



Clinical trial results:

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Magrolimab versus Placebo in Combination with Venetoclax and Azacitidine in Newly Diagnosed, Previously Untreated Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy

Summary

EudraCT number	2021-003434-36
Trial protocol	CZ DE HU BE FR AT PL NL IT ES NO
Global end of trial date	11 April 2024

Results information

Result version number	v1
This version publication date	19 March 2025
First version publication date	19 March 2025

Trial information

Trial identification

Sponsor protocol code	GS-US-590-6154
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05079230
WHO universal trial number (UTN)	-
Other trial identifiers	Israel Clinical Research Site: MOH_2022-08-15_011983

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	11 April 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 April 2024
Global end of trial reached?	Yes
Global end of trial date	11 April 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 study drugs, magrolimab + venetoclax + azacitidine, versus placebo + venetoclax + azacitidine in participants with untreated acute myeloid leukemia (AML) who were not able to have chemotherapy.

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	07 July 2022
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: 6
Country: Number of subjects enrolled	United States: 93
Country: Number of subjects enrolled	Austria: 5
Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	Czechia: 26
Country: Number of subjects enrolled	France: 40
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Netherlands: 21
Country: Number of subjects enrolled	Norway: 4
Country: Number of subjects enrolled	Poland: 6
Country: Number of subjects enrolled	Spain: 52
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	Hong Kong: 9
Country: Number of subjects enrolled	Taiwan: 22

Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Israel: 8
Country: Number of subjects enrolled	Korea, Republic of: 12
Worldwide total number of subjects	378
EEA total number of subjects	207

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)	30
From 65 to 84 years	324
85 years and over	24

Subject disposition

Recruitment

Recruitment details:

502 participants were screened.

Pre-assignment

Screening details:

Participants were enrolled at study sites in Asia, Europe, North America and Australia.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Magrolimab + Venetoclax + Azacitidine

Arm description:

Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m² subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.

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

Dosage and administration details:

Administered intravenously (IV)

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

Dosage and administration details:

Administered according to region-specific drug labeling, either subcutaneously (SC) or intravenously (IV)

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	
Other name	VENCLEXTA
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets administered orally

Arm title	Magrolimab Matching Placebo + Venetoclax + Azacitidine
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Arm description:

Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m² SC or IV on Days 1-7 or

Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.

Arm type	Experimental
Investigational medicinal product name	Magrolimab Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously (IV)

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

Dosage and administration details:

Administered according to region-specific drug labeling, either subcutaneously (SC) or intravenously (IV)

Investigational medicinal product name	Venetoclax
Investigational medicinal product code	
Other name	VENCLEXTA
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets administered orally

Number of subjects in period 1	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine
Started	189	189
Completed	0	0
Not completed	189	189
Death	72	66
Study Terminated by Sponsor	101	102
Withdrew consent	16	18
Lost to follow-up	-	3

Baseline characteristics

Reporting groups

Reporting group title	Magrolimab + Venetoclax + Azacitidine
Reporting group description:	
Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m ² subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.	
Reporting group title	Magrolimab Matching Placebo + Venetoclax + Azacitidine
Reporting group description:	
Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m ² SC or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.	

Reporting group values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine	Total
Number of subjects	189	189	378
Age categorical Units: Subjects			
< 75 Years	93	91	184
>= 75 Years	96	98	194
Age continuous Units: years			
arithmetic mean	74	74	
standard deviation	± 7.0	± 8.0	-
Gender categorical Units: Subjects			
Female	73	83	156
Male	116	106	222
Race Units: Subjects			
White	130	130	260
Not Collected	26	30	56
Asian	26	25	51
Other or More Than One Race	4	2	6
Black or African American	3	2	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	18	12	30
Not Hispanic or Latino	149	149	298
Unknown or Not Reported	22	28	50

End points

End points reporting groups

Reporting group title	Magrolimab + Venetoclax + Azacitidine
Reporting group description: Participants received magrolimab 1 mg/kg priming dose intravenously (IV) on Days 1 and 4; 15 mg/kg on Day 8; and 30 mg/kg on Days 11, 15, and then every week for 5 doses, and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3, and daily thereafter; azacitidine 75 mg/m ² subcutaneously (SC) or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.	
Reporting group title	Magrolimab Matching Placebo + Venetoclax + Azacitidine
Reporting group description: Participants received magrolimab matching placebo IV on Days 1, 4, 8, 11, and 15, then every week for 5 doses and every 2 weeks thereafter; venetoclax 100 mg orally on Cycle 1 Day 1, 200 mg on Cycle 1 Day 2, 400 mg on Cycle 1 Day 3 and daily thereafter; azacitidine 75 mg/m ² SC or IV on Days 1-7 or Days 1-5 and 8-9 of each cycle up to 1.4 years. Each cycle was of 28 days.	

Primary: Overall Survival (OS)

End point title	Overall Survival (OS)
End point description: OS was measured from the date of randomization to the date of death from any cause. Participants were censored at last known alive date. Kaplan-Meier (KM) estimates were used in outcome measure analysis. Analysis Population Description: Participants in the Intent-to-Treat Analysis Set were analyzed. The Intent-to-Treat Analysis Set included all randomized participants according to the treatment arm to which the participants were randomized, unless otherwise specified. 9999: Upper limit of confidence interval (CI) was not estimable due to low number of participants with events.	
End point type	Primary
End point timeframe: Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: months				
median (confidence interval 95%)	10.7 (8.7 to 14.9)	14.1 (9.7 to 9999)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab Matching Placebo + Venetoclax + Azacitidine v Magrolimab + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3276 ^[1]
Method	stratified log-rank test
Parameter estimate	Hazard ratio (HR)
Point estimate	1.178
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.848
upper limit	1.637

Notes:

[1] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization. Stratified hazard ratio (HR) and its 95% CI were calculated using the stratified cox proportional hazards model.

Secondary: Rate of Complete Remission (CR) + Complete Remission With Partial Hematologic Recovery (CRh)

End point title	Rate of Complete Remission (CR) + Complete Remission With Partial Hematologic Recovery (CRh)
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End point description:

The CR + CRh rate was defined as the percentage of participants who achieved a CR (including CR without minimal residual disease (CRM RD-) and CR with positive or unknown MRD (CRM RD+/unk)) or CRh as defined by CR with partial platelet and absolute neutrophil count recovery within 6 cycles of treatment while on study prior to initiation of any new anti-acute myeloid leukemia (AML) therapy or stem cell transplant (SCT). CRM RD- and CRM RD+/unk: neutrophils $>1.0 \times 10^9/L$, platelets $>100 \times 10^9/L$, $<5\%$ bone marrow blasts, no circulating blasts or extramedullary disease (confirmed by flow cytometry $<0.1\%$ sensitivity for CRM RD-) within the response assessment window of 1.6 years. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-to-Treat analysis set were analyzed.

End point type	Secondary
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End point timeframe:

Up to 1.6 years

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: percentage of participants				
number (confidence interval 95%)	47.6 (40.3 to 55.0)	53.4 (46.1 to 60.7)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3616 ^[2]
Method	Stratum-adjusted Mantel-Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	0.826
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.545
upper limit	1.251

Notes:

[2] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

Secondary: Event-Free Survival (EFS)

End point title	Event-Free Survival (EFS)
End point description:	
EFS was defined as time from the date of randomization to the earliest date of the documented relapse from CR, treatment failure (defined as failure to achieve CR within 6 cycles of treatment), or death from any cause within the response window. CR is defined in outcome measure #2. KM estimates were used in outcome measure analysis. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed.	
End point type	Secondary
End point timeframe:	
Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: months				
median (confidence interval 95%)	0.0 (0.0 to 5.4)	1.7 (0.0 to 4.5)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7903 ^[3]
Method	Stratified Log Rank
Parameter estimate	Stratified Hazard Ratio
Point estimate	0.946
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.225

Notes:

[3] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization.

Secondary: Rate of Complete Remission (CR)

End point title	Rate of Complete Remission (CR)
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End point description:

CR was defined as the percentage of the participants who achieved CR (including CRMRD- and CRMRD+/unk) within 6 cycles of treatment as determined by the investigator while on study prior to initiation of any new anti-acute myeloid leukemia (AML) therapy or stem cell transplant (SCT) within the response assessment window of 1.6 years. Definitions for CRMRD- and CRMRD+/unk were mentioned in outcome measure #2. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Up to 1.6 years

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: percentage of participants				
number (confidence interval 95%)	41.3 (34.2 to 48.6)	46.0 (38.8 to 53.4)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4679 ^[4]
Method	Stratum-adjusted Mantel-Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	0.856
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.307

Notes:

[4] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

Secondary: Rate of CR/CRh Without Minimal Residual Disease (CR/CRhMRD-)

End point title	Rate of CR/CRh Without Minimal Residual Disease (CR/CRhMRD-)
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End point description:

The CR/CRhMRD- rate was the percentage of participants who achieved a CRMRD- or CRhMRD- within 6 cycles of treatment while on study prior to initiation of any new anti-AML therapy or SCT within the response assessment window of 1.6 years. Each cycle was of 28 days. KM estimates were used for outcome measure analysis. CRhMRD- : neutrophils > $0.5 \times 10^9/L$; platelets > $50 \times 10^9/L$; bone marrow blasts < 5%; MRD negative (determined using multiparameter flow cytometry with a sensitivity of < 0.1%). Absence of circulating blasts and blasts with Auer rods; absence of extramedullary disease. CRMRD is defined in outcome measure #2. Percentages were rounded off. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

Up to 1.6 years

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: percentage of participants				
number (confidence interval 95%)	24.3 (18.4 to 31.1)	22.2 (16.5 to 28.8)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4873 ^[5]
Method	Stratum-adjusted Mantel Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	1.189
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.727
upper limit	1.945

Notes:

[5] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

Secondary: Duration of Complete Remission (DCR) in Participants who achieved Complete Remission (CR)

End point title	Duration of Complete Remission (DCR) in Participants who achieved Complete Remission (CR)
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End point description:

The DCR measured from the time the assessment criteria were first met for CR (including CRMRD- and CRMRD+/unk) within 6 cycles of treatment until the first date of AML relapse or death (including assessments post SCT). Those who were not observed to have relapsed disease or death while on study were censored at the date of their last response assessment with no evidence of relapse on or prior to the data cutoff date within the response assessment window of 1.6 years. Participants started taking new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse, DCR were censored at the last response assessment before the initiation of the new anti-AML therapies. KM estimates were used in outcome measure analysis. CRMRD- and CRMRD+/unk are defined in outcome measure #2. Each cycle was of 28 days. Participants in the ITT Analysis Set who achieved CR within 6 cycle were analyzed. 9999: Upper limit of CI wasnt estimable due to low number of participants with events.

End point type	Secondary
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End point timeframe:

Up to 1.6 years

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	87		
Units: months				
median (confidence interval 95%)	9.4 (6.3 to 9999)	8.1 (5.7 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of CR + CRh in Participants who achieved Complete Remission

(CR) or Complete Remission With Partial Hematologic Recovery (CRh)

End point title	Duration of CR + CRh in Participants who achieved Complete Remission (CR) or Complete Remission With Partial Hematologic Recovery (CRh)
End point description: The duration of CR + CRh was measured from the time the assessment criteria were first met for CR (including CRMRD- and CRMRD+/unk) or CRh within 6 cycles of treatment until the first date of AML relapse or death (including assessments post SCT). Those who were not observed to have relapsed disease or death while on study were censored at the date of their last response assessment with no evidence of relapse on or prior to the data cut off date within the response assessment window of 1.6 years. Participants started taking new anti-AML therapies (excluding post-SCT maintenance therapy) before relapse, duration of CR + CRh were censored at the last response assessment before the initiation of the new anti-AML therapies. CR and CRh are defined in Outcome Measure #2. Each cycle was of 28 days. Participants in the Intent-To-Treat Analysis Set who achieved CR + CRh within 6 cycles were analyzed. 9999: Upper limit of CI was not estimable due to low number of participants with events.	
End point type	Secondary
End point timeframe: Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90	101		
Units: months				
median (confidence interval 95%)	9.4 (5.9 to 9999)	9.2 (5.8 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of CR Without Minimal Residual Disease (CRMRD-)

End point title	Rate of CR Without Minimal Residual Disease (CRMRD-)
End point description: The CRMRD- rate was the percentage of participants who achieved a CRMRD- within 6 cycles of treatment SCT within the response assessment window of 1.6 years. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. CRMRD- is defined in outcome measure #2. Each cycle was of 28 days. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set were analyzed.	
End point type	Secondary
End point timeframe: Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: percentage of participants				
number (confidence interval 95%)	21.7 (16.0 to 28.3)	20.1 (14.6 to 26.5)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5842 ^[6]
Method	Stratum-adjusted Mantel Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	1.154
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.932

Notes:

[6] - Stratified odds ratio and 2-sided 95% CI were calculated from stratum-adjusted Mantel-Haenszel estimates adjusted for stratification factors.

Secondary: Platelet Transfusion Independence Conversion Rate

End point title	Platelet Transfusion Independence Conversion Rate
End point description:	
The platelet transfusion independence conversion rate was the percentage of participants who had a 56-day or longer period with no platelet transfusions at any time between the date of the first dose of study treatment and discontinuation of study treatment among all participants who were platelet transfusion dependent at baseline. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis. Analysis Population Description: Participants in the Intent-To-Treat Analysis Set with Platelet transfusion dependence at Baseline were analyzed.	
End point type	Secondary
End point timeframe:	
Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: percentage of participants				
number (confidence interval 95%)	48.6 (36.9 to 60.6)	47.3 (35.6 to 59.3)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.579 ^[7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.36

Notes:

[7] - The 2-sided P-value was based on Cochran-Mantel-Haenszel (CMH) method stratified by the stratification factors at randomization (age, genetic risk group, and geographic region).

Secondary: Time to First Deterioration (TTD) on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Global Health Status/Quality of Life (GHS/QoL) Scale

End point title	Time to First Deterioration (TTD) on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Global Health Status/Quality of Life (GHS/QoL) Scale
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End point description:

The TTD on the EORTC QLQ-C30 GHS/QoL scale was defined as time from the date of randomization to the time a participant experienced at least 1 threshold value deterioration from baseline or death, whichever was earlier. Questionnaire includes 30 questions resulting in 5 functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning), 1 GHS/QoL scale, 3 symptom scales (fatigue, nausea and vomiting, pain), and 6 single items (dyspnea, insomnia, loss of appetite, constipation, diarrhea, financial difficulties). After linear transformation, all scales and single item measures range in score from 0-100. Higher score on GHS/QoL scale meant better GHS/QoL. KM estimates were used in outcome measure analysis. Participants in the Intent-To-Treat Analysis Set were analyzed.

End point type	Secondary
End point timeframe:	
Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: months				
median (confidence interval 95%)	4.7 (2.3 to 6.3)	5.1 (2.8 to 6.9)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5796 ^[8]
Method	Stratified Log Rank
Parameter estimate	Stratified Hazard Ratio
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.799
upper limit	1.487

Notes:

[8] - The 2-sided P-value was based on stratified log-rank test, stratified by stratification factors at randomization.

Secondary: Red blood cell (RBC) Transfusion Independence Conversion Rate

End point title	Red blood cell (RBC) Transfusion Independence Conversion Rate
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End point description:

The RBC transfusion independence conversion rate was the percentage of participants who had a 56-day or longer period with no RBC or whole blood transfusions at any time between the date of the first dose of study treatment and discontinuation of study treatment among all participants who were RBC transfusion dependent at baseline. Percentages were rounded-off. Clopper-Pearson method were used in outcome measure analysis.

End point type	Secondary
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End point timeframe:

Up to 1.6 years

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	151		
Units: percentage of participants				
number (confidence interval 95%)	51.7 (43.4 to 59.9)	58.3 (50.0 to 66.2)		

Statistical analyses

Statistical analysis title	Experimental Group vs Control Group
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine
Number of subjects included in analysis	302
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3003 ^[9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Odds Ratio
Point estimate	0.783
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.492
upper limit	1.245

Notes:

[9] - The 2-sided P-value was based on Cochran-Mantel-Haenszel (CMH) method stratified by the stratification factors at randomization (age, genetic risk group, and geographic region).

Secondary: Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)

End point title	Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)
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End point description:

An AE was defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product or other protocol-imposed intervention, regardless of attribution. TEAEs were defined as any AEs with an onset date on or after the study drug start date and no later than 70 days after the study drug last dose date or the day before initiation of new anti-AML therapy including stem cell transplantation, whichever is earlier. Percentages were rounded-off. Analysis Population Description: The Safety Analysis Set included all participants who received at least 1 dose of any study treatment, with treatment assignments designated according to the actual treatment received.

End point type	Secondary
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End point timeframe:

First dose date up to 1.4 years plus 70 days

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	184		
Units: percentage of participants				
number (not applicable)	99.5	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Deterioration (TTD) on the EORTC QLQ-C30 Physical Functioning Scale

End point title	Time to First Deterioration (TTD) on the EORTC QLQ-C30 Physical Functioning Scale
End point description: The TTD on the EORTC QLQ-C30 physical functioning scale was defined as time from the date of randomization to the time a participant experienced at least 1 threshold value deterioration from baseline or death, whichever is earlier. Physical functioning scale is one of the five functional scales of the EORTC QLQ C30 questionnaire. After linear transformation, scale range in score from 0-100. A higher score on functional scales means better functioning and better quality of life. KM estimates were used in outcome measure analysis. Participants in the Intent-To-Treat Analysis Set were analyzed.	
End point type	Secondary
End point timeframe: Up to 1.6 years	

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	189		
Units: months				
number (confidence interval 95%)	3.0 (2.1 to 4.4)	3.9 (2.8 to 6.9)		

Statistical analyses

Statistical analysis title	Time to First Deterioration (TTD) on the EORTC QLQ
Statistical analysis description: -C30 Physical Functioning Scale	
Comparison groups	Magrolimab + Venetoclax + Azacitidine v Magrolimab Matching Placebo + Venetoclax + Azacitidine

Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1026 ^[10]
Method	Stratified Log Rank
Parameter estimate	Stratified Hazard Ratio
Point estimate	1.271
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.948
upper limit	1.704

Notes:

[10] - PLACEHOLDER20

Secondary: Percentage of Participants Experiencing Grade 3 or Higher Treatment-Emergent Laboratory Abnormalities

End point title	Percentage of Participants Experiencing Grade 3 or Higher Treatment-Emergent Laboratory Abnormalities
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End point description:

Treatment-emergent laboratory abnormalities were defined as values that increased by at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of the last dose of study drug plus 70 days or the day before the initiation of new anti-AML therapy including SCT, whichever came first, and were summarized by treatment group. Severity grades were defined by the CTCAE Version 5.0. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Percentages were rounded-off. Participants in the Safety Analysis Set were analyzed.

End point type	Secondary
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End point timeframe:

First dose date up to 1.4 years, plus 70 days

End point values	Magrolimab + Venetoclax + Azacitidine	Magrolimab Matching Placebo + Venetoclax + Azacitidine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	184		
Units: percentage of participants				
number (not applicable)	99.5	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Magrolimab over time

End point title	Serum Concentration of Magrolimab over time ^[11]
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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) post-treatment serum concentration of magrolimab with data available for analysis.

End point type	Secondary
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End point timeframe:

Predose on Day 1, Day 8, Day 15, Day 29; Predose on Day 57 and 1 hour post-dose; Predose on Day 113, Day 169, Day 253, and Day 337.

Notes:

[11] - 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: No statistical comparison was planned or performed.

End point values	Magrolimab + Venetoclax + Azacitidine			
Subject group type	Reporting group			
Number of subjects analysed	156			
Units: µg/mL				
arithmetic mean (standard deviation)				
D 1 Predose N=156	0 (± 0)			
D 8 Predose N=135	0 (± 0)			
D 15 Predose N=143	291 (± 123)			
D 29 Predose N=129	385 (± 206)			
D 57 Predose N=111	503 (± 230)			
D 57, 1 h Postdose N=103	1060 (± 289)			
D 113 Predose N=91	281 (± 140)			
D 169 Predose N=62	274 (± 120)			
D 253 Predose N=28	322 (± 151)			
D 337 Predose N=16	298 (± 72.9)			

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 ^[12]
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End point description:

Percentages were rounded-off. Analysis Population Description: The participants in the Immunogenicity Analysis Set with available data were analyzed. 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
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End point timeframe:

Up to 1.6 years

Notes:

[12] - 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: No statistical comparison was planned or performed.

End point values	Magrolimab + Venetoclax + Azacitidine			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: percentage of participants				
number (not applicable)				
ADA Incidence	2.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Levels of Serum Anti-Magrolimab Antibodies

End point title	Maximum Levels of Serum Anti-Magrolimab Antibodies ^[13]
End point description: The participants in the Immunogenicity Analysis Set were analyzed.	
End point type	Secondary
End point timeframe: Up to 1.6 years	

Notes:

[13] - 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: No statistical comparison was planned or performed.

End point values	Magrolimab + Venetoclax + Azacitidine			
Subject group type	Reporting group			
Number of subjects analysed	185			
Units: Titer				
number (not applicable)	2560			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Up to 1.6 years; Adverse events: 1.4 years plus 70 days

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Magrolimab Matching Placebo + Venetoclax + Azacitidine
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Reporting group description:

Patients who received magrolimab matching placebo + venetoclax + azacitidine

Reporting group title	Magrolimab + Venetoclax + Azacitidine
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Reporting group description:

Patients who received Magrolimab + Venetoclax + Azacitidine

Serious adverse events	Magrolimab Matching Placebo + Venetoclax + Azacitidine	Magrolimab + Venetoclax + Azacitidine	
Total subjects affected by serious adverse events			
subjects affected / exposed	134 / 184 (72.83%)	138 / 189 (73.02%)	
number of deaths (all causes)	70	84	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortitis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial vein thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	1 / 184 (0.54%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 184 (0.54%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health ~ deterioration			
subjects affected / exposed	2 / 184 (1.09%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	2 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			
subjects affected / exposed	4 / 184 (2.17%)	9 / 189 (4.76%)	
occurrences causally related to treatment / all	0 / 4	4 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion site extravasation			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			

subjects affected / exposed	0 / 184 (0.00%)	6 / 189 (3.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 6	
deaths causally related to treatment / all	0 / 0	1 / 4	
Pneumothorax			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary oedema			
subjects affected / exposed	0 / 184 (0.00%)	3 / 189 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary haemorrhage			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary toxicity			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Alanine aminotransferase increased subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition abnormal subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased subjects affected / exposed	0 / 184 (0.00%)	3 / 189 (1.59%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count decreased subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			

subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	3 / 184 (1.63%)	6 / 189 (3.17%)	
occurrences causally related to treatment / all	0 / 3	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Refractoriness to platelet ~ transfusion			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medication error			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	2 / 184 (1.09%)	7 / 189 (3.70%)	
occurrences causally related to treatment / all	2 / 2	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			

subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 184 (0.54%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal fracture			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Sinus bradycardia			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiogenic shock			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina pectoris			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	1 / 184 (0.54%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	4 / 184 (2.17%)	4 / 189 (2.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	4 / 184 (2.17%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	2 / 184 (1.09%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			

subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral microembolism			

subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrapyramidal disorder			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy chronic			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	8 / 184 (4.35%)	8 / 189 (4.23%)	
occurrences causally related to treatment / all	8 / 10	12 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agranulocytosis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	47 / 184 (25.54%)	44 / 189 (23.28%)	
occurrences causally related to treatment / all	39 / 62	38 / 59	
deaths causally related to treatment / all	1 / 2	2 / 2	
Haemolysis			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	2 / 184 (1.09%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	2 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	2 / 184 (1.09%)	5 / 189 (2.65%)	
occurrences causally related to treatment / all	1 / 2	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Enterocolitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth haemorrhage			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 184 (0.00%)	4 / 189 (2.12%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	5 / 184 (2.72%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	2 / 5	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticulum			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal inflammation			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic hypoperfusion			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Renal failure			
subjects affected / exposed	3 / 184 (1.63%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	3 / 4	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute kidney injury			
subjects affected / exposed	5 / 184 (2.72%)	5 / 189 (2.65%)	
occurrences causally related to treatment / all	1 / 5	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haematuria			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arthritis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Septic shock			
subjects affected / exposed	7 / 184 (3.80%)	5 / 189 (2.65%)	
occurrences causally related to treatment / all	1 / 7	1 / 5	
deaths causally related to treatment / all	0 / 3	0 / 2	
Pneumonia			
subjects affected / exposed	15 / 184 (8.15%)	17 / 189 (8.99%)	
occurrences causally related to treatment / all	2 / 16	7 / 19	
deaths causally related to treatment / all	0 / 4	2 / 7	
Covid-19			
subjects affected / exposed	6 / 184 (3.26%)	7 / 189 (3.70%)	
occurrences causally related to treatment / all	0 / 7	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			

subjects affected / exposed	3 / 184 (1.63%)	7 / 189 (3.70%)	
occurrences causally related to treatment / all	1 / 3	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	8 / 184 (4.35%)	17 / 189 (8.99%)	
occurrences causally related to treatment / all	5 / 8	10 / 21	
deaths causally related to treatment / all	2 / 2	4 / 7	
Device related infection			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	3 / 184 (1.63%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	3 / 184 (1.63%)	3 / 189 (1.59%)	
occurrences causally related to treatment / all	1 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	3 / 184 (1.63%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	1 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 184 (1.09%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	3 / 184 (1.63%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	3 / 184 (1.63%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Covid-19 pneumonia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			

subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sinusitis			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pseudomonal sepsis			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	2 / 184 (1.09%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site cellulitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacillus bacteraemia			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematological infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abscess of salivary gland			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			

subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Escherichia sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion site cellulitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Otosalpingitis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal perforated			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia fungal			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial ~ viral			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stenotrophomonas sepsis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Upper respiratory tract infection			

subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	2 / 184 (1.09%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 184 (0.00%)	2 / 189 (1.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	1 / 184 (0.54%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour lysis syndrome			
subjects affected / exposed	1 / 184 (0.54%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	0 / 184 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Magrolimab Matching Placebo + Venetoclax + Azacitidine	Magrolimab + Venetoclax + Azacitidine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	179 / 184 (97.28%)	180 / 189 (95.24%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	19 / 184 (10.33%)	19 / 189 (10.05%)	
occurrences (all)	30	25	
Hypertension			
subjects affected / exposed	16 / 184 (8.70%)	14 / 189 (7.41%)	
occurrences (all)	22	25	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	16 / 184 (8.70%)	22 / 189 (11.64%)	
occurrences (all)	22	34	
Pyrexia			
subjects affected / exposed	51 / 184 (27.72%)	58 / 189 (30.69%)	
occurrences (all)	72	85	
Oedema peripheral			
subjects affected / exposed	39 / 184 (21.20%)	27 / 189 (14.29%)	
occurrences (all)	45	32	
Fatigue			
subjects affected / exposed	36 / 184 (19.57%)	34 / 189 (17.99%)	
occurrences (all)	44	37	
Injection site reaction			
subjects affected / exposed	14 / 184 (7.61%)	7 / 189 (3.70%)	
occurrences (all)	14	7	
Oedema			

subjects affected / exposed occurrences (all)	1 / 184 (0.54%) 1	10 / 189 (5.29%) 11	
Chills subjects affected / exposed occurrences (all)	11 / 184 (5.98%) 18	14 / 189 (7.41%) 18	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea subjects affected / exposed occurrences (all)	19 / 184 (10.33%) 22	26 / 189 (13.76%) 29	
Epistaxis subjects affected / exposed occurrences (all)	16 / 184 (8.70%) 17	15 / 189 (7.94%) 17	
Pleural effusion subjects affected / exposed occurrences (all)	9 / 184 (4.89%) 11	11 / 189 (5.82%) 11	
Rhinorrhoea subjects affected / exposed occurrences (all)	14 / 184 (7.61%) 19	5 / 189 (2.65%) 7	
Hypoxia subjects affected / exposed occurrences (all)	11 / 184 (5.98%) 12	6 / 189 (3.17%) 6	
Cough subjects affected / exposed occurrences (all)	20 / 184 (10.87%) 22	28 / 189 (14.81%) 30	
Oropharyngeal pain subjects affected / exposed occurrences (all)	15 / 184 (8.15%) 16	5 / 189 (2.65%) 5	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	12 / 184 (6.52%) 14	20 / 189 (10.58%) 20	
Anxiety subjects affected / exposed occurrences (all)	10 / 184 (5.43%) 10	3 / 189 (1.59%) 3	
Delirium			

subjects affected / exposed occurrences (all)	10 / 184 (5.43%) 11	3 / 189 (1.59%) 3	
Investigations			
Blood bilirubin increased subjects affected / exposed occurrences (all)	14 / 184 (7.61%) 14	34 / 189 (17.99%) 46	
Neutrophil count decreased subjects affected / exposed occurrences (all)	38 / 184 (20.65%) 126	51 / 189 (26.98%) 170	
Platelet count decreased subjects affected / exposed occurrences (all)	45 / 184 (24.46%) 116	40 / 189 (21.16%) 130	
White blood cell count decreased subjects affected / exposed occurrences (all)	21 / 184 (11.41%) 40	19 / 189 (10.05%) 39	
Weight decreased subjects affected / exposed occurrences (all)	13 / 184 (7.07%) 13	20 / 189 (10.58%) 26	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	11 / 184 (5.98%) 12	17 / 189 (8.99%) 21	
Blood creatinine increased subjects affected / exposed occurrences (all)	14 / 184 (7.61%) 18	12 / 189 (6.35%) 21	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	8 / 184 (4.35%) 8	14 / 189 (7.41%) 16	
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	4 / 184 (2.17%) 7	15 / 189 (7.94%) 18	
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	14 / 184 (7.61%) 15	28 / 189 (14.81%) 39	
Fall			

subjects affected / exposed occurrences (all)	16 / 184 (8.70%) 23	20 / 189 (10.58%) 23	
Contusion subjects affected / exposed occurrences (all)	8 / 184 (4.35%) 13	12 / 189 (6.35%) 12	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	9 / 184 (4.89%) 11	18 / 189 (9.52%) 20	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	24 / 184 (13.04%) 34	22 / 189 (11.64%) 32	
Dizziness subjects affected / exposed occurrences (all)	25 / 184 (13.59%) 31	14 / 189 (7.41%) 19	
Blood and lymphatic system disorders Febrile neutropenia subjects affected / exposed occurrences (all)	31 / 184 (16.85%) 38	38 / 189 (20.11%) 48	
Thrombocytopenia subjects affected / exposed occurrences (all)	47 / 184 (25.54%) 85	39 / 189 (20.63%) 76	
Anaemia subjects affected / exposed occurrences (all)	63 / 184 (34.24%) 141	92 / 189 (48.68%) 198	
Neutropenia subjects affected / exposed occurrences (all)	76 / 184 (41.30%) 232	67 / 189 (35.45%) 239	
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	39 / 184 (21.20%) 53	30 / 189 (15.87%) 39	
Stomatitis subjects affected / exposed occurrences (all)	20 / 184 (10.87%) 20	12 / 189 (6.35%) 12	
Dyspepsia			

subjects affected / exposed	10 / 184 (5.43%)	7 / 189 (3.70%)	
occurrences (all)	12	7	
Abdominal pain			
subjects affected / exposed	20 / 184 (10.87%)	18 / 189 (9.52%)	
occurrences (all)	27	22	
Diarrhoea			
subjects affected / exposed	67 / 184 (36.41%)	76 / 189 (40.21%)	
occurrences (all)	92	110	
Nausea			
subjects affected / exposed	60 / 184 (32.61%)	66 / 189 (34.92%)	
occurrences (all)	86	86	
Haemorrhoids			
subjects affected / exposed	15 / 184 (8.15%)	19 / 189 (10.05%)	
occurrences (all)	17	19	
Constipation			
subjects affected / exposed	76 / 184 (41.30%)	72 / 189 (38.10%)	
occurrences (all)	101	90	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	3 / 184 (1.63%)	10 / 189 (5.29%)	
occurrences (all)	3	10	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	17 / 184 (9.24%)	17 / 189 (8.99%)	
occurrences (all)	17	20	
Rash			
subjects affected / exposed	12 / 184 (6.52%)	17 / 189 (8.99%)	
occurrences (all)	15	21	
Rash maculo-papular			
subjects affected / exposed	14 / 184 (7.61%)	11 / 189 (5.82%)	
occurrences (all)	17	15	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	5 / 184 (2.72%)	15 / 189 (7.94%)	
occurrences (all)	6	15	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	22 / 184 (11.96%)	22 / 189 (11.64%)	
occurrences (all)	25	27	
Back pain			
subjects affected / exposed	18 / 184 (9.78%)	20 / 189 (10.58%)	
occurrences (all)	20	22	
Pain in extremity			
subjects affected / exposed	17 / 184 (9.24%)	12 / 189 (6.35%)	
occurrences (all)	23	13	
Muscular weakness			
subjects affected / exposed	13 / 184 (7.07%)	9 / 189 (4.76%)	
occurrences (all)	17	9	
Infections and infestations			
Covid-19			
subjects affected / exposed	22 / 184 (11.96%)	18 / 189 (9.52%)	
occurrences (all)	24	18	
Pneumonia			
subjects affected / exposed	14 / 184 (7.61%)	15 / 189 (7.94%)	
occurrences (all)	14	19	
Urinary tract infection			
subjects affected / exposed	11 / 184 (5.98%)	6 / 189 (3.17%)	
occurrences (all)	13	10	
Bacteraemia			
subjects affected / exposed	10 / 184 (5.43%)	5 / 189 (2.65%)	
occurrences (all)	10	5	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	54 / 184 (29.35%)	49 / 189 (25.93%)	
occurrences (all)	101	99	
Hypophosphataemia			
subjects affected / exposed	27 / 184 (14.67%)	26 / 189 (13.76%)	
occurrences (all)	39	37	
Hypomagnesaemia			
subjects affected / exposed	10 / 184 (5.43%)	23 / 189 (12.17%)	
occurrences (all)	13	40	
Hypocalcaemia			

subjects affected / exposed	14 / 184 (7.61%)	15 / 189 (7.94%)	
occurrences (all)	19	21	
Hyperglycaemia			
subjects affected / exposed	15 / 184 (8.15%)	10 / 189 (5.29%)	
occurrences (all)	17	10	
Hyponatraemia			
subjects affected / exposed	11 / 184 (5.98%)	9 / 189 (4.76%)	
occurrences (all)	17	12	
Hypoalbuminaemia			
subjects affected / exposed	12 / 184 (6.52%)	6 / 189 (3.17%)	
occurrences (all)	18	7	
Decreased appetite			
subjects affected / exposed	29 / 184 (15.76%)	40 / 189 (21.16%)	
occurrences (all)	39	44	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 September 2021	Herein was a summary of the major changes made to the original protocol dated 30 June 2021 and reflected in Amendment 1 dated 08 September 2021. The protocol had been amended primarily to: incorporate changes based on feedback from the United States (US) Food and Drug Administration (FDA) and 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 1 of the protocol, changes/additions were in bold italicized font and deletions were depicted with strikethrough text.
01 November 2021	Herein was a summary of the major changes made to Amendment 1 dated 08 September 2021 and reflected in Amendment 2 dated 01 November 2021. The protocol had been amended primarily to: incorporate changes based on feedback from the Voluntary Harmonization Procedure (VHP). To highlight the cumulative differences between Amendment 1 and Amendment 2 of the protocol, changes/additions were in bold italicized font and deletions were depicted with strikethrough text.
29 November 2021	The major update(s) to the protocol and related rationale were as follows: A Per-Protocol Analysis Set for the primary and key secondary efficacy endpoints had been added. Details on how the randomization list would be generated had been provided.
30 March 2022	The primary reason for this amendment was to provide additional guidance for anemia management in response to the Dear Investigator Letter dated 17 January 2022. The protocol had been updated with the following additional requirements for monitoring hemoglobin: A minimum hemoglobin threshold prior to the first 2 doses of magrolimab/placebo during treatment initiation. Post-magrolimab/placebo treatment hemoglobin monitoring after the first 2 doses of magrolimab/placebo, during treatment initiation.
27 July 2022	The primary reason for this amendment was to update the contraception requirements for female patients to align with the revised contraception recommendations in the azacitidine prescribing information dated June 2022.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported