Clinical trial results:
A Randomized (1:1), Double-blind, Multi-center, Placebo Controlled Study Evaluating Intensive Chemotherapy With or Without Glasdegib (Pf-04449913) or Azacitidine (AZA) With or Without Glasdegib in Patients With Previously Untreated Acute Myeloid Leukemia

Summary

EudraCT number	2017-002822-19
Trial protocol	FR GB CZ SE BE PL ES DE IT RO
Global end of trial date	

Results information

Result version number	v1
This version publication date	04 August 2021
First version publication date	04 August 2021

Trial information

Trial identification

Sponsor protocol code	B1371019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	
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	Interim
Date of interim/final analysis	05 June 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 June 2020
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that glasdegib is superior to placebo in combination with azacitidine (non-intensive study) or cytarabine and daunorubicin (intensive study) in prolonging OS in subjects with untreated acute myeloid leukemia (AML).

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 Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 April 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 21
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	China: 72
Country: Number of subjects enrolled	Czechia: 60
Country: Number of subjects enrolled	France: 29
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Hungary: 36
Country: Number of subjects enrolled	Israel: 8
Country: Number of subjects enrolled	Italy: 20
Country: Number of subjects enrolled	Japan: 85
Country: Number of subjects enrolled	Korea, Republic of: 29
Country: Number of subjects enrolled	Poland: 24
Country: Number of subjects enrolled	Romania: 8
Country: Number of subjects enrolled	Russian Federation: 33
Country: Number of subjects enrolled	Spain: 72
Country: Number of subjects enrolled	Sweden: 4
Country: Number of subjects enrolled	Taiwan: 19
Country: Number of subjects enrolled	United Kingdom: 19

Country: Number of subjects enrolled	United States: 143
Country: Number of subjects enrolled	Austria: 15
Country: Number of subjects enrolled	Mexico: 3
Worldwide total number of subjects	729
EEA total number of subjects	287

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)	318
From 65 to 84 years	396
85 years and over	15

Subject disposition

Recruitment

Recruitment details:

This study evaluated glasdegib in intensive and non-intensive (NI) chemotherapy populations. Intensive study: Glasdegib was studied in combination with cytarabine and daunorubicin for the treatment of adult patients with previously untreated acute myeloid leukemia (AML).

Pre-assignment

Screening details:

NI study: Glasdegib was studied in combination with azacitidine for treatment of adults with previously untreated AML who were not candidates for intensive induction chemotherapy. Results are reported at primary completion date and data is reported only for primary endpoint. Data for secondary endpoint will be posted at secondary completion date.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Intensive Study: Glasdegib + Cytarabine + Daunorubicin

Arm description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib 100 mg tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. Follow up (FU) was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

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

Dosage and administration details:

Subjects received Glasdegib 100 mg tablet orally (PO) once daily (QD) from Day 1 of chemotherapy up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive (complete remission) CR MRD-negative central laboratory results, whichever came first.

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Cytarabine 100 mg/m^2 daily by IV infusion for 7 days. If greater than or equals to (>=) 5 percent (%) bone marrow blast or investigator judgement for less than (<) 5% bone marrow blasts then subjects received either option 1: cytarabine 100 mg/m^2 IV daily for 5 days or option 2: cytarabine 100 mg/m^2 IV daily for 7 days.

Investigational medicinal product name	Daunorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received daunorubicin 60 mg/m^2 daily IV for 3 days. If >=5% bone marrow blast or investigator judgement for < 5% bone marrow blasts then received daunorubicin 60 mg/m^2 IV daily for 2 days or daunorubicin 60 mg/m^2 IV daily for 3 days.

Arm title	Intensive Study: Placebo + Cytarabine + Daunorubicin

Arm description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib matched placebo tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. FU was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Arm type	Placebo
Investigational medicinal product name	Glasdegib matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Glasdegib 100 mg matching placebo tablet PO QD from Day 1 of chemotherapy up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative central laboratory results, whichever came first.

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Cytarabine 100 mg/m^2 daily by IV infusion for 7 days. If >=5% bone marrow blast or investigator judgement for <5% bone marrow blasts then subjects received either option 1: cytarabine 100 mg/m^2 IV daily for 5 days or option 2: cytarabine 100 mg/m^2 IV daily for 7 days.

Investigational medicinal product name	Daunorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received daunorubicin 60 mg/m^2 daily IV for 3 days. If >=5% bone marrow blast or investigator judgement for < 5% bone marrow blasts then received daunorubicin 60 mg/m^2 IV daily for 2 days or daunorubicin 60 mg/m^2 IV daily for 3 days.

Arm title	Non-intensive Study: Glasdegib + Azacitidine

Arm description:

Subjects received chemotherapy with azacitidine 75 milligram per square meter (mg/m^2) subcutaneous (SC) injection or intravenous (IV) infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subject refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred

first. Eligible subjects underwent hematopoietic stem cell transplantation (HSCT) per local standard of care and received glasdegib up to 2 years following randomization unless 2 consecutive negative minimal residual disease (MRD) assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

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

Dosage and administration details:

Subjects received glasdegib 100 mg PO QD from Day 1 of chemotherapy and continued if subject's demonstrated reasonable evidence of clinical benefit or until disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first.

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, patient refusal or death, whichever occurred first.

Arm title	Non-intensive Study: Placebo + Azacitidine

Arm description:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subjects refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg tablet matching placebo PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent HSCT per local standard of care and glasdegib matching placebo up to 2 years following randomization unless 2 consecutive negative MRD assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Arm type	Placebo
Investigational medicinal product name	Glasdegib matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received glasdegib 100 mg matching placebo PO QD from Day 1 of chemotherapy and continued if subject's demonstrated reasonable evidence of clinical benefit or until disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first.

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, patient refusal or death, whichever occurred first.

Number of subjects in period 1	Intensive Study: Glasdegib + Cytarabine + Daunorubicin	Intensive Study: Placebo + Cytarabine + Daunorubicin	Non-intensive Study: Glasdegib + Azacitidine
Started	201	203	163
Completed	0	0	0
Not completed	201	203	163
Adverse event, serious fatal	67	60	96
Consent withdrawn by subject	13	19	5
Ongoing	121	123	62
Unspecified	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Non-intensive Study: Placebo + Azacitidine
Started	162
Completed	0
Not completed	162
Adverse event, serious fatal	88
Consent withdrawn by subject	6
Ongoing	66
Unspecified	-
Lost to follow-up	2

Baseline characteristics

Reporting groups

Reporting group title	Intensive Study: Glasdegib + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib 100 mg tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. Follow up (FU) was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Intensive Study: Placebo + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib matched placebo tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. FU was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Non-intensive Study: Glasdegib + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 milligram per square meter (mg/m^2) subcutaneous (SC) injection or intravenous (IV) infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subject refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent hematopoietic stem cell transplantation (HSCT) per local standard of care and received glasdegib up to 2 years following randomization unless 2 consecutive negative minimal residual disease (MRD) assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Reporting group title	Non-intensive Study: Placebo + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subjects refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg tablet matching placebo PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent HSCT per local standard of care and glasdegib matching placebo up to 2 years following randomization unless 2 consecutive negative MRD assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Reporting group values	Intensive Study: Glasdegib + Cytarabine + Daunorubicin	Intensive Study: Placebo + Cytarabine + Daunorubicin	Non-intensive Study: Glasdegib + Azacitidine
Number of subjects	201	203	163

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)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	144	141	16
From 65-84 years	57	61	142
85 years and over	0	1	5
Age Continuous Units: years			
arithmetic mean	56.55	55.38	73.19
standard deviation	± 12.60	± 13.61	± 7.17
Sex: Female, Male Units: subjects			
Female	71	97	97
Male	130	106	66
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	66	57	51
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	3	1
White	110	123	97
More than one race	1	0	0
Unknown or Not Reported	20	20	14
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	19	12	12
Not Hispanic or Latino	166	171	140
Unknown or Not Reported	16	20	11

Reporting group values	Non-intensive Study: Placebo + Azacitidine	Total	
Number of subjects	162	729	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	17	318	
From 65-84 years	136	396	
85 years and over	9	15	

Age Continuous Units: years			
arithmetic mean	73.14		
standard deviation	± 6.82	-	
Sex: Female, Male Units: subjects			
Female	89	354	
Male	73	375	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	44	218	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	7	14	
White	99	429	
More than one race	0	1	
Unknown or Not Reported	12	66	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	16	59	
Not Hispanic or Latino	139	616	
Unknown or Not Reported	7	54	

End points

End points reporting groups

Reporting group title	Intensive Study: Glasdegib + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib 100 mg tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. Follow up (FU) was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Intensive Study: Placebo + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib matched placebo tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. FU was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Non-intensive Study: Glasdegib + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 milligram per square meter (mg/m^2) subcutaneous (SC) injection or intravenous (IV) infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subject refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent hematopoietic stem cell transplantation (HSCT) per local standard of care and received glasdegib up to 2 years following randomization unless 2 consecutive negative minimal residual disease (MRD) assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Reporting group title	Non-intensive Study: Placebo + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subjects refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg tablet matching placebo PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent HSCT per local standard of care and glasdegib matching placebo up to 2 years following randomization unless 2 consecutive negative MRD assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Primary: Intensive Study: Overall Survival (OS)

End point title	Intensive Study: Overall Survival (OS)[1]

End point description:

OS is defined as the time from the date of randomization to the date of death due to any cause. Subjects last known to be alive were to be censored at the date of last contact. FA set included all randomised subjects. Here, '99999 =Upper limit of 95 % CI was not estimable due to low number of

subjects with events.'

End point type	Primary

End point timeframe:

Baseline up to 25 months

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistics were only planned for the arms specified

End point values	Intensive Study: Glasdegib + Cytarabine + Daunorubicin	Intensive Study: Placebo + Cytarabine + Daunorubicin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	201	203		
Units: months				
median (confidence interval 95%)	17.3 (15.2 to 18.5)	20.4 (17.6 to 99999)		

Statistical analyses

Statistical analysis title	Glasdegib Vs Placebo

Statistical analysis description:

Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio less than (<) 1 indicated a reduction in hazard rate in favor of Glasdegib 100 mg PO + Cytarabine 100 mg/m^2 IV + Daunorubicin 60 mg/m^2 compared to Placebo + Cytarabine 100 mg/m^2 IV + Daunorubicin 60 mg/m^2.

Comparison groups	Intensive Study: Glasdegib + Cytarabine + Daunorubicin v Intensive Study: Placebo + Cytarabine + Daunorubicin
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6579
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.755
upper limit	1.532

Primary: Non-intensive Study: Overall Survival (OS)

End point title	Non-intensive Study: Overall Survival (OS)[2]

End point description:

Overall survival (OS) was defined as the time from date of first study treatment to date of death from any cause. Subject's last known to be alive were to be censored at the date of last contact. FA set included all randomized subjects.

End point type	Primary

End point timeframe:

Baseline up to 25 months

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistics were only planned for the arms specified

End point values	Non-intensive Study: Glasdegib + Azacitidine	Non-intensive Study: Placebo + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	162		
Units: months				
median (confidence interval 95%)	10.3 (7.7 to 12.4)	10.6 (8.4 to 13.3)		

Statistical analyses

Statistical analysis title	Glasdegib Vs Placebo

Statistical analysis description:

Hazard ratio based on Cox proportional hazards model; under proportional hazards, hazard ratio < 1 indicates a reduction in hazard rate in favor of Glasdegib 100 mg PO QD + Azacitidine compared to Placebo + Azacitidine

Comparison groups	Non-intensive Study: Glasdegib + Azacitidine v Non-intensive Study: Placebo + Azacitidine
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5955
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.775
upper limit	1.388

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 28 days from last dose of study drug (up to 25 months)

Adverse event reporting additional description:

Same event may appear as both an AE and 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. Safety analysis (SA) set included all subjects who received at least one dose of study drug.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Intensive Study: Glasdegib + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib 100 mg tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. FU was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Intensive Study: Placebo + Cytarabine + Daunorubicin

Reporting group description:

Subjects received 28 days induction therapy: Cytarabine 100 mg/m^2 IV daily for 7 days + daunorubicin 60 mg/m^2 daily IV for 3 days. Depending on bone marrow blast or investigator judgement subjects had second induction to receive either same therapy or cytarabine 100 mg/m^2 IV daily for 5 days + daunorubicin 60 mg/m^2 IV daily for 2 days. Subjects with <5% bone marrow blasts entered consolation phase: treated with either or both of: 1) Cytarabine 1 to 3 gm/m^2 IV for adults >= 60 to <60 years twice daily on Days 1, 3, 5 for 4 cycle (1 cycle=28 days) or cytarabine per local prescribing information. 2) Received HSCT per local standard of care. Subjects received Glasdegib matched placebo tablet PO QD from Day 1 up to 28 days in both induction and up to 2 years post randomization or until 2 consecutive CR MRD-negative, whichever came first. FU was up to 2 years from last dose and long term survival FU from last subject randomized up to 5 years or until death or consent withdrawal.

Reporting group title	Non-intensive Study: Glasdegib + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subject refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg orally PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent HSCT per local standard of care and received glasdegib up to 2 years following randomization unless 2 consecutive negative MRD assessments. Subjects were followed up for first 2 years from last dose of drug and had long term follow-up for survival for up to 5 years from randomization of last subject in study, or until death, or consent withdrawal.

Reporting group title	Non-intensive Study: Placebo + Azacitidine

Reporting group description:

Subjects received chemotherapy with azacitidine 75 mg/m^2 SC injection or IV infusion from Day 1 up to Day 7 of each cycle (28 day) and continued for at least 6 cycles or until unacceptable toxicity, subjects refusal or death, whichever occurred first. Subjects also received glasdegib 100 mg tablet matching placebo PO QD from Day 1 of chemotherapy until clinical benefit or disease progression, unacceptable toxicity, consent withdrawal, or death, whichever occurred first. Eligible subjects underwent HSCT per local standard of care and glasdegib matching placebo up to 2 years following randomization unless 2 consecutive negative MRD assessments. Subjects were followed up for first 2

Serious adverse events	Intensive Study: Glasdegib + Cytarabine + Daunorubicin	Intensive Study: Placebo + Cytarabine + Daunorubicin	Non-intensive Study: Glasdegib + Azacitidine
Total subjects affected by serious adverse events			
subjects affected / exposed	85 / 198 (42.93%)	91 / 201 (45.27%)	110 / 162 (67.90%)
number of deaths (all causes)	67	60	96
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Differentiation syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Neoplasm progression			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Neoplasm prostate			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Embolism			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Aneurysm ruptured			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Axillary vein thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Circulatory collapse			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Peripheral ischaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Thrombophlebitis superficial			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	2 / 198 (1.01%)	4 / 201 (1.99%)	14 / 162 (8.64%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Pyrexia			
subjects affected / exposed	4 / 198 (2.02%)	6 / 201 (2.99%)	9 / 162 (5.56%)
occurrences causally related to treatment / all	1 / 4	3 / 6	3 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Chills			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Malaise			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Mucosal inflammation			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Asthenia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Death			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	4 / 162 (2.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Sudden death			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Soft tissue inflammation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Graft versus host disease			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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 in skin			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Cytokine release syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	3 / 162 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	2 / 198 (1.01%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 198 (0.51%)	4 / 201 (1.99%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 198 (0.51%)	3 / 201 (1.49%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 198 (0.51%)	2 / 201 (1.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Oropharyngeal pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonitis			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Hallucination			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	13 / 198 (6.57%)	8 / 201 (3.98%)	5 / 162 (3.09%)
occurrences causally related to treatment / all	9 / 15	8 / 10	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Platelet count decreased			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 198 (0.51%)	2 / 201 (1.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 198 (0.51%)	2 / 201 (1.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	2 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	2 / 198 (1.01%)	3 / 201 (1.49%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	3 / 3	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

C-reactive protein increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electroencephalogram abnormal			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Spinal fracture			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Splenic rupture			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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

Femoral neck fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Hip fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Subdural haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Tooth fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Transfusion reaction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
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 disorders			

Atrial fibrillation			
subjects affected / exposed	3 / 198 (1.52%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	4 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Cardiac failure			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure acute			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Cardiomyopathy			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Intracardiac mass			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Left ventricular dysfunction			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Myocardial infarction			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Atrial flutter			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Cardiorenal syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	2 / 198 (1.01%)	2 / 201 (1.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	2 / 3	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Central nervous system lesion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Encephalopathy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 198 (1.01%)	1 / 201 (0.50%)	5 / 162 (3.09%)
occurrences causally related to treatment / all	2 / 2	1 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	18 / 198 (9.09%)	17 / 201 (8.46%)	24 / 162 (14.81%)
occurrences causally related to treatment / all	20 / 26	22 / 23	14 / 33
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Thrombocytopenia			
subjects affected / exposed	1 / 198 (0.51%)	3 / 201 (1.49%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 1	28 / 28	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Splenic necrosis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	4 / 162 (2.47%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	3 / 162 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 198 (1.52%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Haematemesis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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 haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Large intestine perforation			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	2 / 198 (1.01%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anal fistula			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Enterocolitis			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Intussusception			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Proctalgia			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Small intestinal haemorrhage			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Mechanical ileus			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Glossitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Ileus			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Hyperbilirubinaemia			
subjects affected / exposed	2 / 198 (1.01%)	0 / 201 (0.00%)	0 / 162 (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
Cholecystitis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Cholelithiasis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Hepatitis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Bile duct stone			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			

subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Rash			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Rash maculo-papular			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 198 (1.01%)	3 / 201 (1.49%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary retention			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Back pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Soft tissue necrosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis infective			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacteraemia			
subjects affected / exposed	4 / 198 (2.02%)	2 / 201 (1.00%)	3 / 162 (1.85%)
occurrences causally related to treatment / all	5 / 6	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cellulitis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter bacteraemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	3 / 198 (1.52%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 198 (0.51%)	2 / 201 (1.00%)	3 / 162 (1.85%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Perirectal abscess			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	15 / 198 (7.58%)	11 / 201 (5.47%)	26 / 162 (16.05%)
occurrences causally related to treatment / all	9 / 22	3 / 13	9 / 38
deaths causally related to treatment / all	0 / 5	0 / 1	0 / 9
Pneumonia fungal			
subjects affected / exposed	2 / 198 (1.01%)	2 / 201 (1.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 2	3 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Sepsis			
subjects affected / exposed	15 / 198 (7.58%)	13 / 201 (6.47%)	13 / 162 (8.02%)
occurrences causally related to treatment / all	12 / 26	10 / 14	5 / 18
deaths causally related to treatment / all	0 / 5	0 / 2	1 / 6
Septic shock			
subjects affected / exposed	2 / 198 (1.01%)	4 / 201 (1.99%)	4 / 162 (2.47%)
occurrences causally related to treatment / all	1 / 2	4 / 4	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Soft tissue infection			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	9 / 162 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	3 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Atypical pneumonia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Bacterial sepsis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Brain abscess			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Candida pneumonia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Clostridial sepsis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Clostridium bacteraemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Clostridium colitis			

subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Device related bacteraemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Diarrhoea infectious			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated varicella zoster virus infection			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Enterococcal bacteraemia			
subjects affected / exposed	2 / 198 (1.01%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 198 (0.51%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Fungal infection			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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 sepsis			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Groin abscess			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Herpes ophthalmic			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Herpes zoster			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Peritonitis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Pseudomonal bacteraemia			
subjects affected / exposed	3 / 198 (1.52%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Pulmonary tuberculosis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Streptococcal sepsis			

subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Urethritis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 201 (0.00%)	0 / 162 (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
Abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Anal abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Diverticulitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes dermatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Infected skin ulcer			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Liver abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Otitis media acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Periodontitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Pharyngitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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 staphylococcal			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Systemic infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Systemic mycosis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Wound infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
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			
Decreased appetite			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	3 / 162 (1.85%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Hypokalaemia			
subjects affected / exposed	0 / 198 (0.00%)	1 / 201 (0.50%)	0 / 162 (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
Failure to thrive			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Hyperkalaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	0 / 162 (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
Hyperuricaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	2 / 162 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	1 / 162 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Non-intensive Study: Placebo + Azacitidine		
Total subjects affected by serious adverse events			
subjects affected / exposed	118 / 160 (73.75%)		
number of deaths (all causes)	88		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Differentiation syndrome			
subjects affected / exposed	2 / 160 (1.25%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal neoplasm			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neoplasm progression			
subjects affected / exposed	2 / 160 (1.25%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Neoplasm prostate			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Embolism				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aneurysm ruptured				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Axillary vein thrombosis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Peripheral ischaemia				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis superficial				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombosis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Disease progression				
subjects affected / exposed	22 / 160 (13.75%)			
occurrences causally related to treatment / all	0 / 22			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	11 / 160 (6.88%)			
occurrences causally related to treatment / all	3 / 14			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal inflammation				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Sudden death				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Fatigue				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	3 / 160 (1.88%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Soft tissue inflammation				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Graft versus host disease				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft versus host disease in gastrointestinal tract				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft versus host disease in skin				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytokine release syndrome				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary alveolar haemorrhage				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal pain				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				

subjects affected / exposed	3 / 160 (1.88%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adjustment disorder with depressed mood				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood creatinine increased				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram QT prolonged				
subjects affected / exposed	3 / 160 (1.88%)			
occurrences causally related to treatment / all	5 / 5			
deaths causally related to treatment / all	0 / 0			

Platelet count decreased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alanine aminotransferase increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil count decreased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

C-reactive protein increased				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Creatinine renal clearance decreased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electroencephalogram abnormal				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SARS-CoV-2 test positive				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Weight decreased				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Fall				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic rupture				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Femoral neck fracture				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tooth fracture				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transfusion reaction				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				

Atrial fibrillation				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac failure				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac failure acute				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocarditis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracardiac mass				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular dysfunction				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiorenal syndrome				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular fibrillation				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 1			
Nervous system disorders				
Epilepsy				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Central nervous system lesion				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic encephalopathy				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	5 / 160 (3.13%)			
occurrences causally related to treatment / all	3 / 5			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	18 / 160 (11.25%)			
occurrences causally related to treatment / all	6 / 27			
deaths causally related to treatment / all	0 / 1			
Neutropenia				

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic necrosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Vision blurred				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Colitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal haemorrhagic				

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Gastrointestinal haemorrhage				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal haemorrhage				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic colitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				

subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Proctalgia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal haemorrhage			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			

subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal haematoma			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mechanical ileus			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			

subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal perforation				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Glossitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids thrombosed				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis acute				

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis acute				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Erythema				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash maculo-papular				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis exfoliative generalised				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug eruption				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic kidney disease				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal failure				

subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue necrosis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Arthritis infective			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Bacteraemia			
subjects affected / exposed	4 / 160 (2.50%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	7 / 160 (4.38%)		
occurrences causally related to treatment / all	1 / 7		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterobacter bacteraemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	5 / 160 (3.13%)		
occurrences causally related to treatment / all	4 / 5		
deaths causally related to treatment / all	0 / 0		
Neutropenic sepsis			
subjects affected / exposed	5 / 160 (3.13%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Perirectal abscess			

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	35 / 160 (21.88%)			
occurrences causally related to treatment / all	9 / 49			
deaths causally related to treatment / all	1 / 9			
Pneumonia fungal				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomembranous colitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	9 / 160 (5.63%)			
occurrences causally related to treatment / all	3 / 13			
deaths causally related to treatment / all	1 / 4			
Septic shock				
subjects affected / exposed	5 / 160 (3.13%)			
occurrences causally related to treatment / all	7 / 9			
deaths causally related to treatment / all	1 / 3			
Soft tissue infection				
subjects affected / exposed	3 / 160 (1.88%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				

subjects affected / exposed	4 / 160 (2.50%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Anorectal infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain abscess				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Candida pneumonia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridial sepsis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium bacteraemia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium colitis				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related bacteraemia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea infectious				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated varicella zoster virus infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fungal infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fungal sepsis				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes ophthalmic				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal bacteraemia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethritis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Candida sepsis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Catheter site infection				

subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes dermatitis				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella bacteraemia				
subjects affected / exposed	2 / 160 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				

subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Periodontitis			
subjects affected / exposed	2 / 160 (1.25%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia staphylococcal			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	2 / 160 (1.25%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			

subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdiaphragmatic abscess				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suspected COVID-19				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Systemic infection				
subjects affected / exposed	1 / 160 (0.63%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Systemic mycosis				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 160 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral infection				

subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hyperkalaemia			
subjects affected / exposed	3 / 160 (1.88%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hyperuricaemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypophosphataemia			

subjects affected / exposed	1 / 160 (0.63%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Intensive Study: Glasdegib + Cytarabine + Daunorubicin	Intensive Study: Placebo + Cytarabine + Daunorubicin	Non-intensive Study: Glasdegib + Azacitidine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	194 / 198 (97.98%)	195 / 201 (97.01%)	153 / 162 (94.44%)
Vascular disorders			
Hypertension			
subjects affected / exposed	10 / 198 (5.05%)	25 / 201 (12.44%)	0 / 162 (0.00%)
occurrences (all)	15	39	0
Hypotension			
subjects affected / exposed	18 / 198 (9.09%)	17 / 201 (8.46%)	0 / 162 (0.00%)
occurrences (all)	19	23	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	15 / 198 (7.58%)	11 / 201 (5.47%)	15 / 162 (9.26%)
occurrences (all)	21	14	24
Fatigue			
subjects affected / exposed	31 / 198 (15.66%)	32 / 201 (15.92%)	13 / 162 (8.02%)
occurrences (all)	53	47	17
Oedema peripheral			
subjects affected / exposed	25 / 198 (12.63%)	32 / 201 (15.92%)	11 / 162 (6.79%)
occurrences (all)	36	43	13
Pyrexia			
subjects affected / exposed	84 / 198 (42.42%)	84 / 201 (41.79%)	41 / 162 (25.31%)
occurrences (all)	194	169	68
Chills			
subjects affected / exposed	20 / 198 (10.10%)	11 / 201 (5.47%)	0 / 162 (0.00%)
occurrences (all)	25	17	0
Mucosal inflammation			

subjects affected / exposed	12 / 198 (6.06%)	7 / 201 (3.48%)	0 / 162 (0.00%)
occurrences (all)	16	9	0
Non-cardiac chest pain			
subjects affected / exposed	13 / 198 (6.57%)	8 / 201 (3.98%)	0 / 162 (0.00%)
occurrences (all)	16	10	0
Oedema			
subjects affected / exposed	9 / 198 (4.55%)	19 / 201 (9.45%)	0 / 162 (0.00%)
occurrences (all)	17	22	0
Injection site reaction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	11 / 162 (6.79%)
occurrences (all)	0	0	42
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	23 / 198 (11.62%)	23 / 201 (11.44%)	10 / 162 (6.17%)
occurrences (all)	28	25	10
Dyspnoea			
subjects affected / exposed	15 / 198 (7.58%)	23 / 201 (11.44%)	11 / 162 (6.79%)
occurrences (all)	18	25	11
Epistaxis			
subjects affected / exposed	19 / 198 (9.60%)	20 / 201 (9.95%)	8 / 162 (4.94%)
occurrences (all)	21	25	16
Oropharyngeal pain			
subjects affected / exposed	19 / 198 (9.60%)	19 / 201 (9.45%)	0 / 162 (0.00%)
occurrences (all)	23	21	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	27 / 198 (13.64%)	30 / 201 (14.93%)	12 / 162 (7.41%)
occurrences (all)	29	37	15
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	39 / 198 (19.70%)	53 / 201 (26.37%)	13 / 162 (8.02%)
occurrences (all)	104	138	27
Aspartate aminotransferase increased			
subjects affected / exposed	30 / 198 (15.15%)	41 / 201 (20.40%)	10 / 162 (6.17%)
occurrences (all)	51	83	17
Blood creatinine increased			

subjects affected / exposed	18 / 198 (9.09%)	13 / 201 (6.47%)	20 / 162 (12.35%)
occurrences (all)	24	20	34
Electrocardiogram QT prolonged			
subjects affected / exposed	21 / 198 (10.61%)	20 / 201 (9.95%)	20 / 162 (12.35%)
occurrences (all)	30	35	28
Gamma-glutamyltransferase increased			
subjects affected / exposed	12 / 198 (6.06%)	22 / 201 (10.95%)	10 / 162 (6.17%)
occurrences (all)	36	75	19
Neutrophil count decreased			
subjects affected / exposed	56 / 198 (28.28%)	49 / 201 (24.38%)	22 / 162 (13.58%)
occurrences (all)	308	317	129
Platelet count decreased			
subjects affected / exposed	77 / 198 (38.89%)	73 / 201 (36.32%)	30 / 162 (18.52%)
occurrences (all)	627	504	155
Weight decreased			
subjects affected / exposed	21 / 198 (10.61%)	22 / 201 (10.95%)	34 / 162 (20.99%)
occurrences (all)	37	32	63
White blood cell count decreased			
subjects affected / exposed	63 / 198 (31.82%)	53 / 201 (26.37%)	17 / 162 (10.49%)
occurrences (all)	454	495	114
Blood alkaline phosphatase increased			
subjects affected / exposed	14 / 198 (7.07%)	13 / 201 (6.47%)	0 / 162 (0.00%)
occurrences (all)	26	21	0
Blood bilirubin increased			
subjects affected / exposed	25 / 198 (12.63%)	13 / 201 (6.47%)	0 / 162 (0.00%)
occurrences (all)	62	34	0
Lymphocyte count decreased			
subjects affected / exposed	19 / 198 (9.60%)	21 / 201 (10.45%)	0 / 162 (0.00%)
occurrences (all)	133	111	0
C-reactive protein increased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	7 / 162 (4.32%)
occurrences (all)	0	0	13
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	10 / 162 (6.17%)
occurrences (all)	0	0	19
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	11 / 198 (5.56%)	7 / 201 (3.48%)	0 / 162 (0.00%)
occurrences (all)	13	7	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	23 / 198 (11.62%)	18 / 201 (8.96%)	9 / 162 (5.56%)
occurrences (all)	32	26	9
Dysgeusia			
subjects affected / exposed	39 / 198 (19.70%)	20 / 201 (9.95%)	37 / 162 (22.84%)
occurrences (all)	48	21	41
Headache			
subjects affected / exposed	39 / 198 (19.70%)	47 / 201 (23.38%)	4 / 162 (2.47%)
occurrences (all)	56	62	4
Paraesthesia			
subjects affected / exposed	11 / 198 (5.56%)	0 / 201 (0.00%)	0 / 162 (0.00%)
occurrences (all)	11	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	101 / 198 (51.01%)	97 / 201 (48.26%)	73 / 162 (45.06%)
occurrences (all)	553	530	217
Febrile neutropenia			
subjects affected / exposed	97 / 198 (48.99%)	96 / 201 (47.76%)	22 / 162 (13.58%)
occurrences (all)	134	152	32
Leukopenia			
subjects affected / exposed	10 / 198 (5.05%)	13 / 201 (6.47%)	11 / 162 (6.79%)
occurrences (all)	34	65	52
Neutropenia			
subjects affected / exposed	41 / 198 (20.71%)	43 / 201 (21.39%)	35 / 162 (21.60%)
occurrences (all)	96	180	130
Thrombocytopenia			
subjects affected / exposed	52 / 198 (26.26%)	52 / 201 (25.87%)	37 / 162 (22.84%)
occurrences (all)	271	324	152
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	31 / 198 (15.66%)	29 / 201 (14.43%)	12 / 162 (7.41%)
occurrences (all)	37	38	13
Constipation			
subjects affected / exposed	71 / 198 (35.86%)	61 / 201 (30.35%)	58 / 162 (35.80%)
occurrences (all)	96	87	90
Diarrhoea			
subjects affected / exposed	96 / 198 (48.48%)	88 / 201 (43.78%)	36 / 162 (22.22%)
occurrences (all)	141	133	49
Haemorrhoids			
subjects affected / exposed	13 / 198 (6.57%)	19 / 201 (9.45%)	8 / 162 (4.94%)
occurrences (all)	13	21	11
Nausea			
subjects affected / exposed	110 / 198 (55.56%)	106 / 201 (52.74%)	55 / 162 (33.95%)
occurrences (all)	169	181	96
Vomiting			
subjects affected / exposed	57 / 198 (28.79%)	40 / 201 (19.90%)	35 / 162 (21.60%)
occurrences (all)	77	57	47
Abdominal pain upper			
subjects affected / exposed	12 / 198 (6.06%)	9 / 201 (4.48%)	0 / 162 (0.00%)
occurrences (all)	12	12	0
Dyspepsia			
subjects affected / exposed	12 / 198 (6.06%)	5 / 201 (2.49%)	0 / 162 (0.00%)
occurrences (all)	13	5	0
Proctalgia			
subjects affected / exposed	14 / 198 (7.07%)	6 / 201 (2.99%)	0 / 162 (0.00%)
occurrences (all)	15	7	0
Stomatitis			
subjects affected / exposed	29 / 198 (14.65%)	41 / 201 (20.40%)	0 / 162 (0.00%)
occurrences (all)	45	55	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 201 (0.00%)	11 / 162 (6.79%)
occurrences (all)	0	0	18
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	22 / 198 (11.11%)	26 / 201 (12.94%)	20 / 162 (12.35%)
occurrences (all)	26	29	22
Pruritus			
subjects affected / exposed	12 / 198 (6.06%)	11 / 201 (5.47%)	8 / 162 (4.94%)
occurrences (all)	12	19	8
Rash			
subjects affected / exposed	46 / 198 (23.23%)	51 / 201 (25.37%)	10 / 162 (6.17%)
occurrences (all)	70	80	12
Dry skin			
subjects affected / exposed	13 / 198 (6.57%)	10 / 201 (4.98%)	0 / 162 (0.00%)
occurrences (all)	13	12	0
Petechiae			
subjects affected / exposed	8 / 198 (4.04%)	11 / 201 (5.47%)	0 / 162 (0.00%)
occurrences (all)	10	11	0
Rash maculo-papular			
subjects affected / exposed	21 / 198 (10.61%)	21 / 201 (10.45%)	0 / 162 (0.00%)
occurrences (all)	26	30	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	17 / 198 (8.59%)	14 / 201 (6.97%)	11 / 162 (6.79%)
occurrences (all)	23	16	13
Back pain			
subjects affected / exposed	22 / 198 (11.11%)	17 / 201 (8.46%)	7 / 162 (4.32%)
occurrences (all)	24	18	8
Muscle spasms			
subjects affected / exposed	20 / 198 (10.10%)	3 / 201 (1.49%)	28 / 162 (17.28%)
occurrences (all)	31	3	44
Myalgia			
subjects affected / exposed	15 / 198 (7.58%)	11 / 201 (5.47%)	0 / 162 (0.00%)
occurrences (all)	27	12	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	32 / 198 (16.16%)	33 / 201 (16.42%)	19 / 162 (11.73%)
occurrences (all)	44	53	27
Upper respiratory tract infection			

subjects affected / exposed	9 / 198 (4.55%)	11 / 201 (5.47%)	12 / 162 (7.41%)
occurrences (all)	13	16	14
Urinary tract infection			
subjects affected / exposed	5 / 198 (2.53%)	11 / 201 (5.47%)	16 / 162 (9.88%)
occurrences (all)	5	12	24
Bacteraemia			
subjects affected / exposed	16 / 198 (8.08%)	11 / 201 (5.47%)	0 / 162 (0.00%)
occurrences (all)	20	14	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	52 / 198 (26.26%)	41 / 201 (20.40%)	45 / 162 (27.78%)
occurrences (all)	67	68	55
Hyperglycaemia			
subjects affected / exposed	10 / 198 (5.05%)	10 / 201 (4.98%)	5 / 162 (3.09%)
occurrences (all)	12	17	5
Hypoalbuminaemia			
subjects affected / exposed	32 / 198 (16.16%)	30 / 201 (14.93%)	11 / 162 (6.79%)
occurrences (all)	78	57	28
Hypocalcaemia			
subjects affected / exposed	25 / 198 (12.63%)	17 / 201 (8.46%)	10 / 162 (6.17%)
occurrences (all)	41	37	25
Hypokalaemia			
subjects affected / exposed	76 / 198 (38.38%)	83 / 201 (41.29%)	35 / 162 (21.60%)
occurrences (all)	200	217	65
Hypomagnesaemia			
subjects affected / exposed	29 / 198 (14.65%)	24 / 201 (11.94%)	11 / 162 (6.79%)
occurrences (all)	52	49	17
Hyponatraemia			
subjects affected / exposed	24 / 198 (12.12%)	15 / 201 (7.46%)	16 / 162 (9.88%)
occurrences (all)	34	23	21
Hypophosphataemia			
subjects affected / exposed	42 / 198 (21.21%)	44 / 201 (21.89%)	10 / 162 (6.17%)
occurrences (all)	88	84	21
Hyperuricaemia			
subjects affected / exposed	13 / 198 (6.57%)	9 / 201 (4.48%)	0 / 162 (0.00%)
occurrences (all)	20	28	0

Non-serious adverse events	Non-intensive Study: Placebo + Azacitidine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	149 / 160 (93.13%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	18 / 160 (11.25%)		
occurrences (all)	40		
Fatigue			
subjects affected / exposed	23 / 160 (14.38%)		
occurrences (all)	32		
Oedema peripheral			
subjects affected / exposed	18 / 160 (11.25%)		
occurrences (all)	25		
Pyrexia			
subjects affected / exposed	39 / 160 (24.38%)		
occurrences (all)	65		
Chills			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		

Injection site reaction			
subjects affected / exposed	7 / 160 (4.38%)		
occurrences (all)	19		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	20 / 160 (12.50%)		
occurrences (all)	26		
Dyspnoea			
subjects affected / exposed	18 / 160 (11.25%)		
occurrences (all)	25		
Epistaxis			
subjects affected / exposed	10 / 160 (6.25%)		
occurrences (all)	14		
Oropharyngeal pain			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	8 / 160 (5.00%)		
occurrences (all)	13		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	11 / 160 (6.88%)		
occurrences (all)	20		
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	20		
Blood creatinine increased			
subjects affected / exposed	13 / 160 (8.13%)		
occurrences (all)	15		
Electrocardiogram QT prolonged			
subjects affected / exposed	19 / 160 (11.88%)		
occurrences (all)	33		
Gamma-glutamyltransferase increased			

subjects affected / exposed occurrences (all)	8 / 160 (5.00%) 13		
Neutrophil count decreased subjects affected / exposed occurrences (all)	22 / 160 (13.75%) 153		
Platelet count decreased subjects affected / exposed occurrences (all)	26 / 160 (16.25%) 162		
Weight decreased subjects affected / exposed occurrences (all)	19 / 160 (11.88%) 36		
White blood cell count decreased subjects affected / exposed occurrences (all)	18 / 160 (11.25%) 143		
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 160 (0.00%) 0		
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 160 (0.00%) 0		
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 160 (0.00%) 0		
C-reactive protein increased subjects affected / exposed occurrences (all)	9 / 160 (5.63%) 20		
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	10 / 160 (6.25%) 11		
Cardiac disorders Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 160 (0.00%) 0		
Nervous system disorders			

Dizziness			
subjects affected / exposed	14 / 160 (8.75%)		
occurrences (all)	24		
Dysgeusia			
subjects affected / exposed	8 / 160 (5.00%)		
occurrences (all)	8		
Headache			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	20		
Paraesthesia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	70 / 160 (43.75%)		
occurrences (all)	335		
Febrile neutropenia			
subjects affected / exposed	20 / 160 (12.50%)		
occurrences (all)	37		
Leukopenia			
subjects affected / exposed	4 / 160 (2.50%)		
occurrences (all)	10		
Neutropenia			
subjects affected / exposed	30 / 160 (18.75%)		
occurrences (all)	120		
Thrombocytopenia			
subjects affected / exposed	32 / 160 (20.00%)		
occurrences (all)	123		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	10 / 160 (6.25%)		
occurrences (all)	12		
Constipation			
subjects affected / exposed	50 / 160 (31.25%)		
occurrences (all)	69		
Diarrhoea			

subjects affected / exposed	31 / 160 (19.38%)		
occurrences (all)	46		
Haemorrhoids			
subjects affected / exposed	10 / 160 (6.25%)		
occurrences (all)	10		
Nausea			
subjects affected / exposed	44 / 160 (27.50%)		
occurrences (all)	70		
Vomiting			
subjects affected / exposed	32 / 160 (20.00%)		
occurrences (all)	44		
Abdominal pain upper			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Proctalgia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	3 / 160 (1.88%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	9		
Rash			

subjects affected / exposed	13 / 160 (8.13%)		
occurrences (all)	16		
Dry skin			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	11 / 160 (6.88%)		
occurrences (all)	20		
Back pain			
subjects affected / exposed	12 / 160 (7.50%)		
occurrences (all)	15		
Muscle spasms			
subjects affected / exposed	4 / 160 (2.50%)		
occurrences (all)	4		
Myalgia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	15 / 160 (9.38%)		
occurrences (all)	19		
Upper respiratory tract infection			
subjects affected / exposed	11 / 160 (6.88%)		
occurrences (all)	11		
Urinary tract infection			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	11		
Bacteraemia			

subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	21 / 160 (13.13%)		
occurrences (all)	32		
Hyperglycaemia			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	19		
Hypoalbuminaemia			
subjects affected / exposed	13 / 160 (8.13%)		
occurrences (all)	28		
Hypocalcaemia			
subjects affected / exposed	13 / 160 (8.13%)		
occurrences (all)	32		
Hypokalaemia			
subjects affected / exposed	22 / 160 (13.75%)		
occurrences (all)	42		
Hypomagnesaemia			
subjects affected / exposed	5 / 160 (3.13%)		
occurrences (all)	6		
Hyponatraemia			
subjects affected / exposed	9 / 160 (5.63%)		
occurrences (all)	19		
Hypophosphataemia			
subjects affected / exposed	15 / 160 (9.38%)		
occurrences (all)	30		
Hyperuricaemia			
subjects affected / exposed	0 / 160 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 November 2017	In schedule of activities of Intenstive study, pregnancy testing added for Day 1 of each Consolidation Cycle with single-agent cytarabine and Day 1 of each cycle where single-agent glasdegib/placebo administered to ensure appropriate safety monitoring.

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.

Inadvertently 1 subject was enrolled twice into the study resulting in enrollment number as 730. However, a total of 729 subject were randomized and received treatment in the study.

Notes: