Clinical trial results:
A Phase 1b/Randomized Phase 2 Study to Evaluate LY3039478 in Combination with Dexamethasone in T-ALL/T-LBL Patients

Summary

EudraCT number	2014-005024-10
Trial protocol	DE SE IT
Global end of trial date	15 January 2018

Results information

Result version number	v1 (current)
This version publication date	09 February 2019
First version publication date	09 February 2019

Trial information

Trial identification

Sponsor protocol code	I6F-MC-JJCB

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02518113
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 14548

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	15 January 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase1: to determine the recommended dose of LY3039478 in combination with dexamethasone in adult patients with relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL) (Part A) and pediatric patients (Part B)
Phase2: to determine if the overall remission rate (ORR) (CR plus CR with incomplete blood count recovery [CRi]) in adult patients with relapsed/refractory T-ALL/T-LBL treated with LY3039478 in combination with dexamethasone exceeds that of those patients treated with placebo in combination with dexamethasone

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	United States: 17
Country: Number of subjects enrolled	Italy: 4
Worldwide total number of subjects	36
EEA total number of subjects	19

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)	34
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No text entered

Pre-assignment

Screening details:

Study completers are those participants that completed Part A cycle 1 or experienced a DLT. There were no participants enrolled to Part B and Phase 2 of the study.

Period 1

Period 1 title	Period 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	50 mg LY3039478 + Dexamethasone

Arm description:

Part A: 50 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Arm type	Experimental
Investigational medicinal product name	LY3039478
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

50 mg LY3039478 administered orally three times per week (TIW).

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

Dosage and administration details:

24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles.

Arm title	75 mg LY3039478 + Dexamethasone

Arm description:

Part A: 75 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Arm type	Experimental
Investigational medicinal product name	LY3039478
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

75 mg LY3039478 administered orally three times per week (TIW).

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

Dosage and administration details:

24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles.

Arm title	100 mg LY3039478 + Dexamethasone

Arm description:

Part A: 100 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Arm type	Experimental
Investigational medicinal product name	LY3039478
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

100 mg LY3039478 administered orally three times per week (TIW).

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

Dosage and administration details:

24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles.

Arm title	125 mg LY3039478 + Dexamethasone

Arm description:

Part A: 125 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Arm type	Experimental
Investigational medicinal product name	LY3039478
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

125 mg LY3039478 administered orally three times per week (TIW).

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

Dosage and administration details:

24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles.

Number of subjects in period 1	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone
Started	6	12	15
Completed	3	7	11
Not completed	3	5	4
Physician decision	-	1	-
Adverse Event	1	-	1
Death	1	2	-
Progressive Disease	1	2	3

Number of subjects in period 1	125 mg LY3039478 + Dexamethasone
Started	3
Completed	3
Not completed	0
Physician decision	-
Adverse Event	-
Death	-
Progressive Disease	-

Baseline characteristics

Reporting groups	
Reporting group title	50 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 50 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	75 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 75 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	100 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 100 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	125 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 125 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	

Reporting group values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone
Number of subjects	6	12	15
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
All participants who received at least one dose of study drug.			
Units: years			
arithmetic mean	38.8	36.4	45.8
standard deviation	± 12.2	± 13.4	± 14.4
Gender categorical Units: Subjects			
Female	0	5	5
Male	6	7	10
Ethnicity Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	4	8	11

Unknown or Not Reported	1	3	3
Race Units: Subjects			
Asian	0	1	0
Black or African American	0	1	1
White	5	10	12
Unknown or Not Reported	1	0	2
Region Of Enrollment Units: Subjects			
United States	2	7	7
Italy	0	0	2
France	3	4	4
Germany	1	1	2

Reporting group values	125 mg LY3039478 + Dexamethasone	Total	
Number of subjects	3	36	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
All participants who received at least one dose of study drug.			
Units: years			
arithmetic mean	26.6		
standard deviation	± 10.6	-	
Gender categorical Units: Subjects			
Female	1	11	
Male	2	25	
Ethnicity Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	2	25	
Unknown or Not Reported	0	7	
Race Units: Subjects			
Asian	0	1	
Black or African American	0	2	
White	3	30	
Unknown or Not Reported	0	3	
Region Of Enrollment Units: Subjects			

United States	1	17	
Italy	2	4	
France	0	11	
Germany	0	4	

End points

End points reporting groups

Reporting group title	50 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 50 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	75 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 75 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	100 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 100 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Reporting group title	125 mg LY3039478 + Dexamethasone
Reporting group description:	
Part A: 125 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.	
Subject analysis set title	All Participants
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A data.	

Primary: Number of Participants With Dose Limiting Toxicities (DLTs)

End point title	Number of Participants With Dose Limiting Toxicities (DLTs)[1]
End point description:	
A DLT was an Adverse Event(AE) observed during the first 28 day cycle that is determined by the investigator to be at least possibly related to LY3039478 according to CTCAE v 4.0 and fulfills any of the following criteria: CTCAE Grade 3 nonhematological toxicity with a few exceptions, any other significant toxicity deemed to be dose limiting (eg, any toxicity that is possibly related to the study medication that requires the withdrawal of the patient from the study during Cycle 1). Analysis Population Description (APD) : All participants who received at least one dose of study drug in Part A.	
End point type	Primary
End point timeframe:	
Cycle 1 (Up To 28 Days)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No arm comparison analyses were planned or conducted.

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	15	3
Units: participants	0	2	2	3

Statistical analyses

No statistical analyses for this end point

Primary: Recommended Dose of LY3039478 in Combination With Dexamethasone

End point title	Recommended Dose of LY3039478 in Combination With Dexamethasone[2]

End point description:

A DLT was an Adverse Event(AE) observed during the first 28 day cycle that is determined by the investigator to be at least possibly related to LY3039478 according to CTCAE v 4.0 and fulfills any of the following criteria:CTCAE Grade 3 nonhematological toxicity with a few exceptions, any other significant toxicity deemed to be dose limiting.A dose-limiting equivalent toxicity (DLET) was defined as an AE occurring between Day 1 and Day 28 of any cycle (other than Cycle 1) for a patient enrolled in the Phase 1 portion or in any cycle (including Cycle 1) for a patient enrolled in the Phase 2 portion that would have met the criteria for DLT if it had occurred during Cycle 1 for a patient enrolled in the Phase 1 portion.

APD: All participants who received at least one dose of study drug in Part A.

End point type	Primary

End point timeframe:

Cycle 1 (28 Days)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No arm comparison analyses were planned or conducted.

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	36			
Units: mg				
number (not applicable)	75			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Who Achieve Complete Remission (CR) or CR With Incomplete Blood Count Recovery (CRi): Overall Remission Rate (ORR)

End point title	Number of Participants Who Achieve Complete Remission (CR) or CR With Incomplete Blood Count Recovery (CRi): Overall Remission Rate (ORR)[3]

End point description:

ORR is defined as the number of participants who achieved a best overall response of either complete remission (CR) or incomplete remission (CRi). The ORR (CR and CRi) is the sum of patients achieving a CR or a CRi divided by the total number of patients randomized in that arm. CR is defined as the number of participants who achieved a best overall response of complete remission (CR), out of the total number of participants randomized in that arm.

APD: All participants who received at least one dose of study drug in Part A.

End point type	Primary

End point timeframe:

Baseline to Objective Disease Progression (Up To 2 Months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No arm comparison analyses were planned or conducted.

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	15	3
Units: participants	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0-∞]) of LY3039478 in Combination With Dexamethasone in Day 1

End point title	Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0-∞]) of LY3039478 in Combination With Dexamethasone in Day 1

End point description:

Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0-∞]) of LY3039478 in Combination with Dexamethasone in Day 1.

APD: All participants who received at least one dose of study drug in Part A and had evaluable PK data.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: Predose, 1-2, 3-4,6-8,24-30 hours

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	12	15	2[4]
Units: nanogram hour per milliliter (ng*h/mL)				
geometric mean (geometric coefficient of variation)	3480 (± 26)	5000 (± 45)	5870 (± 49)	6330 (± 9999)

Notes:

[4] - 9999 = NA (For n=2, range 3180-12600 was reported)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0- 48]) of LY3039478 in Combination With Dexamethasone in Day 8

End point title	Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0- 48]) of LY3039478 in Combination With Dexamethasone in Day 8

End point description:

Pharmacokinetics (PK): Area Under the Concentration-Time Curve (AUC[0- 48]) of LY3039478 in Combination with Dexamethasone in Day 8.

APD: All participants who received at least one dose of study drug in Part A and had evaluable PK data.

End point type	Secondary

End point timeframe:

Cycle 1 Day 8: Predose, 1-2, 3-4,6-8,24-30 hours

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	8	12	2[5]
Units: ng*h/mL				
geometric mean (geometric coefficient of variation)	3050 (± 18)	4070 (± 92)	4640 (± 55)	8240 (± 9999)

Notes:

[5] - 9999=NA (For n=2, range 4410-16100 was reported.)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With CR or CRi and Notch-1 or FBXW7 Mutations

End point title	Number of Participants With CR or CRi and Notch-1 or FBXW7 Mutations

End point description:

ORR is defined as the number of participants who achieved a best overall response of either complete remission (CR) or incomplete remission (CRi). The ORR (CR and CRi) is the sum of participants achieving a CR or a CRi divided by the total number of participants randomized in that arm. CR is defined as the number of participants who achieved a best overall response of complete remission (CR), out of the total number of participants randomized in that arm.

APD: All participants who received at least one dose of study drug in Part A.

End point type	Secondary

End point timeframe:

Baseline to Objective Disease Progression (Up To 12 Months)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	15	3
Units: Participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants Who Achieve CR, CRi or Partial Remission (PR): Overall Remission Rate (ORR) Plus PR

End point title	Phase 2: Number of Participants Who Achieve CR, CRi or Partial Remission (PR): Overall Remission Rate (ORR) Plus PR

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Baseline to Objective Disease Progression (Up To 12 Months)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[6]	0[7]	0[8]	0[9]
Units: participants				

Notes:

[6] - There were no participants enrolled to Part B and Phase 2 of the study.

[7] - There were no participants enrolled to Part B and Phase 2 of the study.

[8] - There were no participants enrolled to Part B and Phase 2 of the study.

[9] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants Who Achieve PR

End point title	Phase 2: Number of Participants Who Achieve PR

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Date of CR, CRi, or PR to Date of Relapse or Death from Any Cause (Approximately 1 Year)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[10]	0[11]	0[12]	0[13]
Units: participants				

Notes:

[10] - There were no participants enrolled to Part B and Phase 2 of the study.

[11] - There were no participants enrolled to Part B and Phase 2 of the study.

[12] - There were no participants enrolled to Part B and Phase 2 of the study.

[13] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of Remission (DoR)

End point title	Phase 2: Duration of Remission (DoR)

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Date of CR, CRi, or PR to Date of Relapse or Death from Any Cause (Approximately 1 Year)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	0[15]	0[16]	0[17]
Units: years				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[14] - There were no participants enrolled to Part B and Phase 2 of the study.

[15] - There were no participants enrolled to Part B and Phase 2 of the study.

[16] - There were no participants enrolled to Part B and Phase 2 of the study.

[17] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2:Relapse Free Survival (RFS)

End point title	Phase 2:Relapse Free Survival (RFS)

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Date of CR to Relapse or Death from any Cause (Approximately 1 Year)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[18]	0[19]	0[20]	0[21]
Units: Years				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[18] - There were no participants enrolled to Part B and Phase 2 of the study.

[19] - There were no participants enrolled to Part B and Phase 2 of the study.

[20] - There were no participants enrolled to Part B and Phase 2 of the study.

[21] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Event Free Survival (EFS)

End point title	Phase 2: Event Free Survival (EFS)

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Baseline to Objective Disease Progression or Death from Any Cause (Approximately 1 Year)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[22]	0[23]	0[24]	0[25]
Units: Years				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[22] - There were no participants enrolled to Part B and Phase 2 of the study.

[23] - There were no participants enrolled to Part B and Phase 2 of the study.

[24] - There were no participants enrolled to Part B and Phase 2 of the study.

[25] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS)

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Baseline to the Date of Death from Any Cause (Approximately 1.5 Years)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	0[27]	0[28]	0[29]
Units: Years				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[26] - There were no participants enrolled to Part B and Phase 2 of the study.

[27] - There were no participants enrolled to Part B and Phase 2 of the study.

[28] - There were no participants enrolled to Part B and Phase 2 of the study.

[29] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Change From Baseline in the Functional Assessment of Cancer Therapy-Leukemia-General (FACT-Leu-G) Score

End point title	Phase 2: Change From Baseline in the Functional Assessment of Cancer Therapy-Leukemia-General (FACT-Leu-G) Score

End point description:

There were no participants enrolled to Part B and Phase 2 of the study. The plan for Phase 2 was to randomize participants into two groups: LY3039478 + Dexamethasone and Placebo + Dexamethasone. Due to system limitation we cannot present data in the two arms for this outcome measure because number started is "0". The database does not allow a started number/enrolled number of "0" therefore reported data in the existing 4 Part A arms.

End point type	Secondary

End point timeframe:

Baseline, End of Study (Approximately 1.5 Years)

End point values	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone	125 mg LY3039478 + Dexamethasone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[30]	0[31]	0[32]	0[33]
Units: units on a scale				
least squares mean (standard error)	()	()	()	()

Notes:

[30] - There were no participants enrolled to Part B and Phase 2 of the study.

[31] - There were no participants enrolled to Part B and Phase 2 of the study.

[32] - There were no participants enrolled to Part B and Phase 2 of the study.

[33] - There were no participants enrolled to Part B and Phase 2 of the study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I6F-MC-JJCB

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	50 mg LY3039478 + Dexamethasone

Reporting group description:

50 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Reporting group title	75 mg LY3039478 + Dexamethasone

Reporting group description:

Part A: 75 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Reporting group title	100 mg LY3039478 + Dexamethasone

Reporting group description:

Part A: 100 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Reporting group title	125 mg LY3039478 + Dexamethasone

Reporting group description:

Part A: 125 mg LY3039478 administered orally three times per week (TIW) and 24 mg dexamethasone administered orally on days 1-5 every other week during 28 day cycles. Participants receiving benefit may continue until disease progression.

Serious adverse events	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	11 / 12 (91.67%)	9 / 15 (60.00%)
number of deaths (all causes)	1	4	1
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
nasopharyngeal cancer			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
hypotension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	3 / 12 (25.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 15 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
pyrexia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (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			
aspiration			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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

dyspnoea			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
hypoxia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (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 failure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
Investigations			
lipase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
weight decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
Injury, poisoning and procedural complications			
overdose			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (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
Nervous system disorders			

generalised tonic-clonic seizure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhage intracranial			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
syncope			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 15 (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
febrile neutropenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 15 (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
Gastrointestinal disorders			
colitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	2 / 2	3 / 3	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 15 (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
ileus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

vomiting			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
Musculoskeletal and connective tissue disorders			
muscular weakness			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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			
atypical pneumonia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
bacteraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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 infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
h1n1 influenza			

alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (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
infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perirectal abscess			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
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			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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
septic shock			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
upper respiratory tract infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	3 / 12 (25.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 0	1 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
failure to thrive			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour lysis syndrome			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (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

Serious adverse events	125 mg LY3039478 + Dexamethasone		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
nasopharyngeal cancer			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
hypotension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pain			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyrexia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
aspiration				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dyspnoea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypoxia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
respiratory failure				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
lipase increased				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
weight decreased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
overdose				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
generalised tonic-clonic seizure				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhage intracranial				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
syncope				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
febrile neutropenia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
colitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diarrhoea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	5 / 5			
deaths causally related to treatment / all	0 / 0			
gastric ulcer				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ileus				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intestinal obstruction				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nausea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vomiting				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
acute kidney injury				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
muscular weakness				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
atypical pneumonia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
device related infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
h1n1 influenza				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
lung infection				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
neutropenic infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
perirectal abscess				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
septic shock				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
upper respiratory tract infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
failure to thrive			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypokalaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
tumour lysis syndrome			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	50 mg LY3039478 + Dexamethasone	75 mg LY3039478 + Dexamethasone	100 mg LY3039478 + Dexamethasone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	12 / 12 (100.00%)	15 / 15 (100.00%)
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
hypertension			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
hypotension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	2	1	2
peripheral artery thrombosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	3 / 12 (25.00%)	3 / 15 (20.00%)
occurrences (all)	0	5	3
chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
chills			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
complication associated with device			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
face oedema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
fatigue			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	3 / 12 (25.00%)	6 / 15 (40.00%)
occurrences (all)	0	3	10
malaise			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
mucosal inflammation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
multiple organ dysfunction syndrome			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
oedema peripheral			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	2	3	2
pyrexia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	4 / 15 (26.67%)
occurrences (all)	2	4	4
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
cough			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	3 / 6 (50.00%)	1 / 12 (8.33%)	6 / 15 (40.00%)
occurrences (all)	3	1	6
dysphonia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
dyspnoea			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	3 / 15 (20.00%)
occurrences (all)	1	2	3
epistaxis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	3 / 6 (50.00%)	1 / 12 (8.33%)	4 / 15 (26.67%)
occurrences (all)	3	1	4
hiccups			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
hypoxia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1

pleural effusion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	3
pneumonitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
productive cough			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
pulmonary fibrosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
pulmonary oedema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
respiratory failure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
sinus congestion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
tachypnoea			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
wheezing			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
depressed mood			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
dysphoria			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
insomnia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	4 / 15 (26.67%)
occurrences (all)	0	1	5
mental disorder			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	3 / 15 (20.00%)
occurrences (all)	2	4	5
amylase increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
aspartate aminotransferase increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	4 / 15 (26.67%)
occurrences (all)	1	6	8
blood bilirubin increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	1	1	4
blood creatinine increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
blood glucose increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
blood lactate dehydrogenase increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	3
blood phosphorus increased alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
c-reactive protein increased alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	5
chest x-ray abnormal			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	2
immunoglobulins decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
lipase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	4 / 15 (26.67%)
occurrences (all)	2	8	8
platelet count decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	1	1	9
weight decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
weight increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
white blood cell count decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	6	0	0

Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
fall			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
muscle strain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
overdose			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
bradycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
cardiac failure congestive			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
pericardial effusion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
sinus bradycardia			

alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
sinus tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
supraventricular tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	3 / 15 (20.00%)
occurrences (all)	0	2	3
ventricular fibrillation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
ventricular tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
aphonia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
depressed level of consciousness			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
dizziness			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
dysgeusia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
headache			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
lethargy			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
metabolic encephalopathy			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
seizure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
syncope			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	3 / 6 (50.00%)	2 / 12 (16.67%)	3 / 15 (20.00%)
occurrences (all)	4	3	4
febrile neutropenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
immune thrombocytopenic purpura			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
increased tendency to bruise			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	4
thrombocytopenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	2	1	2
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
hypoacusis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
tinnitus			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
exophthalmos			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
eye pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
ocular hyperaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
periorbital oedema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
photophobia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
vision blurred			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
vitritis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
abdominal distension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
abdominal pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	3 / 15 (20.00%)
occurrences (all)	1	1	3
abdominal pain upper			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
colitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	4 / 15 (26.67%)
occurrences (all)	0	1	4
diarrhoea			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	3 / 6 (50.00%)	7 / 12 (58.33%)	8 / 15 (53.33%)
occurrences (all)	3	20	19
dry mouth			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	3 / 15 (20.00%)
occurrences (all)	0	0	3
dyspepsia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	2 / 15 (13.33%)
occurrences (all)	0	2	2

dysphagia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
eructation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
flatulence			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
gastric haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
gingival bleeding			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
haematemesis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
haematochezia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
ileus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
lip dry			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
mouth haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	5 / 12 (41.67%)	5 / 15 (33.33%)
occurrences (all)	1	8	6
oesophagitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
pancreatitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
proctalgia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1

proctitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
rectal haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
stomatitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	3 / 15 (20.00%)
occurrences (all)	1	0	3
toothache			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	8 / 15 (53.33%)
occurrences (all)	2	4	8
Hepatobiliary disorders			
hepatomegaly			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
dermatitis acneiform			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
dermatitis allergic			

alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
dry skin			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
ecchymosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
erythema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
hand dermatitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
night sweats			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
pruritus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
rash			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
rash maculo-papular			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	1 / 15 (6.67%)
occurrences (all)	1	2	3
scab			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
skin ulcer			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
dysuria			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
urinary retention			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
diabetes insipidus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	2	2
back pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
bone pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
muscular weakness			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
musculoskeletal pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
myalgia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
pain in extremity			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Infections and infestations			

bacteraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
bronchitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
bronchopulmonary aspergillosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
candida infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
cellulitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
clostridium difficile colitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
clostridium difficile infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	1 / 15 (6.67%)
occurrences (all)	0	3	1
conjunctivitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
corona virus infection			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
cytomegalovirus infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
dermatophytosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
enterococcal infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
epstein-barr virus infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
gastroenteritis norovirus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
hordeolum			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
infective glossitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

influenza			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
lung infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	2	0	2
mucosal infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
oral candidiasis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
pharyngitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
pneumonia cytomegaloviral			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
pneumonia fungal			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
pseudomonas infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
rhinitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
rhinovirus infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
sepsis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
septic encephalopathy			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

upper respiratory tract infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
urinary tract infection			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	5 / 15 (33.33%)
occurrences (all)	1	3	5
dehydration			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
fluid overload			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
hyperglycaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
hyperkalaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 15 (13.33%)
occurrences (all)	0	1	3
hypernatraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	4
hyperphosphataemia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
hyperuricaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
hypocalcaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	5 / 15 (33.33%)
occurrences (all)	0	2	7
hypokalaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	8 / 15 (53.33%)
occurrences (all)	2	5	14
hypomagnesaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	2 / 15 (13.33%)
occurrences (all)	2	8	3
hyponatraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
hypophosphataemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	4 / 15 (26.67%)
occurrences (all)	1	0	4
hypoproteinaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

hypouricaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
lactic acidosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
malnutrition			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
tumour lysis syndrome			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	125 mg LY3039478 + Dexamethasone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hypertension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hypotension			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
peripheral artery thrombosis			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
chills			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
complication associated with device			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
face oedema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
fatigue			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	2 / 3 (66.67%)		
occurrences (all)	8		
malaise			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
mucosal inflammation			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
multiple organ dysfunction syndrome			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
oedema peripheral			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dysphonia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
dyspnoea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
epistaxis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
hiccups				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
hypoxia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
nasal congestion				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
oropharyngeal pain				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pleural effusion				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pneumonitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

productive cough				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pulmonary fibrosis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pulmonary oedema				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
respiratory failure				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
rhinitis allergic				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
sinus congestion				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
tachypnoea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
wheezing				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Psychiatric disorders				

anxiety			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
depressed mood			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
depression			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dysphoria			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
insomnia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
mental disorder			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
amylase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
aspartate aminotransferase increased			
alternative dictionary used:			

MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	3			
blood bilirubin increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
blood creatinine increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
blood glucose increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
blood lactate dehydrogenase increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
blood phosphorus increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
c-reactive protein increased				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
chest x-ray abnormal				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
gamma-glutamyltransferase increased				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	5		
immunoglobulins decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
lipase increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
platelet count decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
weight decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
weight increased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
white blood cell count decreased			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
fall			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
muscle strain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
overdose			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
bradycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
cardiac failure congestive			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
pericardial effusion			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
sinus bradycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
sinus tachycardia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
supraventricular tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
ventricular fibrillation			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
ventricular tachycardia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
aphonia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
depressed level of consciousness			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dizziness			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dysgeusia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
headache			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
lethargy			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
metabolic encephalopathy			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
seizure			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
syncope			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
febrile neutropenia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
immune thrombocytopenic purpura			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
increased tendency to bruise			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
leukocytosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
thrombocytopenia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hypoacusis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
tinnitus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye disorders			
exophthalmos			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
eye pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
ocular hyperaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
periorbital oedema			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
photophobia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
vision blurred			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
vitritis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
abdominal distension			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
abdominal pain				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
abdominal pain upper				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
colitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
constipation				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
diarrhoea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	2 / 3 (66.67%)			
occurrences (all)	6			
dry mouth				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
dyspepsia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
dysphagia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

eructation				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
flatulence				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
gastric haemorrhage				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
gingival bleeding				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
haematemesis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
haematochezia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
haemorrhoids				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
ileus				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
lip dry				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
mouth haemorrhage				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
nausea				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	3 / 3 (100.00%)			
occurrences (all)	8			
oesophagitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pancreatitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
proctalgia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
proctitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

rectal haemorrhage			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
stomatitis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
toothache			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
vomiting			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	3 / 3 (100.00%)		
occurrences (all)	9		
Hepatobiliary disorders			
hepatomegaly			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dermatitis acneiform			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dermatitis allergic			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dry skin			

alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
ecchymosis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
erythema				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hand dermatitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
night sweats				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pruritus				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
rash				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
rash maculo-papular				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
scab				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
skin ulcer			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dysuria			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
urinary retention			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Endocrine disorders			
adrenal insufficiency			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
diabetes insipidus			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
bone pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
muscular weakness			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
musculoskeletal pain			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
myalgia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
pain in extremity			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
bronchitis			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
bronchopulmonary aspergillosis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
candida infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
cellulitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
clostridium difficile colitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
clostridium difficile infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
conjunctivitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
corona virus infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
cytomegalovirus infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

dermatophytosis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
enterococcal infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
epstein-barr virus infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
folliculitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
gastroenteritis norovirus				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hordeolum				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
infective glossitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
influenza				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
lung infection				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
mucosal infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
nasopharyngitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
oral candidiasis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pneumonia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pneumonia cytomegaloviral				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pneumonia fungal				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
pseudomonas infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

rhinitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
rhinovirus infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
sepsis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
septic encephalopathy				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
sinusitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
staphylococcal infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
tonsillitis				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
upper respiratory tract infection				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
urinary tract infection				
alternative dictionary used: MedDRA 20.1				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
dehydration			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
fluid overload			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hyperglycaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hyperkalaemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hypernatraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hyperphosphataemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
hyperuricaemia			
alternative dictionary used: MedDRA 20.1			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hypoalbuminaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
hypocalcaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hypokalaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hypomagnesaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hyponatraemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hypophosphataemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	5			
hypoproteinaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
hypouricaemia				
alternative dictionary used: MedDRA 20.1				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

lactic acidosis			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
malnutrition			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
tumour lysis syndrome			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 June 2015	This study was amended at the request of the Food and Drug Administration (FDA) to clarify the criteria for DLTs and to change the PK sampling. In addition, CSF sampling was simplified based on new data; the CSF sampling has been reduced to one draw. PK sampling for Dexamethasone during the phase 1 portion of the study was added and one additional time point for the determination of plasma concentrations of LY3039478 and dexamethasone was added during Phase 2 portion of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

There were no participants enrolled to Part B and Phase 2 of the study.

Notes: