Clinical trial results:
A Phase 3, Randomized, Open-Label Study Evaluating the Safety and Efficacy of Magrolimab in Combination With Azacitidine versus Physician's Choice of Venetoclax in Combination With Azacitidine or Intensive Chemotherapy in Previously Untreated Patients With TP53 Mutant Acute Myeloid Leukemia

Summary

EudraCT number	2020-003949-11
Trial protocol	DK BE DE SE FR ES IT AT
Global end of trial date	25 March 2024
Results information	
Result version number	v2 (current)
This version publication date	20 February 2025
First version publication date	02 January 2025
Version creation reason	• Correction of full data set To update the explanation for '0000' in endpoints Event-free Survival, Duration of Complete Response and Duration of CR+CRh.

Trial information

Trial identification	
Sponsor protocol code	GS-US-546-5857
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04778397
WHO universal trial number (UTN)	-
Other trial identifiers	jRCT2071220076: Japan Registry of Clinical Trials

Notes:

Sponsors	
Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com

Notes:

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 March 2024
Global end of trial reached?	Yes
Global end of trial date	25 March 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The goal of this clinical study was to compare the effectiveness of the study drugs, magrolimab in combination with azacitidine, versus venetoclax in combination with azacitidine in participants with previously untreated TP53 mutant acute myeloid leukemia (AML).

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements. This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 26
Country: Number of subjects enrolled	United States: 65
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	France: 32
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Italy: 18
Country: Number of subjects enrolled	Spain: 35
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	Switzerland: 8
Country: Number of subjects enrolled	Hong Kong: 5
Country: Number of subjects enrolled	Australia: 20
Country: Number of subjects enrolled	Canada: 4

Country: Number of subjects enrolled	Japan: 21
Worldwide total number of subjects	257
EEA total number of subjects	108

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)	78
From 65 to 84 years	172
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in North America, the United Kingdom, Europe, Asia, and, Australia. 1 participant was enrolled but was not randomized.

Pre-assignment

Screening details:

841 participants were screened.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Magrolimab + Azacitidine (Non-Intensive Therapy)

Arm description:

Participants who were appropriate for non-intensive therapy received 1 mg/kg magrolimab intravenously (IV) on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then every week (QW) x 5 weekly 30 mg/kg dose; 30 mg/kg every 2 weeks (Q2W) beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine subcutaneously (SC) or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Arm type	Experimental
Investigational medicinal product name	Magrolimab
Investigational medicinal product code	GS-4721
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously.

Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Administered either subcutaneously or intravenously according to region-specific drug labeling.

Arm title	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)

Arm description:

Participants who were appropriate for non-intensive therapy received venetoclax 100 mg orally on Cycle 1 Day 1; 200 mg orally on Cycle 1 Day 2; 400 mg orally on Cycle 1 Day 3 everyday and throughout all the cycles. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Arm type	Active comparator
Investigational medicinal product name	Venetoclax
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details: Administered orally.	
Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intravenous use, Subcutaneous use
Dosage and administration details: Administered either subcutaneously or intravenously according to region-specific drug labeling.	
Arm title	Magrolimab + Azacitidine (Intensive Therapy)
Arm description: Participants who were appropriate for intensive therapy received 1 mg/kg magrolimab IV on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then QW x 5 weekly 30 mg/kg dose; 30 mg/kg Q2W beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.	
Arm type	Experimental
Investigational medicinal product name	Magrolimab
Investigational medicinal product code	GS-4721
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously.	
Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intravenous use, Subcutaneous use
Dosage and administration details: Administered either subcutaneously or intravenously according to region-specific drug labeling.	
Arm title	Control Arm: 7+3 Chemotherapy (Intensive Therapy)
Arm description: Participants who were appropriate for intensive therapy received 7+3 chemotherapy: 7 day treatment with cytarabine 100 or 200 mg/m^2 continuous infusion and 3 day treatment with daunorubicin 60 mg/m^2 IV push or idarubicin 60 mg/m^2 IV during induction and high-dose cytarabine 1500 or 3000 mg/m^2 IV every 12 hours on Days 1, 3, and 5 up to 4 cycles and steroidal eye drops during consolidation. Each cycle was 28 days.	
Arm type	Active comparator
Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Infusion
Dosage and administration details: Administered as continuous infusion.	
Investigational medicinal product name	Daunorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Infusion
Dosage and administration details: Administered intravenous peripherally.	

Investigational medicinal product name	Idarubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Infusion

Dosage and administration details:

Administered intravenously.

Investigational medicinal product name	Steroidal Eye Drops
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ocular use

Dosage and administration details:

Administered per institutional standard during consolidation.

Number of subjects in period 1	Magrolimab + Azacitidine (Non-Intensive Therapy)	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)	Magrolimab + Azacitidine (Intensive Therapy)
Started	101	104	27
Completed	0	0	0
Not completed	101	104	27
Missing Study Discontinuation Reason	1	3	-
Withdrew Consent	5	4	1
Death	59	54	11
Lost to Follow-up	2	1	-
Study Terminated by Sponsor	34	42	15

Number of subjects in period 1	Control Arm: 7+3 Chemotherapy (Intensive Therapy)
Started	25
Completed	0
Not completed	25
Missing Study Discontinuation Reason	2
Withdrew Consent	1
Death	9
Lost to Follow-up	1
Study Terminated by Sponsor	12

Baseline characteristics

Reporting groups	
Reporting group title	Magrolimab + Azacitidine (Non-Intensive Therapy)
Reporting group description:	
Participants who were appropriate for non-intensive therapy received 1 mg/kg magrolimab intravenously (IV) on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then every week (QW) x 5 weekly 30 mg/kg dose; 30 mg/kg every 2 weeks (Q2W) beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine subcutaneously (SC) or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.	
Reporting group title	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)
Reporting group description:	
Participants who were appropriate for non-intensive therapy received venetoclax 100 mg orally on Cycle 1 Day 1; 200 mg orally on Cycle 1 Day 2; 400 mg orally on Cycle 1 Day 3 everyday and throughout all the cycles. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.	
Reporting group title	Magrolimab + Azacitidine (Intensive Therapy)
Reporting group description:	
Participants who were appropriate for intensive therapy received 1 mg/kg magrolimab IV on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then QW x 5 weekly 30 mg/kg dose; 30 mg/kg Q2W beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.	
Reporting group title	Control Arm: 7+3 Chemotherapy (Intensive Therapy)
Reporting group description:	
Participants who were appropriate for intensive therapy received 7+3 chemotherapy: 7 day treatment with cytarabine 100 or 200 mg/m^2 continuous infusion and 3 day treatment with daunorubicin 60 mg/m^2 IV push or idarubicin 60 mg/m^2 IV during induction and high-dose cytarabine 1500 or 3000 mg/m^2 IV every 12 hours on Days 1, 3, and 5 up to 4 cycles and steroidal eye drops during consolidation. Each cycle was 28 days.	

Reporting group values	Magrolimab + Azacitidine (Non-Intensive Therapy)	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)	Magrolimab + Azacitidine (Intensive Therapy)
Number of subjects	101	104	27
Age categorical Units: Subjects			
Adults (18 – 64 Years)	19	23	21
Geriatrics (65 – 84 Years)	79	77	6
Geriatrics (85 Years and Over)	3	4	0
Age continuous Units: years			
arithmetic mean	70	71	57
standard deviation	± 9.6	± 8.0	± 9.6
Gender categorical Units: Subjects			
Female	43	43	5
Male	58	61	22
Race Units: Subjects			
White	75	72	12
Asian	12	11	3
Other or More Than One Race	4	2	1

Black or African American	2	2	2
Native Hawaiian or Other Pacific Islander	0	0	1
Not Reported	8	17	8
Ethnicity Units: Subjects			
Not Hispanic or Latino	82	74	19
Hispanic or Latino	9	13	1
Unknown or Not Reported	10	17	7

Reporting group values	Control Arm: 7+3 Chemotherapy (Intensive Therapy)	Total	
Number of subjects	25	257	
Age categorical Units: Subjects			
Adults (18 – 64 Years)	15	78	
Geriatrics (65 – 84 Years)	10	172	
Geriatrics (85 Years and Over)	0	7	
Age continuous Units: years			
arithmetic mean	61		
standard deviation	± 8.6	-	
Gender categorical Units: Subjects			
Female	11	102	
Male	14	155	
Race Units: Subjects			
White	15	174	
Asian	4	30	
Other or More Than One Race	2	9	
Black or African American	0	6	
Native Hawaiian or Other Pacific Islander	0	1	
Not Reported	4	37	
Ethnicity Units: Subjects			
Not Hispanic or Latino	20	195	
Hispanic or Latino	2	25	
Unknown or Not Reported	3	37	

End points reporting groups

Reporting group title	Magrolimab + Azacitidine (Non-Intensive Therapy)

Reporting group description:

Participants who were appropriate for non-intensive therapy received 1 mg/kg magrolimab intravenously (IV) on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then every week (QW) x 5 weekly 30 mg/kg dose; 30 mg/kg every 2 weeks (Q2W) beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine subcutaneously (SC) or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Reporting group title	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)

Reporting group description:

Participants who were appropriate for non-intensive therapy received venetoclax 100 mg orally on Cycle 1 Day 1; 200 mg orally on Cycle 1 Day 2; 400 mg orally on Cycle 1 Day 3 everyday and throughout all the cycles. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Reporting group title	Magrolimab + Azacitidine (Intensive Therapy)

Reporting group description:

Participants who were appropriate for intensive therapy received 1 mg/kg magrolimab IV on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then QW x 5 weekly 30 mg/kg dose; 30 mg/kg Q2W beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Reporting group title	Control Arm: 7+3 Chemotherapy (Intensive Therapy)

Reporting group description:

Participants who were appropriate for intensive therapy received 7+3 chemotherapy: 7 day treatment with cytarabine 100 or 200 mg/m^2 continuous infusion and 3 day treatment with daunorubicin 60 mg/m^2 IV push or idarubicin 60 mg/m^2 IV during induction and high-dose cytarabine 1500 or 3000 mg/m^2 IV every 12 hours on Days 1, 3, and 5 up to 4 cycles and steroidal eye drops during consolidation. Each cycle was 28 days.

Subject analysis set title	Magrolimab + Azacitidine
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who were appropriate for intensive and non-intensive therapy received 1 mg/kg magrolimab intravenously (IV) on Days 1, 4; 15 mg/kg on Day 8; 30 mg/kg on Days 11, 15, and then QW x 5 weekly 30 mg/kg dose; 30 mg/kg Q2W beginning 1 week after the 5 weekly 30 mg/kg dose. Participants received azacitidine subcutaneously (SC) or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.

Subject analysis set title	Venetoclax + Azacitidine or 7+3 Chemotherapy
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who were appropriate for non-intensive therapy received venetoclax 100 mg orally on Cycle 1 Day 1; 200 mg orally on Cycle 1 Day 2; 400 mg orally on Cycle 1 Day 3 everyday and throughout all the cycles. Participants received azacitidine SC or IV, 75 mg/m^2 on Days 1-7 or Days 1-5, 8 and 9 during every cycle of 28 days. The treatment duration was up to a maximum of 1.3 years.
Participants who were appropriate for intensive therapy received 7+3 chemotherapy: 7 day treatment with cytarabine 100 or 200 mg/m^2 continuous infusion and 3 day treatment with daunorubicin 60 mg/m^2 IV push or idarubicin 60 mg/m^2 IV during induction and high-dose cytarabine 1500 or 3000 mg/m^2 IV every 12 hours on Days 1, 3, and 5 up to 4 cycles and steroidal eye drops during consolidation. Each cycle was 28 days.

Primary: Overall Survival (OS) in Participants Appropriate for Non-intensive Therapy

End point title	Overall Survival (OS) in Participants Appropriate for Non-intensive Therapy[1]

End point description:

OS was measured from the date of randomization to the date of death from any cause. Deaths which were not observed during the study were censored at their last known alive date. Kaplan-Meier (KM) estimates were used in endpoint analysis.

Participants from the Intent-to-Treat Analysis (ITT) Set who were appropriate for non-intensive therapy were analyzed. The ITT Analysis Set included all randomized participants according to the treatment arm to which the participant was randomized, unless otherwise specified. As per the pre-specified analysis, the data in this endpoint was reported only for the non-intensive therapy groups.

End point type	Primary

End point timeframe:

Up to 2.1 years

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: As per the pre-specified analysis, the data in this endpoint was reported only for the non-intensive therapy groups.

End point values	Magrolimab + Azacitidine (Non-Intensive Therapy)	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	104		
Units: months				
median (confidence interval 95%)	4.4 (3.6 to 6.0)	6.6 (4.8 to 8.1)		

Statistical analyses

Statistical analysis title	OS in Participants in Non-intensive Therapy

Statistical analysis description:

Hazard ratio and 95% CIs were calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (appropriateness for non-intensive therapy vs intensive therapy, age (< 75 years, >=75 years), geographic region (US sites, outside the US sites)).

Comparison groups	Magrolimab + Azacitidine (Non-Intensive Therapy) v Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.507 [2]
Method	Stratified log-rank test
Parameter estimate	Stratified Hazard Ratio
Point estimate	1.132
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.783
upper limit	1.637

Notes:

[2] - P-value from stratified log-rank test.

Secondary: Overall Survival in All Participants

End point title	Overall Survival in All Participants

End point description:

OS was measured from the date of randomization to the date of death from any cause. Deaths which were not observed during the study were censored at their last known alive date. KM estimates were used in endpoint analysis.

Participants from the Intend-To-Treat Analysis Set were analyzed. As per the pre-specified analysis, the data for this endpoint were analyzed together for all participants for both intensive and non-intensive therapy groups.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	128	129		
Units: months				
median (confidence interval 95%)	4.4 (3.7 to 6.6)	6.6 (4.9 to 8.9)		

Statistical analyses

Statistical analysis title	OS in All Participants

Statistical analysis description:

Hazard ratio and 95% CIs were calculated using the Cox proportional hazards model, adjusted for randomization stratification factors (appropriateness for non-intensive therapy vs intensive therapy, age (< 75 years, >=75 years), geographic region (US sites, outside the US sites)).

Comparison groups	Magrolimab + Azacitidine v Venetoclax + Azacitidine or 7+3 Chemotherapy
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3237 [3]
Method	Stratified Log-rank test
Parameter estimate	Stratified Hazard Ratio
Point estimate	1.183
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.845
upper limit	1.654

Notes:

[3] - P-value from stratified log-rank test.

Secondary: Event-Free Survival (EFS) in All Participants

End point title	Event-Free Survival (EFS) in All Participants

End point description:

EFS: time from randomization to earliest relapse from CR(CR without minimal residual disease (CRMRD-) and CR with MRD positive/MRD unknown (CRMRD+/unk)), treatment failure (failure to achieve CR in 6 months of magrolimab/venetoclax+azacitidine; 2 months after chemotherapy), or death within response window. CRMRD- and CRMRD+/unk: neutrophils>1.0 ×10^9/L, platelets>100 ×10^9/L, <5% bone marrow blasts, no circulating blasts or extramedullary disease (confirmed by flow cytometry <0.1% sensitivity for CRMRD-). Post-SCT assessments or new AML therapies were included. Date of randomization was assigned as event date for participants with treatment failure. Participants without

events were censored at their last assessment. KM estimates for analysis. ITT Analysis Set. Data analyzed together for magrolimab+azacitidine and venetoclax+azacitidine or chemotherapy. 9999=Upper and lower limits of CI could not be estimated due to limitation in KM model as EFS values were below quantification limit.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	128	129		
Units: months				
median (confidence interval 95%)	0.0 (-9999 to 9999)	0.0 (-9999 to 9999)		

Statistical analyses

Statistical analysis title	EFS in All Participants

Statistical analysis description:

Hazard ratio and 95% CIs were calculated using the Cox proportional hazards model, adjusted for randomization stratification factors: therapy appropriateness, age (< 75 years, >=75 years), geographic region (US sites, outside the US sites).

Comparison groups	Magrolimab + Azacitidine v Venetoclax + Azacitidine or 7+3 Chemotherapy
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0661 [4]
Method	Stratified Log-rank test
Parameter estimate	Stratified Hazard Ratio
Point estimate	1.389
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.043
upper limit	1.848

Notes:

[4] - P-value for comparing the event free survival functions from the two treatment groups was from stratified log-rank test, adjusted for randomization.

Secondary: Rate of Complete Remission (CR) in All Participants

End point title	Rate of Complete Remission (CR) in All Participants

End point description:

Rate of CR was the percentage of participants who achieved a CR, including CR without minimal residual disease (CR MRD-) and CR with positive or unknown minimal residual disease (CR MRD+/unk) within 6 months of treatment with magrolimab + azacitidine or venetoclax + azacitidine, or within 2 months of treatment with chemotherapy, as defined by investigators based on European Leukemia Net (ELN) 2017 AML (ELN 2017 AML) with modifications, while on study prior to initiation of any new anti-AML therapy

or stem cell transplant (SCT) within the response assessment window of 2.1 years. CR MRD- and CR MRD+/unk were defined in endpoint #3 (EFS). Percentages were rounded-off. Clopper-Pearson method were used in endpoint analysis.
Participants from ITT Analysis Set were analyzed. As per the pre-specified analysis, the data for this endpoint were analyzed together for all participants who received magrolimab + azacitidine and participants who received venetoclax + azacitidine or chemotherapy.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	128	129		
Units: percentage of participants				
number (confidence interval 95%)	9.4 (4.9 to 15.8)	29.5 (21.8 to 38.1)		

Statistical analyses

Statistical analysis title	Rate of CR in All Participants

Statistical analysis description:

Odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for randomization stratification factors (appropriateness for non-intensive therapy versus intensive therapy, age (< 75 years, >=75 years), geographic region (US sites, outside US sites)).

Comparison groups	Magrolimab + Azacitidine v Venetoclax + Azacitidine or 7+3 Chemotherapy
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Stratified Odds Ratio
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.123
upper limit	0.506

Secondary: Rate of CR Without Minimal Residual Disease (CR MRD-) in All Participants

End point title	Rate of CR Without Minimal Residual Disease (CR MRD-) in All Participants

End point description:

Rate of CR MRD- was the percentage of participants who achieve a CR MRD- within 6 months treatment with magrolimab + azacitidine or venetoclax + azacitidine, or within 2 months of treatment with 7 + 3 chemotherapy, as defined by investigators based on ELN 2017 AML with modifications, while on study prior to initiation of any new anti-AML therapy or SCT within the response assessment window of 2.1

years. CR MRD- is defined in endpoint #3 (EFS). Percentages were rounded-off. Clopper-Pearson method were used in endpoint analysis.
Participants from the Intent-To-Treat Analysis Set were analyzed. As per the pre-specified analysis, the data for this endpoint were analyzed together for all participants who received magrolimab + azacitidine and participants who received venetoclax + azacitidine or 7+3 chemotherapy.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	128	129		
Units: percentage of participants				
number (confidence interval 95%)	0.8 (0.0 to 4.3)	10.1 (5.5 to 16.6)		

Statistical analyses

Statistical analysis title	Rate of CR MRD- in All Participants

Statistical analysis description:

Odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for randomization stratification factors (appropriateness for non-intensive therapy versus intensive therapy, age (< 75 years, >=75 years), geographic region (US sites, outside US sites)).

Comparison groups	Magrolimab + Azacitidine v Venetoclax + Azacitidine or 7+3 Chemotherapy
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Stratified Odds Ratio
Point estimate	0.072
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.009
upper limit	0.559

Secondary: Rate of CR and CR with Partial Hematologic Recovery (CR+CRh) in All Participants

End point title	Rate of CR and CR with Partial Hematologic Recovery (CR+CRh) in All Participants

End point description:

CR+CRh rate was the percentage of participants who achieved a CR (including CR MRD- and CR MRD+/unk) or CRh as defined by CR with partial platelet and absolute neutrophil count (ANC) recovery while on study prior to initiation of any new anti-AML therapy or SCT up to the response assessment window of 2.1 years. CRh is defined as neutrophils > 0.5 x 10^9/L; platelets > 50 x 10^9/L; bone marrow blasts < 5%; Absence of circulating blasts and blasts with Auer rods; absence of extramedullary

disease. CR MRD- and CR MRD+/unk are defined in endpoint #3 (EFS). Percentages were rounded-off. Clopper-Pearson method were used in endpoint analysis.
Participants from the Intent-To-Treat Analysis Set were analyzed. As per the pre-specified analysis, the data for this endpoint were analyzed together for all participants who received magrolimab + azacitidine and participants who received venetoclax + azacitidine or 7+3 chemotherapy.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	128	129		
Units: percentage of participants				
number (confidence interval 95%)	10.2 (5.5 to 16.7)	34.1 (26.0 to 43.0)		

Statistical analyses

Statistical analysis title	Rate of CR+CRh in All Participants

Statistical analysis description:

Odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for randomization stratification factors (appropriateness for non-intensive therapy versus intensive therapy, age (< 75 years, >=75 years), geographic region (US sites, outside US sites)).

Comparison groups	Magrolimab + Azacitidine v Venetoclax + Azacitidine or 7+3 Chemotherapy
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Stratified Odds Ratio
Point estimate	0.215
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.108
upper limit	0.428

Secondary: Duration of Complete Remission (DCR)

End point title	Duration of Complete Remission (DCR)

End point description:

DCR was measured from first assessment meeting CR criteria (including CR MRD- and CR MRD+/unk) within 6 months of magrolimab/venetoclax + azacitidine; 2 months of chemotherapy, until AML relapse or death (including post-SCT). Participants without relapse or death or starting new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse were censored at last response assessment or last assessment prior to starting new treatment respectively. CR MRD- and CR MRD+/unk defined in Endpoint #3 (EFS). KM estimates were used for analysis.
Participants from ITT Analysis Set who achieved CR within 6 months in all participants (2 months for

participants receiving 7 + 3 chemotherapy) were analyzed. Data analyzed together for magrolimab+azacitidine and venetoclax+azacitidine or chemotherapy.
'9999'=Upper limit of CI was not estimable due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	38		
Units: months				
median (confidence interval 95%)	9.5 (2.0 to 9999)	4.9 (3.1 to 6.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CR+CRh

End point title	Duration of CR+CRh

End point description:

Duration of CR+CRh was measured from first assessment meeting CR criteria (CR MRD- and CR MRD+/unk) or CRh in 6 months of magrolimab/venetoclax+azacitidine; 2 months of chemotherapy, until AML relapse or death (including post-SCT). Participants without relapse or death or starting new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse were censored at their last response assessment or last assessment prior to starting new treatment. CR MRD-, CR MRD+/unk defined in endpoint#3, CRh defined in endpoint#6. KM estimates were used for analysis.
Participants from ITT Analysis Set who achieved CR within 6 months in all participants (2 months for participants receiving chemotherapy were analyzed. Data analyzed together for magrolimab+azacitidine and venetoclax+azacitidine or chemotherapy.
'9999'=Upper limit of CI was not estimable due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

Up to 2.1 years

End point values	Magrolimab + Azacitidine	Venetoclax + Azacitidine or 7+3 Chemotherapy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	44		
Units: months				
median (confidence interval 95%)	9.5 (2.0 to 9999)	4.9 (3.1 to 6.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Grade ≥ 3 Treatment-Emergent Adverse Events (TEAEs) According to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0

End point title	Percentage of Participants Experiencing Grade ≥ 3 Treatment-Emergent Adverse Events (TEAEs) According to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0

End point description:

TEAEs were defined as any AE that began on or after the date of first dose of study treatment up to the date of last dose of study treatment plus 70 days or the day before initiation of new anti-AML therapy including SCT, whichever occurred first.
The Safety Analysis Set included all participants who took at least 1 dose of any study treatment, with treatment assignment designated according to the actual treatment received.

End point type	Secondary

End point timeframe:

First dose date up to 1.3 years plus 70 days

End point values	Magrolimab + Azacitidine (Non-Intensive Therapy)	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)	Magrolimab + Azacitidine (Intensive Therapy)	Control Arm: 7+3 Chemotherapy (Intensive Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96	98	27	23
Units: percentage of participants				
number (not applicable)	96.9	95.9	92.6	95.7

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Grade 3 or 4 Treatment-Emergent Laboratory Abnormalities According to the NCI CTCAE Version 5.0

End point title	Percentage of Participants Experiencing Grade 3 or 4 Treatment-Emergent Laboratory Abnormalities According to the NCI CTCAE Version 5.0

End point description:

Treatment-emergent laboratory abnormalities were defined as values that increased at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of last dose of study treatment plus 70 days or the day before initiation of any new anti-AML therapy including SCT, whichever occurred first. Percentages were rounded-off. Participants from Safety Analysis Set were

analyzed.

End point type	Secondary

End point timeframe:

First dose date up to 1.3 years plus 70 days

End point values	Magrolimab + Azacitidine (Non-Intensive Therapy)	Control Arm: Venetoclax + Azacitidine (Non-Intensive Therapy)	Magrolimab + Azacitidine (Intensive Therapy)	Control Arm: 7+3 Chemotherapy (Intensive Therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96	98	27	23
Units: percentage of participants				
number (not applicable)				
Grade 3 or 4	96.9	99.0	100	95.7

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Magrolimab

End point title	Serum Concentration of Magrolimab

End point description:

The Pharmacokinetic (PK) Analysis Set included all randomized participants who took at least one dose of magrolimab and have at least 1 measurable (non-below the limit of quantitation (BLQ) numeric values) posttreatment serum concentration of magrolimab. Participants with available data were analyzed.
'9999'= Standard deviation cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Predose on Days 1, 4, 8, 11; Days 29 and 57 Predose and 1 hour Postdose; Predose on Days 113, 169, 253, 281 and 337

End point values	Magrolimab + Azacitidine			
Subject group type	Subject analysis set			
Number of subjects analysed	88[5]			
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1 Predose	0.0 (± 0.0)			
Day 4 Predose	0.0 (± 9999)			
Day 8 Predose	0.0 (± 0.0)			
Day 11 Predose	111 (± 9999)			
Day 29 Predose	311 (± 195)			
Day 29 1 hour Postdose	376 (± 9999)			
Day 57 Predose	402 (± 262)			

Day 57 1 hour Postdose	967 (± 351)			
Day 113 Predose	138 (± 96.0)			
Day 169 Predose	198 (± 129)			
Day 253 Predose	294 (± 181)			
Day 281 Predose	263 (± 9999)			
Day 337 Predose	251 (± 114)			

Notes:

[5] - n= 88, 1, 83, 1, 69, 1, 43, 36, 20, 10, 8, 1, 3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Anti-Magrolimab Antibodies

End point title	Percentage of Participants with Anti-Magrolimab Antibodies[6]

End point description:

Percentages were rounded-off.
The Immunogenicity Analysis Set included all randomized participants who received at least one dose of magrolimab and had at least one evaluable anti-magrolimab antibody test result.

End point type	Secondary

End point timeframe:

Up to 2.1 years

Notes:

[6] - 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: As per the pre-specified analysis, the data in this endpoint was reported only for the non-intensive therapy groups.

End point values	Magrolimab + Azacitidine (Non-Intensive Therapy)	Magrolimab + Azacitidine (Intensive Therapy)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	27		
Units: percentage of participants				
number (not applicable)	10.4	11.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Up to 2.1 years; Adverse events: Up to 1.3 years plus 70 days

Adverse event reporting additional description:

Death: ITT Analysis Set included all participants who were randomized in study, with treatment assignment designated according to treatment arm participant was randomized to.
AEs: Safety Analysis Set included all participants who took at least 1 dose of any study drugs, with treatment assignment designated according to actual treatment received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Appropriate for Non-intensive Therapy Magro + Aza

Reporting group description:

Patients who received Appropriate for Non-intensive Therapy Magro + Aza

Reporting group title	Appropriate for Non-intensive Therapy Ven + Aza

Reporting group description:

Patients who received Appropriate for Non-intensive Therapy Ven + Aza

Reporting group title	Appropriate for intensive Therapy Magro + Aza

Reporting group description:

Patients who received Appropriate for intensive Therapy Magro + Aza

Reporting group title	Appropriate for intensive Therapy 7+3 Chemo

Reporting group description:

Patients who received Appropriate for intensive Therapy 7+3 Chemo

Serious adverse events	Appropriate for Non-intensive Therapy Magro + Aza	Appropriate for Non-intensive Therapy Ven + Aza	Appropriate for intensive Therapy Magro + Aza
Total subjects affected by serious adverse events			
subjects affected / exposed	84 / 96 (87.50%)	76 / 98 (77.55%)	20 / 27 (74.07%)
number of deaths (all causes)	61	57	14
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian cancer recurrent			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Shock			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	1 / 1
Asthenia			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (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
Pyrexia			
subjects affected / exposed	10 / 96 (10.42%)	4 / 98 (4.08%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	4 / 10	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (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
Device related thrombosis			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Sudden death			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 96 (3.13%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	2 / 96 (2.08%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			

subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Organising pneumonia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Lung infiltration			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	3 / 96 (3.13%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Lymphocyte count decreased			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Liver function test increased			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Blood glucose increased			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Blood creatinine increased			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Fractured sacrum			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Fall			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (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
Transfusion reaction			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			

subjects affected / exposed	5 / 96 (5.21%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	3 / 96 (3.13%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Angina pectoris			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Myocardial ischaemia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Left ventricular failure			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Cardiogenic shock			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Pericardial effusion			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Ventricular tachycardia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Seizure			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Encephalopathy			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Dizziness postural			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Cerebral small vessel ischaemic ~ disease			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Cerebral infarction			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Cerebral haemorrhage			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (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
Lethargy			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Spinal cord compression			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
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			
Febrile neutropenia			
subjects affected / exposed	32 / 96 (33.33%)	34 / 98 (34.69%)	7 / 27 (25.93%)
occurrences causally related to treatment / all	13 / 47	25 / 46	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	9 / 96 (9.38%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	6 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Febrile bone marrow aplasia			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular ~ coagulation			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Haemolytic anaemia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Pancytopenia			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (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
Red blood cell abnormality			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Thrombocytopenia			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Eye disorders			
Retinal vascular thrombosis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Retinal haemorrhage			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Orbital haematoma			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Constipation			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal strangulated hernia			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Anal fistula			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Colitis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Haemorrhoids			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Haemorrhoids thrombosed			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Ileus			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Large intestine perforation			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Neutropenic colitis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Toothache			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Pancreatitis			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Vomiting			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Oliguria			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Muscular weakness			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Bone pain			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Pain in extremity			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	13 / 96 (13.54%)	10 / 98 (10.20%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	1 / 13	4 / 10	2 / 3
deaths causally related to treatment / all	0 / 1	2 / 5	0 / 0
Sepsis			
subjects affected / exposed	7 / 96 (7.29%)	5 / 98 (5.10%)	3 / 27 (11.11%)
occurrences causally related to treatment / all	1 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0

Neutropenic sepsis			
subjects affected / exposed	3 / 96 (3.13%)	3 / 98 (3.06%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	2 / 3	2 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Infection			
subjects affected / exposed	3 / 96 (3.13%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	2 / 4	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	2 / 96 (2.08%)	4 / 98 (4.08%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (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
Atypical pneumonia			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (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
Pneumonia fungal			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cellulitis			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (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
Respiratory tract infection			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (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
Pseudomonal sepsis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Anal fistula infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Clostridial sepsis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Covid-19			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dermo-hypodermitis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Diverticulitis intestinal perforated			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Endophthalmitis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Erysipelas			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Escherichia bacteraemia			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Klebsiella infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Klebsiella sepsis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Lymph node tuberculosis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (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
Mediastinitis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Parotitis			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (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 aspiration			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Perineal abscess			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
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 pseudomonal			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Respiratory tract infection fungal			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (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 infection			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Soft tissue infection			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Rhinocerebral mucormycosis			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Respiratory tract infection viral			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Vascular device infection			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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 respiratory tract infection			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Tooth infection			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			

subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Failure to thrive			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Hyperglycaemic hyperosmolar ~ nonketotic syndrome			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (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
Metabolic acidosis			

subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 27 (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

Serious adverse events	Appropriate for intensive Therapy 7+3 Chemo		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 23 (60.87%)		
number of deaths (all causes)	10		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian cancer recurrent			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			

subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Asthenia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related thrombosis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic reaction				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemophagocytic lymphohistiocytosis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				

Prostatitis				
subjects affected / exposed	0 / 23 (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	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 23 (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 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pulmonary embolism				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercapnia				
subjects affected / exposed	0 / 23 (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 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Organising pneumonia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Platelet count decreased				
subjects affected / exposed	0 / 23 (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 / 23 (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 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphocyte count decreased				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood glucose increased				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Subdural haematoma				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured sacrum				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transfusion reaction				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Cardiac failure				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 23 (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 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure acute				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Seizure				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness postural				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral small vessel ischaemic ~ disease				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lethargy				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorder				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Febrile neutropenia				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Anaemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytopenia				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile bone marrow aplasia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular ~ coagulation				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolysis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Red blood cell abnormality				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Retinal vascular thrombosis				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal haemorrhage				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orbital haematoma				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal strangulated hernia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Anal fistula				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea haemorrhagic				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids thrombosed				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic colitis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toothache				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 23 (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	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic kidney disease				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oliguria				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract obstruction				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				

subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Neutropenic sepsis			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Anorectal infection			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Anal fistula infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridial sepsis				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis perforated				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermo-hypodermitis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis intestinal perforated				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endophthalmitis				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	0 / 23 (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 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymph node tuberculosis				

subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mediastinitis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parotitis				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perineal abscess				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pseudomonal				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection fungal				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinocerebral mucormycosis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular device infection				

subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth infection				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemic hyperosmolar ~ nonketotic syndrome				

subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypervolaemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour lysis syndrome			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Appropriate for Non-intensive Therapy Magro + Aza	Appropriate for Non-intensive Therapy Ven + Aza	Appropriate for intensive Therapy Magro + Aza
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 96 (95.83%)	94 / 98 (95.92%)	27 / 27 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	12 / 96 (12.50%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	13	7	2
Haematoma			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	1 / 96 (1.04%)	5 / 98 (5.10%)	2 / 27 (7.41%)
occurrences (all)	1	7	2
General disorders and administration site conditions			

Oedema peripheral			
subjects affected / exposed	17 / 96 (17.71%)	19 / 98 (19.39%)	4 / 27 (14.81%)
occurrences (all)	21	24	4
Fatigue			
subjects affected / exposed	24 / 96 (25.00%)	20 / 98 (20.41%)	2 / 27 (7.41%)
occurrences (all)	32	21	3
Pyrexia			
subjects affected / exposed	40 / 96 (41.67%)	24 / 98 (24.49%)	11 / 27 (40.74%)
occurrences (all)	64	37	17
Generalised oedema			
subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	2 / 27 (7.41%)
occurrences (all)	2	1	2
Non-cardiac chest pain			
subjects affected / exposed	3 / 96 (3.13%)	5 / 98 (5.10%)	0 / 27 (0.00%)
occurrences (all)	3	7	0
Asthenia			
subjects affected / exposed	13 / 96 (13.54%)	13 / 98 (13.27%)	3 / 27 (11.11%)
occurrences (all)	13	14	3
Oedema			
subjects affected / exposed	3 / 96 (3.13%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences (all)	3	0	1
Chills			
subjects affected / exposed	9 / 96 (9.38%)	4 / 98 (4.08%)	0 / 27 (0.00%)
occurrences (all)	11	4	0
Injection site reaction			
subjects affected / exposed	5 / 96 (5.21%)	15 / 98 (15.31%)	3 / 27 (11.11%)
occurrences (all)	13	21	3
Mucosal inflammation			
subjects affected / exposed	3 / 96 (3.13%)	2 / 98 (2.04%)	2 / 27 (7.41%)
occurrences (all)	3	2	2
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	9 / 96 (9.38%)	6 / 98 (6.12%)	0 / 27 (0.00%)
occurrences (all)	10	7	0
Pleural effusion			

subjects affected / exposed	11 / 96 (11.46%)	5 / 98 (5.10%)	0 / 27 (0.00%)
occurrences (all)	11	6	0
Cough			
subjects affected / exposed	9 / 96 (9.38%)	10 / 98 (10.20%)	0 / 27 (0.00%)
occurrences (all)	9	11	0
Epistaxis			
subjects affected / exposed	8 / 96 (8.33%)	15 / 98 (15.31%)	3 / 27 (11.11%)
occurrences (all)	9	16	3
Dyspnoea			
subjects affected / exposed	18 / 96 (18.75%)	16 / 98 (16.33%)	2 / 27 (7.41%)
occurrences (all)	25	17	2
Respiratory failure			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	7 / 96 (7.29%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	9	6	2
Pulmonary oedema			
subjects affected / exposed	5 / 96 (5.21%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences (all)	5	2	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	9 / 96 (9.38%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	9	6	2
Anxiety			
subjects affected / exposed	5 / 96 (5.21%)	5 / 98 (5.10%)	1 / 27 (3.70%)
occurrences (all)	5	5	1
Confusional state			
subjects affected / exposed	5 / 96 (5.21%)	5 / 98 (5.10%)	0 / 27 (0.00%)
occurrences (all)	5	5	0
Investigations			
Platelet count decreased			
subjects affected / exposed	17 / 96 (17.71%)	24 / 98 (24.49%)	4 / 27 (14.81%)
occurrences (all)	34	52	4
Blood bilirubin increased			

subjects affected / exposed	19 / 96 (19.79%)	11 / 98 (11.22%)	3 / 27 (11.11%)
occurrences (all)	23	12	3
Neutrophil count decreased			
subjects affected / exposed	9 / 96 (9.38%)	22 / 98 (22.45%)	2 / 27 (7.41%)
occurrences (all)	28	42	3
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 96 (13.54%)	9 / 98 (9.18%)	2 / 27 (7.41%)
occurrences (all)	13	15	2
Blood creatinine increased			
subjects affected / exposed	8 / 96 (8.33%)	14 / 98 (14.29%)	1 / 27 (3.70%)
occurrences (all)	9	26	1
Alanine aminotransferase increased			
subjects affected / exposed	13 / 96 (13.54%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	15	9	2
White blood cell count decreased			
subjects affected / exposed	6 / 96 (6.25%)	14 / 98 (14.29%)	1 / 27 (3.70%)
occurrences (all)	16	26	1
Weight decreased			
subjects affected / exposed	9 / 96 (9.38%)	8 / 98 (8.16%)	1 / 27 (3.70%)
occurrences (all)	9	8	1
Blood alkaline phosphatase increased			
subjects affected / exposed	6 / 96 (6.25%)	10 / 98 (10.20%)	0 / 27 (0.00%)
occurrences (all)	7	12	0
Lymphocyte count decreased			
subjects affected / exposed	4 / 96 (4.17%)	11 / 98 (11.22%)	0 / 27 (0.00%)
occurrences (all)	4	34	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	19 / 96 (19.79%)	3 / 98 (3.06%)	5 / 27 (18.52%)
occurrences (all)	25	4	6
Fall			
subjects affected / exposed	9 / 96 (9.38%)	10 / 98 (10.20%)	3 / 27 (11.11%)
occurrences (all)	10	10	6
Contusion			

subjects affected / exposed	6 / 96 (6.25%)	5 / 98 (5.10%)	1 / 27 (3.70%)
occurrences (all)	7	5	1
Allergic transfusion reaction			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	5 / 96 (5.21%)	4 / 98 (4.08%)	2 / 27 (7.41%)
occurrences (all)	5	5	2
Sinus tachycardia			
subjects affected / exposed	6 / 96 (6.25%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences (all)	8	2	0
Atrial fibrillation			
subjects affected / exposed	5 / 96 (5.21%)	6 / 98 (6.12%)	0 / 27 (0.00%)
occurrences (all)	9	6	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 96 (7.29%)	8 / 98 (8.16%)	2 / 27 (7.41%)
occurrences (all)	12	9	3
Dysgeusia			
subjects affected / exposed	5 / 96 (5.21%)	6 / 98 (6.12%)	0 / 27 (0.00%)
occurrences (all)	5	7	0
Presyncope			
subjects affected / exposed	3 / 96 (3.13%)	0 / 98 (0.00%)	2 / 27 (7.41%)
occurrences (all)	3	0	2
Headache			
subjects affected / exposed	13 / 96 (13.54%)	11 / 98 (11.22%)	5 / 27 (18.52%)
occurrences (all)	13	14	5
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	25 / 96 (26.04%)	28 / 98 (28.57%)	7 / 27 (25.93%)
occurrences (all)	49	45	7
Thrombocytopenia			
subjects affected / exposed	8 / 96 (8.33%)	16 / 98 (16.33%)	3 / 27 (11.11%)
occurrences (all)	8	20	3
Haemolysis			

subjects affected / exposed	7 / 96 (7.29%)	0 / 98 (0.00%)	4 / 27 (14.81%)
occurrences (all)	7	0	4
Neutropenia			
subjects affected / exposed	8 / 96 (8.33%)	26 / 98 (26.53%)	1 / 27 (3.70%)
occurrences (all)	12	46	2
Febrile neutropenia			
subjects affected / exposed	20 / 96 (20.83%)	25 / 98 (25.51%)	7 / 27 (25.93%)
occurrences (all)	23	32	10
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	33 / 96 (34.38%)	37 / 98 (37.76%)	13 / 27 (48.15%)
occurrences (all)	47	45	20
Diarrhoea			
subjects affected / exposed	27 / 96 (28.13%)	38 / 98 (38.78%)	5 / 27 (18.52%)
occurrences (all)	39	51	5
Nausea			
subjects affected / exposed	27 / 96 (28.13%)	32 / 98 (32.65%)	11 / 27 (40.74%)
occurrences (all)	39	49	14
Vomiting			
subjects affected / exposed	15 / 96 (15.63%)	22 / 98 (22.45%)	4 / 27 (14.81%)
occurrences (all)	18	25	6
Stomatitis			
subjects affected / exposed	5 / 96 (5.21%)	15 / 98 (15.31%)	3 / 27 (11.11%)
occurrences (all)	5	16	3
Abdominal pain			
subjects affected / exposed	11 / 96 (11.46%)	11 / 98 (11.22%)	3 / 27 (11.11%)
occurrences (all)	13	11	3
Haemorrhoids			
subjects affected / exposed	5 / 96 (5.21%)	8 / 98 (8.16%)	3 / 27 (11.11%)
occurrences (all)	5	8	3
Abdominal pain upper			
subjects affected / exposed	6 / 96 (6.25%)	6 / 98 (6.12%)	1 / 27 (3.70%)
occurrences (all)	6	7	1
Dyspepsia			
subjects affected / exposed	4 / 96 (4.17%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	6	6	2

Enterocolitis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	1 / 27 (3.70%)
occurrences (all)	1	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 96 (2.08%)	0 / 98 (0.00%)	2 / 27 (7.41%)
occurrences (all)	2	0	2
Dry mouth			
subjects affected / exposed	2 / 96 (2.08%)	3 / 98 (3.06%)	2 / 27 (7.41%)
occurrences (all)	3	3	2
Proctalgia			
subjects affected / exposed	0 / 96 (0.00%)	8 / 98 (8.16%)	2 / 27 (7.41%)
occurrences (all)	0	8	2
Tongue coated			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	2 / 27 (7.41%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	4 / 96 (4.17%)	6 / 98 (6.12%)	2 / 27 (7.41%)
occurrences (all)	5	6	2
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	4 / 96 (4.17%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences (all)	5	3	0
Night sweats			
subjects affected / exposed	0 / 96 (0.00%)	3 / 98 (3.06%)	2 / 27 (7.41%)
occurrences (all)	0	4	2
Toxic skin eruption			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	3 / 96 (3.13%)	9 / 98 (9.18%)	0 / 27 (0.00%)
occurrences (all)	3	10	0
Erythema			

subjects affected / exposed	4 / 96 (4.17%)	5 / 98 (5.10%)	3 / 27 (11.11%)
occurrences (all)	4	7	3
Rash maculo-papular			
subjects affected / exposed	6 / 96 (6.25%)	5 / 98 (5.10%)	1 / 27 (3.70%)
occurrences (all)	6	5	1
Rash macular			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	2 / 27 (7.41%)
occurrences (all)	1	0	2
Purpura			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	5 / 96 (5.21%)	6 / 98 (6.12%)	0 / 27 (0.00%)
occurrences (all)	5	6	0
Acute kidney injury			
subjects affected / exposed	5 / 96 (5.21%)	4 / 98 (4.08%)	2 / 27 (7.41%)
occurrences (all)	6	4	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	11 / 96 (11.46%)	10 / 98 (10.20%)	1 / 27 (3.70%)
occurrences (all)	11	10	1
Back pain			
subjects affected / exposed	9 / 96 (9.38%)	6 / 98 (6.12%)	1 / 27 (3.70%)
occurrences (all)	9	6	1
Pain in extremity			
subjects affected / exposed	5 / 96 (5.21%)	8 / 98 (8.16%)	1 / 27 (3.70%)
occurrences (all)	5	9	1
Bone pain			
subjects affected / exposed	2 / 96 (2.08%)	1 / 98 (1.02%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	10 / 96 (10.42%)	10 / 98 (10.20%)	2 / 27 (7.41%)
occurrences (all)	10	10	2
Influenza			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	2 / 27 (7.41%)
occurrences (all)	1	1	2
Furuncle			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	2 / 27 (7.41%)
occurrences (all)	0	3	2
Urinary tract infection			
subjects affected / exposed	5 / 96 (5.21%)	0 / 98 (0.00%)	0 / 27 (0.00%)
occurrences (all)	5	0	0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	0 / 27 (0.00%)
occurrences (all)	1	3	0
Sepsis			
subjects affected / exposed	2 / 96 (2.08%)	3 / 98 (3.06%)	1 / 27 (3.70%)
occurrences (all)	2	3	2
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	21 / 96 (21.88%)	22 / 98 (22.45%)	5 / 27 (18.52%)
occurrences (all)	37	39	5
Decreased appetite			
subjects affected / exposed	20 / 96 (20.83%)	21 / 98 (21.43%)	2 / 27 (7.41%)
occurrences (all)	26	23	4
Hypoalbuminaemia			
subjects affected / exposed	10 / 96 (10.42%)	12 / 98 (12.24%)	0 / 27 (0.00%)
occurrences (all)	18	19	0
Hyponatraemia			
subjects affected / exposed	8 / 96 (8.33%)	14 / 98 (14.29%)	0 / 27 (0.00%)
occurrences (all)	13	19	0
Hypophosphataemia			
subjects affected / exposed	12 / 96 (12.50%)	8 / 98 (8.16%)	1 / 27 (3.70%)
occurrences (all)	17	10	1
Hypomagnesaemia			
subjects affected / exposed	11 / 96 (11.46%)	8 / 98 (8.16%)	0 / 27 (0.00%)
occurrences (all)	17	15	0

Hyperglycaemia			
subjects affected / exposed	4 / 96 (4.17%)	5 / 98 (5.10%)	3 / 27 (11.11%)
occurrences (all)	8	10	3
Hypocalcaemia			
subjects affected / exposed	7 / 96 (7.29%)	8 / 98 (8.16%)	0 / 27 (0.00%)
occurrences (all)	9	11	0
Hypervolaemia			
subjects affected / exposed	7 / 96 (7.29%)	4 / 98 (4.08%)	1 / 27 (3.70%)
occurrences (all)	8	4	1

Non-serious adverse events	Appropriate for intensive Therapy 7+3 Chemo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 23 (100.00%)		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Hypertension			
subjects affected / exposed	5 / 23 (21.74%)		
occurrences (all)	5		
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	6 / 23 (26.09%)		
occurrences (all)	7		
Fatigue			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	7 / 23 (30.43%)		
occurrences (all)	10		
Generalised oedema			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		

Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0		
Asthenia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1		
Oedema subjects affected / exposed occurrences (all)	6 / 23 (26.09%) 6		
Chills subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0		
Injection site reaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0		
Mucosal inflammation subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1		
Respiratory, thoracic and mediastinal disorders			
Hypoxia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0		
Pleural effusion subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2		
Cough subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0		
Epistaxis subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1		
Dyspnoea subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2		
Respiratory failure			

subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Pulmonary oedema			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	3		
Confusional state			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Investigations			
Platelet count decreased			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Blood bilirubin increased			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Blood creatinine increased			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			

subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
White blood cell count decreased			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	2		
Fall			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Contusion			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Allergic transfusion reaction			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	3		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Sinus tachycardia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			

subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 23 (21.74%)		
occurrences (all)	5		
Thrombocytopenia			
subjects affected / exposed	5 / 23 (21.74%)		
occurrences (all)	6		
Haemolysis			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	4		
Febrile neutropenia			
subjects affected / exposed	11 / 23 (47.83%)		
occurrences (all)	13		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	4 / 23 (17.39%)		
occurrences (all)	4		
Diarrhoea			

subjects affected / exposed	9 / 23 (39.13%)			
occurrences (all)	9			
Nausea				
subjects affected / exposed	6 / 23 (26.09%)			
occurrences (all)	6			
Vomiting				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	1			
Stomatitis				
subjects affected / exposed	6 / 23 (26.09%)			
occurrences (all)	6			
Abdominal pain				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences (all)	2			
Haemorrhoids				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	1			
Abdominal pain upper				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
Enterocolitis				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences (all)	2			
Colitis				
subjects affected / exposed	3 / 23 (13.04%)			
occurrences (all)	3			
Gastrooesophageal reflux disease				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences (all)	2			
Dry mouth				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
Proctalgia				

subjects affected / exposed occurrences (all) Tongue coated subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0 0 / 23 (0.00%) 0		
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	 0 / 23 (0.00%) 0		
Skin and subcutaneous tissue disorders Petechiae subjects affected / exposed occurrences (all) Night sweats subjects affected / exposed occurrences (all) Toxic skin eruption subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Rash maculo-papular subjects affected / exposed occurrences (all) Rash macular subjects affected / exposed occurrences (all) Purpura subjects affected / exposed occurrences (all)	 2 / 23 (8.70%) 2 0 / 23 (0.00%) 0 3 / 23 (13.04%) 4 4 / 23 (17.39%) 5 1 / 23 (4.35%) 1 2 / 23 (8.70%) 2 0 / 23 (0.00%) 0 2 / 23 (8.70%) 2		
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Acute kidney injury			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Infections and infestations			
Pneumonia			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	3		
Influenza			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Staphylococcal bacteraemia			

subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Sepsis			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	8 / 23 (34.78%)		
occurrences (all)	9		
Decreased appetite			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	3		
Hypoalbuminaemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences (all)	2		
Hypervolaemia			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 February 2021	In response to regulatory feedback received from the FDA, the participant population had been expanded to include all TP53 mutant AML participants irrespective of their fitness to receive intensive chemotherapy. This necessitated that an additional control arm (7+3 chemotherapy) be included for participants appropriate for intensive chemotherapy, allowing physician's choice between venetoclax +azacitidine or 7+3 chemotherapy for the control arm. Various sections of the protocol were modified to reflect this change.
28 April 2021	A clinical trial application was submitted via the Voluntary Harmonization Procedure (VHP), including the following countries: Belgium, Denmark, France, Germany, Italy, Spain, and Sweden. In response to regulatory feedback received from the Reference National Competent Authority (Ref-NCA), Paul-Ehrlich-Institut (PEI) in Germany, various sections of the protocol were modified to reflect Gilead's response to the grounds for non-acceptance (GNA).
09 August 2021	The protocol had been amended primarily to: - Incorporate changes based on feedback from the United States (US) Food and Drug Administration (FDA). - Incorporate changes based on feedback from the Medicines and Healthcare products Regulatory Agency (MHRA). To highlight the cumulative differences between the original protocol and Amendment 3 of the protocol, changes/additions were in bold italicized font and deletions are depicted with strikethrough text.
31 March 2022	The primary reason for this amendment was to provide additional guidance for enhanced anemia management. Anemia is a known and well-described risk for magrolimab that could occur in early doses and is transient. Adequate monitoring and management of anemia during the first 2 doses of magrolimab are needed to ensure patient safety, especially in participants with low baseline hemoglobin. A minimum hemoglobin threshold prior to the first 2 doses of magrolimab treatment during treatment initiation along with hemoglobin monitoring after magrolimab treatment were included in the protocol. This amendment was also to allow the enrollment of participants based on local TP53 testing results, after central review. This minimized the time participants already diagnosed with TP53-mutated AML had to wait before starting treatment. The study added an interim superiority analysis to be conducted after 128 deaths (75% of the expected 171 overall survival events) were observed in participants appropriate for non-intensive therapy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
07 February 2024	The study met futility based on an adhoc analysis with futility assessment conducted in August 2023, and sites were informed of the outcome and sponsor's decision to terminate the study earlier than planned in a communication in September 2023.	-

Notes:

Limitations and caveats

None reported