	Maribavir All Doses			
Subject group type	Subject analysis set			
Number of subjects analysed	119			
Units: subjects				
Baseline	10			
Week 1 (observed)	31			
Week 1 (LOCF)	0			
Week 2 (observed)	56			
Week 2 (LOCF)	1			
Week 3 (observed)	71			
Week 3 (LOCF)	8			
Week 4 (observed)	80			
Week 4 (LOCF)	15			
Week 5 (observed)	72			
Week 5 (LOCF)	27			
Week 6 (observed)	68			

Week 6 (LOCF)	31			
Week 8 (observed)	48			
Week 8 (LOCF)	48			
Week 10 (observed)	35			
Week 10 (LOCF)	59			
Week 12 (observed)	32			
Week 12 (LOCF)	62			
Follow-up Week 1 (observed)	78			
Follow-up Week 1 (LOCF)	7			
Follow-up Week 4 (observed)	70			
Follow-up Week 4 (LOCF)	5			
Follow-up Week 8 (observed)	83			
Follow-up Week 8 (LOCF)	8			
Follow-up Week 12 (observed)	83			
Follow-up Week 12 (LOCF)	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number Of Subjects With Cytomegalovirus (CMV) Recurrence Within the Study Participation Period

End point title	Number Of Subjects With Cytomegalovirus (CMV) Recurrence Within the Study Participation Period

End point description:

CMV recurrence during the study was defined as the first of at least 2 consecutive samples, separated by at least 5 days, with detectable plasma CMV DNA (central laboratory) after achievement of undetectable plasma CMV DNA (central laboratory) in at least 2 consecutive samples, separated by at least 5 days, at any time after Day 1 within the study participation period. Number of subjects analysed included those subjects who had confirmed undetectable CMV DNA. ITT-S population.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	34	31	28
Units: subjects	10	8	4	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Cytomegalovirus (CMV) Recurrence During The Study

End point title	Number of Subjects With Cytomegalovirus (CMV) Recurrence During The Study

End point description:

Confirmed undetectable plasma CMV DNA to CMV recurrence during the study was defined as the first of at least 2 consecutive samples, separated by at least 5 days, with detectable plasma CMV DNA (central laboratory) after achievement of undetectable plasma CMV DNA (central laboratory) in at least 2 consecutive samples, separated by at least 5 days. Censored observations included subjects who did not meet the criteria for CMV recurrence and subjects who discontinued the study for any reason prior to achieving undetectable plasma CMV DNA. ITT-S population.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects				
Subjects achieving confirmed undetectable CMV DNA	33	34	31	28
Subjects with event	10	8	4	5
Subjects censored, discontinued	2	3	4	2
Subjects censored, ongoing	21	23	23	21

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Cytomegalovirus (CMV) Recurrence From Last Dose of Study Drug During The Study

End point title	Number of Subjects With Cytomegalovirus (CMV) Recurrence From Last Dose of Study Drug During The Study

End point description:

Last Dose Of Study Drug To CMV recurrence during the study was defined as the first of at least 2 consecutive samples, separated by at least 5 days, with detectable plasma CMV DNA (central laboratory) after achievement of undetectable plasma CMV DNA (central laboratory) in at least 2 consecutive samples, separated by at least 5 days, after the last dose of study drug. Censored observations included subjects who did not meet the criteria for CMV recurrence and subjects who discontinued the study for any reason prior to achieving undetectable plasma CMV DNA. ITT-S population.

End point type	Secondary

End point timeframe:

Up to week 24

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects				
Subjects with CMV recurrence through last dose	30	32	30	28
Subjects with event	8	6	4	5
Subjects censored, discontinued	1	3	3	2
Subjects censored, ongoing	21	23	23	21

Statistical analyses

No statistical analyses for this end point

Secondary: Number Of Subjects Using Any Non-Study Systemic Anti-Cytomegalovirus (Anti-CMV) Therapies Within 6 Weeks

End point title	Number Of Subjects Using Any Non-Study Systemic Anti-Cytomegalovirus (Anti-CMV) Therapies Within 6 Weeks

End point description:

Non-study systemic anti-CMV therapies included ganciclovir, valganciclovir, foscarnet, cidofovir, CMV immune globulin (CMV-IGIV, Cytogam®), leflunomide, or artesunate. ITT-S population.

End point type	Secondary

End point timeframe:

Within 6 Weeks

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects	7	4	7	8

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Days of Use of Non-Study Systemic Anti-Cytomegalovirus (CMV) Therapies after Day 1 and within 6 Weeks

End point title	Number of Days of Use of Non-Study Systemic Anti-Cytomegalovirus (CMV) Therapies after Day 1 and within 6 Weeks

End point description:

Non-study systemic anti-CMV therapies included ganciclovir, valganciclovir, foscarnet, cidofovir, CMV immune globulin (CMV-IGIV, Cytogam®), leflunomide, or artesunate. ITT-S population.

End point type	Secondary

End point timeframe:

Day 1 up to Week 6

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: days				
arithmetic mean (standard deviation)	2.6 (± 7.44)	1 (± 5.53)	3.2 (± 9.27)	2.5 (± 7.04)

Statistical analyses

No statistical analyses for this end point

Secondary: Time To First Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 Weeks: Kaplan Meier Estimate

End point title	Time To First Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 Weeks: Kaplan Meier Estimate

End point description:

Time to first undetectable plasma CMV DNA within 6 Weeks defined as the date of the first of at least 2 consecutive post-baseline, on-treatment undetectable results (<200 copies/mL) separated by at least 5 days. Median analyzed using Kaplan Meier estimates data were reported. ITT-S population.

End point type	Secondary

End point timeframe:

Within 6 weeks

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: days				
median (confidence interval 95%)				
Kaplan-Meier estimate-Median	15 (15 to 22)	22 (16 to 29)	21 (14 to 22)	17 (8 to 25)

Statistical analyses

No statistical analyses for this end point

Secondary: Time To First Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 Weeks: Median Observed Event Time

End point title	Time To First Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) Within 6 Weeks: Median Observed Event Time

End point description:

Time to first undetectable plasma CMV DNA within 6 Weeks defined as the date of the first of at least 2 consecutive post-baseline, on-treatment undetectable results (<200 copies/mL) separated by at least 5 days. Median analyzed using Kaplan Meier estimates data were reported. ITT-S population.

End point type	Secondary

End point timeframe:

Within 6 weeks

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: days				
number (not applicable)				
Median observed event time	15	22	15	8.5

Statistical analyses

No statistical analyses for this end point

Secondary: Time from Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) to Cytomegalovirus (CMV) Recurrence During The Study

End point title	Time from Confirmed Undetectable Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) to Cytomegalovirus (CMV) Recurrence During The Study

End point description:

Time from confirmed undetectable plasma CMV DNA to CMV recurrence during the study was defined as the first of at least 2 consecutive samples, separated by at least 5 days, with detectable plasma CMV DNA (central laboratory) after achievement of undetectable plasma CMV DNA (central laboratory) in at least 2 consecutive samples, separated by at least 5 days, at any time after the confirmed undetectable plasma CMV DNA. Data was presented with median observed event time. ITT-S population.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: days				
number (not applicable)				
Median observed event time	72	43	83.5	80

Statistical analyses

No statistical analyses for this end point

Secondary: Time From Last Dose Of Study Drug To Cytomegalovirus (CMV) Recurrence During The Study

End point title	Time From Last Dose Of Study Drug To Cytomegalovirus (CMV) Recurrence During The Study

End point description:

Time From Last Dose Of Study Drug To CMV recurrence during the study was defined as the first of at least 2 consecutive samples, separated by at least 5 days, with detectable plasma CMV DNA (central laboratory) after achievement of undetectable plasma CMV DNA (central laboratory) in at least 2 consecutive samples, separated by at least 5 days, after the last dose of study drug. Data was presented with median observed event time. ITT-S population.

End point type	Secondary

End point timeframe:

Up to week 24

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: days				
number (not applicable)				
Median observed event time	28	7.5	28	23

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up Week (1, 4, 8, 12)

End point title	Change from Baseline in Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) at Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up Week (1, 4, 8, 12)

End point description:

Plasma CMV DNA was assayed using PCR testing, this method was linear over the range 200-100,000 viral copies/mL with a LLOQ of 200 copies/mL and any results below this LLOQ are referred to as undetectable. ITT-S population.

End point type	Secondary

End point timeframe:

Week 1, 2, 3, 4, 5, 6, 8, 10, 12, Follow-up Week (1, 4, 8, 12)

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: log10 copies per milliliter				
arithmetic mean (standard deviation)				
Week 1	-0.7 (± 0.508)	-0.72 (± 0.643)	-0.77 (± 0.579)	-0.63 (± 0.614)
Week 2	-1.01 (± 0.773)	-0.85 (± 0.804)	-1.02 (± 0.859)	-0.86 (± 0.795)
Week 3	-1.24 (± 0.853)	-1.31 (± 0.816)	-1.19 (± 0.82)	-1.09 (± 0.841)
Week 4	-1.35 (± 0.911)	-1.5 (± 0.909)	-1.27 (± 0.921)	-1.18 (± 0.921)
Week 5	-1.34 (± 0.917)	-1.56 (± 0.961)	-1.27 (± 0.921)	-1.19 (± 0.934)
Week 6	-1.28 (± 0.957)	-1.52 (± 1.033)	-1.28 (± 0.921)	-1.2 (± 0.939)
Week 8	-1.26 (± 0.959)	-1.48 (± 1.013)	-1.26 (± 0.924)	-1.21 (± 0.938)
Week 10	-1.2 (± 0.969)	-1.45 (± 1.005)	-1.25 (± 0.937)	-1.2 (± 0.929)
Week 12	-1.18 (± 0.982)	-1.4 (± 1.061)	-1.23 (± 0.958)	-1.23 (± 0.935)
Follow-up Week 1	-1.19 (± 0.983)	-1.28 (± 1.031)	-1.26 (± 0.909)	-1.18 (± 0.856)
Follow-up Week 4	-1.19 (± 0.916)	-1.08 (± 1.097)	-1.38 (± 0.943)	-0.93 (± 0.909)
Follow-up Week 8	-1.2 (± 0.999)	-1.53 (± 0.942)	-1.42 (± 0.973)	-0.95 (± 1.045)
Follow-up Week 12	-1.23 (± 0.894)	-1.55 (± 0.905)	-1.43 (± 0.975)	-1.14 (± 0.947)

Statistical analyses

No statistical analyses for this end point

Secondary: Rate Of Change In Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) At Weeks 3 And 6

End point title	Rate Of Change In Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) At Weeks 3 And 6

End point description:

Rate of change in plasma CMV DNA was measured by change from baseline divided by number of weeks. Mean rate of change in plasma CMV DNA is reported. ITT-S population.

End point type	Secondary

End point timeframe:

Week 3 and 6

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: log10 Copies/mL per Week				
arithmetic mean (confidence interval 95%)				
Week 3	-0.41 (-0.5 to -0.32)	-0.44 (-0.52 to -0.35)	-0.4 (-0.49 to -0.31)	-0.36 (-0.45 to -0.27)
Week 6	-0.21 (-0.26 to -0.16)	-0.25 (-0.31 to -0.2)	-0.21 (-0.26 to -0.16)	-0.2 (-0.25 to -0.15)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Change in Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) At Weeks 3 And 6

End point title	Number of Subjects With Change in Plasma Cytomegalovirus (CMV) Deoxyribonucleic Acid (DNA) (Central Laboratory) At Weeks 3 And 6

End point description:

Data was presented for number of subjects with LOCF. ITT-S population.

End point type	Secondary

End point timeframe:

Week 3 and 6

End point values	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg	Valganciclovir 900 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	40	39	40
Units: subjects	7	3	10	12

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to Follow-up Week 24	
Adverse event reporting additional description:	
National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)	
Assessment type	Systematic

Dictionary used	
Dictionary name	NCI CTCAE
Dictionary version	4.03

Reporting groups	
Reporting group title	Maribavir 400 mg
Reporting group description:	
Maribavir 400 mg table orally twice daily up to 12 weeks	
Reporting group title	Maribavir 800 mg
Reporting group description:	
Maribavir 800 mg table orally twice daily up to 12 weeks	
Reporting group title	Maribavir 1200 mg
Reporting group description:	
Maribavir 1200 mg table orally twice daily up to 12 weeks	
Reporting group title	Valganciclovir 900 mg
Reporting group description:	
Valganciclovir 900 mg tablet orally twice daily for three weeks and post that daily once up to 12 weeks.	

Serious adverse events	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 40 (40.00%)	17 / 40 (42.50%)	19 / 39 (48.72%)
number of deaths (all causes)	2	1	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Plasma cell myeloma			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Catheter site haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-Organ failure			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (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
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 39 (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
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	3 / 39 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney transplant rejection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Liver transplant rejection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (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
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 39 (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
C-Reactive protein increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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			
Toxic encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Aplasia pure red cell			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic anaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (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
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 toxicity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic artery thrombosis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 and urinary disorders			
Renal failure			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 abscess			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bk virus infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 39 (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
Hepatitis c			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pseudomonal sepsis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
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 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
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 abscess			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxoplasmosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
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	0 / 40 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (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
Diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
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	Valganciclovir 900		

	mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 40 (32.50%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Catheter site haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multi-Organ failure			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney transplant rejection			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver transplant rejection			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
C-Reactive protein increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrocardiogram abnormal			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Toxic encephalopathy			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Aplasia pure red cell			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrogenic anaemia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombotic microangiopathy			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal toxicity			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			

Bile duct stone				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic artery thrombosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Renal failure				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteolysis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Adenovirus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	3 / 40 (7.50%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Biliary abscess				

subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary sepsis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bk virus infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter gastroenteritis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Catheter site infection				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus gastroenteritis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Enterobacter sepsis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis c				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral herpes				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal abscess				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Staphylococcal bacteraemia				
subjects affected / exposed	1 / 40 (2.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxoplasmosis				
subjects affected / exposed	0 / 40 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				

subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Maribavir 400 mg	Maribavir 800 mg	Maribavir 1200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 40 (95.00%)	36 / 40 (90.00%)	37 / 39 (94.87%)
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	2	2	2
Hypertension			
subjects affected / exposed	3 / 40 (7.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	3	0	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 40 (2.50%)	3 / 40 (7.50%)	1 / 39 (2.56%)
occurrences (all)	1	3	1
Malaise			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Fatigue			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	2 / 39 (5.13%)
occurrences (all)	2	3	2
Oedema peripheral			
subjects affected / exposed	3 / 40 (7.50%)	9 / 40 (22.50%)	5 / 39 (12.82%)
occurrences (all)	4	10	5
Pyrexia			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	4 / 39 (10.26%)
occurrences (all)	3	2	4
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	3 / 40 (7.50%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	4	1	1
Kidney transplant rejection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Drug hypersensitivity			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	1	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 40 (12.50%)	6 / 40 (15.00%)	6 / 39 (15.38%)
occurrences (all)	7	6	6
Dyspnoea			
subjects affected / exposed	3 / 40 (7.50%)	3 / 40 (7.50%)	6 / 39 (15.38%)
occurrences (all)	3	3	6
Oropharyngeal pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Epistaxis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Psychiatric disorders			

Apathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	1	2	2
Blood magnesium decreased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	0 / 39 (0.00%)
occurrences (all)	2	3	0
C-Reactive protein increased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Immunosuppressant drug level increased			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	5 / 39 (12.82%)
occurrences (all)	2	2	6
Weight decreased			
subjects affected / exposed	6 / 40 (15.00%)	2 / 40 (5.00%)	3 / 39 (7.69%)
occurrences (all)	6	2	3
Weight increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0

Wound			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	1	1	2
Dysgeusia			
subjects affected / exposed	18 / 40 (45.00%)	16 / 40 (40.00%)	14 / 39 (35.90%)
occurrences (all)	19	16	16
Headache			
subjects affected / exposed	4 / 40 (10.00%)	4 / 40 (10.00%)	6 / 39 (15.38%)
occurrences (all)	4	4	6
Paraesthesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	3 / 39 (7.69%)
occurrences (all)	0	0	3
Tremor			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	4 / 39 (10.26%)
occurrences (all)	1	1	4
Syncope			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 40 (5.00%)	7 / 40 (17.50%)	3 / 39 (7.69%)
occurrences (all)	2	7	3
Leukopenia			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	2	2	0
Nephrogenic anaemia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	1	1	2
Neutropenia			
subjects affected / exposed	1 / 40 (2.50%)	3 / 40 (7.50%)	1 / 39 (2.56%)
occurrences (all)	1	3	1
Thrombocytopenia			

subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	2	1	1
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	4 / 39 (10.26%)
occurrences (all)	2	4	4
Abdominal pain upper			
subjects affected / exposed	4 / 40 (10.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	4	2	1
Constipation			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	4 / 39 (10.26%)
occurrences (all)	2	4	4
Diarrhoea			
subjects affected / exposed	7 / 40 (17.50%)	6 / 40 (15.00%)	8 / 39 (20.51%)
occurrences (all)	8	7	9
Dry mouth			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	1	2	2
Dyspepsia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Haemorrhoids			

subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	1 / 39 (2.56%)
occurrences (all)	2	1	1
Nausea			
subjects affected / exposed	9 / 40 (22.50%)	7 / 40 (17.50%)	11 / 39 (28.21%)
occurrences (all)	10	8	13
Stomatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	4 / 40 (10.00%)	7 / 40 (17.50%)	11 / 39 (28.21%)
occurrences (all)	5	7	15
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	3 / 40 (7.50%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Rash			
subjects affected / exposed	2 / 40 (5.00%)	4 / 40 (10.00%)	1 / 39 (2.56%)
occurrences (all)	4	4	1
Pruritus			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	2	2	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	3 / 39 (7.69%)
occurrences (all)	1	0	3
Nocturia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Proteinuria			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Renal failure			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	4 / 39 (10.26%)
occurrences (all)	2	1	4
Renal impairment			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Muscular weakness			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	2	0	0
Pain in extremity			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	3 / 40 (7.50%)	3 / 40 (7.50%)	1 / 39 (2.56%)
occurrences (all)	3	3	1
Herpes zoster			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	7 / 40 (17.50%)	5 / 40 (12.50%)	0 / 39 (0.00%)
occurrences (all)	8	5	0
Oral candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Oesophageal candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Pneumonia			

subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	1 / 39 (2.56%)
occurrences (all)	2	0	1
Oral herpes			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	2 / 39 (5.13%)
occurrences (all)	3	2	2
Rhinitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Urinary tract infection			
subjects affected / exposed	5 / 40 (12.50%)	4 / 40 (10.00%)	5 / 39 (12.82%)
occurrences (all)	6	5	6
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 40 (10.00%)	5 / 40 (12.50%)	4 / 39 (10.26%)
occurrences (all)	4	5	4
Diabetes mellitus			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 39 (5.13%)
occurrences (all)	1	0	2
Hypercalcaemia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	1 / 39 (2.56%)
occurrences (all)	2	2	1
Hypokalaemia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	5 / 39 (12.82%)
occurrences (all)	2	1	7
Metabolic acidosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	3 / 39 (7.69%)
occurrences (all)	0	0	3

Non-serious adverse events	Valganciclovir 900 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 40 (70.00%)		
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Hypertension			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	7		
Pyrexia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Acute graft versus host disease			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Kidney transplant rejection			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	6		
Dyspnoea			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Apathy			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Investigations			
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Blood magnesium decreased			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Hepatic enzyme increased			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
C-Reactive protein increased			

subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Immunosuppressant drug level increased			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Weight increased			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	2		
Paraesthesia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Syncope			

subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Leukopenia			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Nephrogenic anaemia			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Thrombocytopenia			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
Abdominal pain upper			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		

Constipation subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Diarrhoea subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 4		
Dry mouth subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 3		
Dyspepsia subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	6 / 40 (15.00%) 6		
Stomatitis subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	4 / 40 (10.00%) 4		
Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1		
Rash subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 4		
Pruritus			

subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1		
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) Nocturia subjects affected / exposed occurrences (all) Proteinuria subjects affected / exposed occurrences (all) Renal failure subjects affected / exposed occurrences (all) Renal impairment subjects affected / exposed occurrences (all)	 1 / 40 (2.50%) 1 0 / 40 (0.00%) 0 0 / 40 (0.00%) 0 0 / 40 (0.00%) 0 0 / 40 (0.00%) 0		
Musculoskeletal and connective tissue disorders Muscle spasms subjects affected / exposed occurrences (all) Muscular weakness subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all)	 1 / 40 (2.50%) 1 2 / 40 (5.00%) 2 2 / 40 (5.00%) 2 2 / 40 (5.00%) 2		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Cytomegalovirus infection	 3 / 40 (7.50%) 3 		

subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Oral candidiasis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Oesophageal candidiasis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 40 (0.00%)		
occurrences (all)	0		
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Urinary tract infection			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		

Diabetes mellitus subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1		
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2		
Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2013	Added a new protocol section to clarify medications that were used for prevention or treatment of Herpes simplex virus (HSV) or Varicella zoster virus (VZV) infections during the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported