Clinical trial results:
Gemtuzumab Ozogamicin (Mylotarg) Expanded Access Protocol for Treatment of Patients in the United States With Relapsed/Refractory Acute Myelogenous Leukemia Who May Benefit From Treatment and Have no Access to Other Comparable/Alternative Therapy.

Summary

EudraCT number	2018-001321-68
Trial protocol	Outside EU/EEA
Global end of trial date	04 December 2017

Results information

Result version number	v1 (current)
This version publication date	15 June 2018
First version publication date	15 June 2018

Trial information

Trial identification

Sponsor protocol code	B1761026

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02312037
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 January 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to allow compassionate access to Mylotarg for treatment of subjects with acute myeloid leukemia (AML) who were thought to have the potential to derive clinical benefit and who had exhausted other appropriate and reasonable treatment options including investigational studies.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 331
Worldwide total number of subjects	331
EEA total number of subjects	0

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)	11
Children (2-11 years)	62
Adolescents (12-17 years)	32
Adults (18-64 years)	117
From 65 to 84 years	103
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 331 subjects were enrolled in multiple sites of United States from 27 Dec 2014 to 04 Dec 2017

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Mylotarg: Monotherapy

Arm description:

Subjects received a single dose of Mylotarg less than or equal to (<=) 9 milligram per meter square (mg/m^2), intravenous (IV) infusion on Day 1 and Day 15 for a 28-day treatment cycle (up to a maximum of 2 cycles). Alternate treatment regimens tested in clinical trial settings and reported in peer reviewed journals were also permitted where published results demonstrated that the regimen was tolerated and effective. The subjects were followed up to 60 days after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Mylotarg
Investigational medicinal product code	
Other name	Gemtuzumab ozogamicin
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received a single dose of Mylotarg <=9 milligram per meter square (mg/m^2), intravenous (IV) infusion on Day 1 and Day 15 for a 28-day treatment cycle (up to a maximum of 2 cycles). Alternate treatment regimens tested in clinical trial settings and reported in peer reviewed journals were also permitted where published results demonstrated that the regimen was tolerated and effective.

Arm title	Mylotarg with Standard Chemotherapy

Arm description:

Subjects received Mylotarg <=9 mg/m^2 in split doses over 8 days (Days 1, 4 and 7), with no single dose more than (>) 3 mg/m^2 (maximum, 5 mg per dose) in combination with standard anthracycline and/or cytarabine (AraC), according to the standard of treatment care. The subjects were followed up 60 days after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Mylotarg
Investigational medicinal product code	
Other name	Gemtuzumab ozogamicin
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Mylotarg <=9 mg/m^2 in split doses over 8 days (Days 1, 4 and 7), with no single dose >3 mg/m^2 (maximum, 5 mg per dose).

Investigational medicinal product name	Anthracycline/Ara-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion

Routes of administration	Intravenous use

Dosage and administration details:

Subjects received standard anthracycline and/or AraC, according to the standard of treatment care.

Arm title	Mylotarg: Treatment for Acute Promyelocytic Leukemia

Arm description:

Subjects received Mylotarg <=9 mg/m^2 on Day 1 and Day 15 for 28-day treatment cycle (up to 2 cycles in absence of a complete remission,) either as a monotherapy or in tested combinations with all-trans retinoic acid (ATRA) and/or arsenic trioxide. The subjects were followed up 60 days after the last dose of the study drug.

Arm type	Experimental
Investigational medicinal product name	Mylotarg, Standard Chemotherapy
Investigational medicinal product code	
Other name	Gemtuzumab ozogamicin
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Mylotarg <=9 mg/m^2 on Day 1 and Day 15 for 28-day treatment cycle (up to 2 cycles in absence of a complete remission,) either as a monotherapy or in tested combinations with all-trans retinoic acid (ATRA) and/or arsenic trioxide, according to the standard of treatment care.

Number of subjects in period 1	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia
Started	139	183	9
Completed	45	112	6
Not completed	94	71	3
Subject refused further follow up	5	1	-
Study terminated by sponsor	-	1	-
Unspecified	28	31	1
Lost to follow-up	1	-	-
Subject Died	60	38	2

Baseline characteristics

Reporting groups

Reporting group title	Mylotarg: Monotherapy

Reporting group description:

Subjects received a single dose of Mylotarg less than or equal to (<=) 9 milligram per meter square (mg/m^2), intravenous (IV) infusion on Day 1 and Day 15 for a 28-day treatment cycle (up to a maximum of 2 cycles). Alternate treatment regimens tested in clinical trial settings and reported in peer reviewed journals were also permitted where published results demonstrated that the regimen was tolerated and effective. The subjects were followed up to 60 days after the last dose of the study drug.

Reporting group title	Mylotarg with Standard Chemotherapy

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 in split doses over 8 days (Days 1, 4 and 7), with no single dose more than (>) 3 mg/m^2 (maximum, 5 mg per dose) in combination with standard anthracycline and/or cytarabine (AraC), according to the standard of treatment care. The subjects were followed up 60 days after the last dose of the study drug.

Reporting group title	Mylotarg: Treatment for Acute Promyelocytic Leukemia

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 on Day 1 and Day 15 for 28-day treatment cycle (up to 2 cycles in absence of a complete remission,) either as a monotherapy or in tested combinations with all-trans retinoic acid (ATRA) and/or arsenic trioxide. The subjects were followed up 60 days after the last dose of the study drug.

Reporting group values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia
Number of subjects	139	183	9
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	2	9	0
Children (2-11 years)	13	49	0
Adolescents (12-17 years)	6	26	0
Adults (18-64 years)	47	64	6
From 65-84 years	66	35	2
85 years and over	5	0	1
Age Continuous Units: years			
arithmetic mean	54.6	32.1	56.7
standard deviation	± 25.0	± 26.7	± 19.1
Gender Categorical Units: Subjects			
Female	60	86	1
Male	79	97	8
Race/Ethnicity, Customized Units: Subjects			
White	121	142	7
Black	10	14	1
Asian	2	8	0

Other	6	19	1

Reporting group values	Total		
Number of subjects	331		
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)	11		
Children (2-11 years)	62		
Adolescents (12-17 years)	32		
Adults (18-64 years)	117		
From 65-84 years	103		
85 years and over	6		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	147		
Male	184		
Race/Ethnicity, Customized Units: Subjects			
White	270		
Black	25		
Asian	10		
Other	26		

End points

End points reporting groups

Reporting group title	Mylotarg: Monotherapy

Reporting group description:

Subjects received a single dose of Mylotarg less than or equal to (<=) 9 milligram per meter square (mg/m^2), intravenous (IV) infusion on Day 1 and Day 15 for a 28-day treatment cycle (up to a maximum of 2 cycles). Alternate treatment regimens tested in clinical trial settings and reported in peer reviewed journals were also permitted where published results demonstrated that the regimen was tolerated and effective. The subjects were followed up to 60 days after the last dose of the study drug.

Reporting group title	Mylotarg with Standard Chemotherapy

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 in split doses over 8 days (Days 1, 4 and 7), with no single dose more than (>) 3 mg/m^2 (maximum, 5 mg per dose) in combination with standard anthracycline and/or cytarabine (AraC), according to the standard of treatment care. The subjects were followed up 60 days after the last dose of the study drug.

Reporting group title	Mylotarg: Treatment for Acute Promyelocytic Leukemia

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 on Day 1 and Day 15 for 28-day treatment cycle (up to 2 cycles in absence of a complete remission,) either as a monotherapy or in tested combinations with all-trans retinoic acid (ATRA) and/or arsenic trioxide. The subjects were followed up 60 days after the last dose of the study drug.

Primary: Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)[1]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. AEs included both serious and non-serious adverse events. Safety analysis set included all subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects				
AEs	134	172	9	
SAEs	101	86	6	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment Related Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment Related Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)[2]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a subject who received study drug. AEs included both serious and non-serious adverse events. Safety analysis set included all subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects				
AEs	84	102	7	
SAEs	29	39	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Events of Grade 3 or 4 Severity

End point title	Number of Subjects With Treatment-Emergent Adverse Events of Grade 3 or 4 Severity[3]

End point description:

An AE was any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe (unacceptable or intolerable events), Grade 4= life threatening AEs and Grade 5= death related to AE. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. AEs included both serious and non-serious adverse events. Safety analysis set included all enrolled subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects	122	168	8	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment Related Treatment-Emergent Adverse Events of Grade 3 or 4 Severity

End point title	Number of Subjects With Treatment Related Treatment-Emergent Adverse Events of Grade 3 or 4 Severity[4]

End point description:

An AE was any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe (unacceptable or intolerable events), Grade 4= life threatening AEs and Grade 5= death related to AE. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a subject who received study drug. AEs included both serious and non-serious adverse events. Safety analysis set included all enrolled subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

Notes:

[4] - 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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects	83	101	7	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Events of Grade 5 Severity

End point title	Number of Subjects With Treatment-Emergent Adverse Events of Grade 5 Severity[5]

End point description:

An AE was any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe (unacceptable or intolerable events), Grade 4= life threatening AEs and Grade 5= death related to AE. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. AEs included both serious and non-serious adverse events. Safety analysis set included all enrolled subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

Notes:

[5] - 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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects	72	40	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment Related Treatment-Emergent Adverse Events of Grade 5 Severity

End point title	Number of Subjects With Treatment Related Treatment-Emergent Adverse Events of Grade 5 Severity[6]

End point description:

An AE was any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe (unacceptable or intolerable events), Grade 4= life threatening AEs and Grade 5= death related to AE. Treatment-emergent were events between the first dose of study drug and up to 60 days after the last dose, which initiated after the treatment or worsened during the treatment period. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a subject who received study drug. AEs included both serious and non-serious adverse events. Safety analysis set included all enrolled subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

Notes:

[6] - 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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects	6	9	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Discontinued the Study Treatment Due to Adverse Events

End point title	Number of Subjects Who Discontinued the Study Treatment Due to Adverse Events[7]

End point description:

An AE was any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. Safety analysis set included all enrolled subjects who received at least 1 dose of Mylotarg.

End point type	Primary

End point timeframe:

Baseline (Day 1) up to 60 days after the last dose

Notes:

[7] - 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: Only descriptive data was planned to be analyzed for this endpoint. It is applicable for all the primary endpoints

End point values	Mylotarg: Monotherapy	Mylotarg with Standard Chemotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	139	183	9	
Units: subjects	25	11	2	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline (Day 1) up to 60 days after the last dose

Adverse event reporting additional description:

Same event may appear as both an adverse event (AE) and serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Mylotarg: Monotherapy

Reporting group description:

Subjects received a single dose of Mylotarg less than or equal to (<=) 9 milligram per meter square (mg/m^2), intravenous (IV) infusion on Day 1 and Day 15 for a 28-day treatment cycle (up to a maximum of 2 cycles). Alternate treatment regimens tested in clinical trial settings and reported in peer reviewed journals were also permitted where published results demonstrated that the regimen was tolerated and effective. The subjects were followed up to 60 days after the last dose of the study drug.

Reporting group title	Mylotarg: Treatment for Acute Promyelocytic Leukemia

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 on Day 1 and Day 15 for 28-day treatment cycle (up to 2 cycles in absence of a complete remission,) either as a monotherapy or in tested combinations with all-trans retinoic acid (ATRA) and/or arsenic trioxide. The subjects were followed up 60 days after the last dose of the study drug.

Reporting group title	Mylotarg with Standard Chemotherapy

Reporting group description:

Subjects received Mylotarg <=9 mg/m^2 in split doses over 8 days (Days 1, 4 and 7), with no single dose more than (>) 3 mg/m^2 (maximum, 5 mg per dose) in combination with standard anthracycline and/or cytarabine (AraC), according to the standard of treatment care. The subjects were followed up 60 days after the last dose of the study drug.

Serious adverse events	Mylotarg: Monotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	Mylotarg with Standard Chemotherapy
Total subjects affected by serious adverse events			
subjects affected / exposed	101 / 139 (72.66%)	6 / 9 (66.67%)	86 / 183 (46.99%)
number of deaths (all causes)	49	2	36
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	17 / 139 (12.23%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0
Chloroma			

subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Neoplasm progression			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Hypertension			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
General disorders and administration site conditions			

Disease progression			
subjects affected / exposed	32 / 139 (23.02%)	1 / 9 (11.11%)	14 / 183 (7.65%)
occurrences causally related to treatment / all	1 / 33	0 / 1	0 / 14
deaths causally related to treatment / all	1 / 19	0 / 0	0 / 2
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences causally related to treatment / all	0 / 3	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 3	0 / 0	1 / 2
Sudden death			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Cytokine release syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Graft versus host disease			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Acute respiratory failure			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0

Epistaxis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Pleural effusion			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pulmonary haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
Pulmonary oedema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory distress			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Respiratory failure			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	8 / 183 (4.37%)
occurrences causally related to treatment / all	1 / 5	0 / 0	2 / 10
deaths causally related to treatment / all	0 / 3	0 / 0	1 / 5
Stridor			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte count decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutrophil count decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	4 / 5	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	3 / 139 (2.16%)	1 / 9 (11.11%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	2 / 3	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Subdural haematoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Transfusion reaction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 2
Cardiac failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Cerebrovascular accident			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Haemorrhage intracranial			
subjects affected / exposed	1 / 139 (0.72%)	1 / 9 (11.11%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 2
Occipital neuralgia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Syncope			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Febrile neutropenia			
subjects affected / exposed	15 / 139 (10.79%)	4 / 9 (44.44%)	12 / 183 (6.56%)
occurrences causally related to treatment / all	14 / 15	5 / 5	12 / 13
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s disease			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Drug-induced liver injury			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Cystitis haemorrhagic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Bacteraemia			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Device related infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Fungal infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Liver abscess			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Meningitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia			

subjects affected / exposed	5 / 139 (3.60%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	9 / 139 (6.47%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	6 / 10	0 / 0	1 / 3
deaths causally related to treatment / all	5 / 7	0 / 0	1 / 2
Septic shock			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Streptococcal bacteraemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection viral			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viraemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (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
Hypokalaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Mylotarg: Monotherapy	Mylotarg: Treatment for Acute Promyelocytic Leukemia	Mylotarg with Standard Chemotherapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	114 / 139 (82.01%)	5 / 9 (55.56%)	159 / 183 (86.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Chloroma			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Infected neoplasm			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Vascular disorders			
Capillary leak syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Hypertension			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	10 / 183 (5.46%)
occurrences (all)	3	0	11
Hypotension			
subjects affected / exposed	6 / 139 (4.32%)	0 / 9 (0.00%)	9 / 183 (4.92%)
occurrences (all)	7	0	9
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Chills			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Disease progression			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Face oedema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Facial pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	8 / 139 (5.76%)	0 / 9 (0.00%)	7 / 183 (3.83%)
occurrences (all)	8	0	8
Mucosal inflammation			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	1	0	3
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Oedema			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences (all)	1	0	5
Pyrexia			
subjects affected / exposed	5 / 139 (3.60%)	0 / 9 (0.00%)	10 / 183 (5.46%)
occurrences (all)	5	0	12
Immune system disorders			

Serum sickness			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Vulvovaginal inflammation			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Acute respiratory failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Aspiration			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Atelectasis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	6 / 139 (4.32%)	0 / 9 (0.00%)	8 / 183 (4.37%)
occurrences (all)	6	0	9
Epistaxis			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences (all)	4	0	9
Hypoxia			
subjects affected / exposed	8 / 139 (5.76%)	1 / 9 (11.11%)	15 / 183 (8.20%)
occurrences (all)	9	1	18
Nasal congestion			

subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	3	0	3
Pleuritic pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	4	0	4
Respiratory disorder			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Respiratory distress			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	2	0	1
Stridor			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Tachypnoea			

subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	7 / 139 (5.04%)	1 / 9 (11.11%)	15 / 183 (8.20%)
occurrences (all)	7	1	17
Amylase increased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	10 / 139 (7.19%)	1 / 9 (11.11%)	17 / 183 (9.29%)
occurrences (all)	14	1	18
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Blood bilirubin increased			
subjects affected / exposed	7 / 139 (5.04%)	1 / 9 (11.11%)	3 / 183 (1.64%)
occurrences (all)	9	1	3
Blood creatinine increased			

subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	3	0	3
Blood fibrinogen decreased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	4	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fungal test positive			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	2	0	7
Granulocyte count decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	2
Haemoglobin decreased			
subjects affected / exposed	8 / 139 (5.76%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	34	0	13
Lipase			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Lipase increased			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	5
Lymphocyte count decreased			
subjects affected / exposed	29 / 139 (20.86%)	0 / 9 (0.00%)	52 / 183 (28.42%)
occurrences (all)	42	0	137
Neutrophil count abnormal			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	20 / 139 (14.39%)	2 / 9 (22.22%)	57 / 183 (31.15%)
occurrences (all)	28	3	124
Platelet count			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	12	0	0
Platelet count decreased			
subjects affected / exposed	49 / 139 (35.25%)	3 / 9 (33.33%)	64 / 183 (34.97%)
occurrences (all)	229	8	361
Streptococcus test positive			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Urine output decreased			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Weight decreased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	52 / 139 (37.41%)	1 / 9 (11.11%)	66 / 183 (36.07%)
occurrences (all)	123	6	146
Injury, poisoning and procedural			

complications			
Fall			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Infusion related reaction			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	4	0	3
Radiation skin injury			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Cardiac failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Left ventricular dysfunction			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	3
Left ventricular failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Ventricular tachycardia			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Encephalopathy			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	1	0	3
Hydrocephalus			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Idiopathic intracranial hypertension			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Paraplegia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	2	0	1
Tremor			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	54 / 139 (38.85%)	2 / 9 (22.22%)	86 / 183 (46.99%)
occurrences (all)	112	4	198
Coagulopathy			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Febrile neutropenia			
subjects affected / exposed	30 / 139 (21.58%)	3 / 9 (33.33%)	60 / 183 (32.79%)
occurrences (all)	40	3	90
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	3	0	2
Leukopenia			
subjects affected / exposed	9 / 139 (6.47%)	0 / 9 (0.00%)	19 / 183 (10.38%)
occurrences (all)	15	0	23
Lymphopenia			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	3	0	5
Neutropenia			
subjects affected / exposed	12 / 139 (8.63%)	0 / 9 (0.00%)	14 / 183 (7.65%)
occurrences (all)	24	0	20
Pancytopenia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	16 / 139 (11.51%)	0 / 9 (0.00%)	19 / 183 (10.38%)
occurrences (all)	31	0	25
Eye disorders			

Eye pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 139 (0.72%)	1 / 9 (11.11%)	8 / 183 (4.37%)
occurrences (all)	1	1	9
Abdominal pain upper			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Constipation			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences (all)	0	0	5
Dysphagia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	2
Enterocolitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Ileus			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Mouth haemorrhage			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	2	0	2
Nausea			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	7 / 183 (3.83%)
occurrences (all)	1	0	8
Oral pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Pancreatitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Periodontal disease			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Stomatitis			
subjects affected / exposed	1 / 139 (0.72%)	1 / 9 (11.11%)	3 / 183 (1.64%)
occurrences (all)	1	3	3
Toothache			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0

Cholecystitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Cholecystitis acute			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Hepatic failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	1	0	3
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	2	0	1
Haematuria			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	4	0	2
Renal failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Renal mass			

subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Urogenital haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Back pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Bone pain			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Muscular weakness			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Infections and infestations			

Appendicitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
BK virus infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Bacillus infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Bacteraemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	6 / 183 (3.28%)
occurrences (all)	2	0	6
Bacterial infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences (all)	0	0	6
Cystitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Device related infection			
subjects affected / exposed	3 / 139 (2.16%)	0 / 9 (0.00%)	7 / 183 (3.83%)
occurrences (all)	3	0	8
Endophthalmitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Enterococcal infection			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	2	0	0
Enterocolitis infectious			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Enterovirus infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Fungaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Fungal skin infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	1	0	1
Lung infection			
subjects affected / exposed	2 / 139 (1.44%)	2 / 9 (22.22%)	6 / 183 (3.28%)
occurrences (all)	2	2	6
Meningitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Micrococcal sepsis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Myelitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Neutropenic sepsis			
subjects affected / exposed	2 / 139 (1.44%)	1 / 9 (11.11%)	1 / 183 (0.55%)
occurrences (all)	3	1	1
Parainfluenzae virus infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Periorbital cellulitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Pneumonia			
subjects affected / exposed	5 / 139 (3.60%)	0 / 9 (0.00%)	5 / 183 (2.73%)
occurrences (all)	5	0	5
Pneumonia fungal			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	0	0	4
Pseudomonas infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Pulmonary mycosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Respiratory tract infection viral			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	7 / 139 (5.04%)	0 / 9 (0.00%)	11 / 183 (6.01%)
occurrences (all)	7	0	14
Urinary tract infection			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	2	0	2
Sinusitis fungal			
subjects affected / exposed	0 / 139 (0.00%)	1 / 9 (11.11%)	0 / 183 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Stoma site infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Streptococcal infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1

Streptococcal sepsis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	0	0	2
Subcutaneous abscess			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	0	0	3
Systemic candida			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Viraemia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	2	0	4
Alkalosis			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	2	0	4
Decreased appetite			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	12 / 183 (6.56%)
occurrences (all)	2	0	13
Dehydration			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2
Hyperammonaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hyperglycaemia			

subjects affected / exposed	11 / 139 (7.91%)	1 / 9 (11.11%)	15 / 183 (8.20%)
occurrences (all)	18	1	23
Hyperkalaemia			
subjects affected / exposed	5 / 139 (3.60%)	0 / 9 (0.00%)	4 / 183 (2.19%)
occurrences (all)	8	0	4
Hypermagnesaemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	3	0	3
Malnutrition			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	3	0	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	2	0	3
Hypocalcaemia			
subjects affected / exposed	4 / 139 (2.88%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	4	0	3
Hypoglycaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	22 / 139 (15.83%)	0 / 9 (0.00%)	43 / 183 (23.50%)
occurrences (all)	39	0	82
Hypomagnesaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 9 (0.00%)	1 / 183 (0.55%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	6 / 139 (4.32%)	1 / 9 (11.11%)	8 / 183 (4.37%)
occurrences (all)	7	2	9
Hypophosphataemia			

subjects affected / exposed	14 / 139 (10.07%)	1 / 9 (11.11%)	15 / 183 (8.20%)
occurrences (all)	14	1	17
Iron overload			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	0 / 183 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	3 / 183 (1.64%)
occurrences (all)	1	0	4
Tumour lysis syndrome			
subjects affected / exposed	1 / 139 (0.72%)	0 / 9 (0.00%)	2 / 183 (1.09%)
occurrences (all)	1	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

Due to the expanded access to the protocol only, no efficacy evaluations were performed. The prioritization of the endpoints were based on study team discretion.

Notes: