Clinical trial results:
A Phase 2, Multi-Arm Study of Magrolimab in Patients with Solid Tumors
Summary

EudraCT number	2020-005265-14
Trial protocol	ES FR
Global end of trial date	01 October 2024

Results information

Result version number	v1 (current)
This version publication date	09 May 2025
First version publication date	09 May 2025

Trial information

Trial identification

Sponsor protocol code	GS-US-548-5918

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04827576
WHO universal trial number (UTN)	-

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	01 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 October 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The goals of this clinical study was to learn about the safety, tolerability, dosing and effectiveness of magrolimab in combination with docetaxel in participants with solid tumors.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Poland: 6
Country: Number of subjects enrolled	Spain: 40
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	United States: 39
Worldwide total number of subjects	106
EEA total number of subjects	64

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	57
From 65 to 84 years	49
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Spain, Poland, France, United States and the United Kingdom.

Pre-assignment

Screening details:

159 participants were screened.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)

Arm description:

Participants with solid tumors (including metastatic non small cell lung cancer (mNSCLC), metastatic urothelial cancer (mUC), and metastatic small cell lung cancer (mSCLC)) received 1 mg/kg magrolimab intravenously (IV) on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 113 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 113 weeks; each cycle length = 21 days.

Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	Taxotere®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

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

Arm title	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)

Arm description:

Participants with mNSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 90 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 69 weeks; each cycle length = 21 days.

Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	Taxotere®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details: Administered intravenously.	
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.	
Arm title	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Arm description: Participants with mUC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 68 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 68 weeks; each cycle length = 21 days.	
Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	Taxotere®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously.	
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.	
Arm title	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Arm description: Participants with mSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 72 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 72 weeks; each cycle length = 21 days.	
Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	Taxotere®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously	
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	

Number of subjects in period 1	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Started	9	29	26
Completed	0	0	0
Not completed	9	29	26
Consent withdrawn by subject	-	3	-
Lost to follow-up	1	-	-
Death	5	17	17
Investigator's Discretion	1	-	2
Study Terminated by Sponsor	2	9	7

Number of subjects in period 1	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Started	42
Completed	0
Not completed	42
Consent withdrawn by subject	-
Lost to follow-up	-
Death	32
Investigator's Discretion	5
Study Terminated by Sponsor	5

Baseline characteristics

Reporting groups	
Reporting group title	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)
Reporting group description:	
Participants with solid tumors (including metastatic non small cell lung cancer (mNSCLC), metastatic urothelial cancer (mUC), and metastatic small cell lung cancer (mSCLC)) received 1 mg/kg magrolimab intravenously (IV) on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 113 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 113 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mNSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 90 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 69 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mUC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 68 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 68 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 72 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 72 weeks; each cycle length = 21 days.	

Reporting group values	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Number of subjects	9	29	26
Age categorical Units: Subjects			
Between 18 and 65 years	5	13	12
>=65 years	4	16	14
Gender categorical Units: Subjects			
Female	4	6	7
Male	5	23	19
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	7	27	19
More than one race	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	3	0

Not Hispanic or Latino	8	25	20
Unknown or Not Reported	1	1	6

Reporting group values	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	Total	
Number of subjects	42	106	
Age categorical Units: Subjects			
Between 18 and 65 years	27	57	
>=65 years	15	49	
Gender categorical Units: Subjects			
Female	17	34	
Male	25	72	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	3	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	2	
White	30	83	
More than one race	11	18	
Ethnicity Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	30	83	
Unknown or Not Reported	11	19	

End points

End points reporting groups

Reporting group title	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)
Reporting group description:	
Participants with solid tumors (including metastatic non small cell lung cancer (mNSCLC), metastatic urothelial cancer (mUC), and metastatic small cell lung cancer (mSCLC)) received 1 mg/kg magrolimab intravenously (IV) on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 113 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 113 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mNSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 90 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 69 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mUC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 68 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 68 weeks; each cycle length = 21 days.	
Reporting group title	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Reporting group description:	
Participants with mSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 72 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 72 weeks; each cycle length = 21 days.	

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

End point title	Percentage of Participants Experiencing Treatment-Emergent Adverse Events (TEAEs)[1]
End point description:	
TEAEs were defined as any adverse events (AE) not present prior to the study treatment, or any events already present but worsening in either intensity or frequency following exposure to the study treatment. The TEAE reporting period is defined as the period from the date of the first dose of study treatment up to 30 days after the date of the last dose of study treatment or the day before initiation of subsequent antineoplastic therapy, whichever comes first. 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. Analysis Population Description: Participants in the Safety Analysis Set were analyzed. The Safety Analysis Set included all participants who took at least 1 dose of any study drug.	
End point type	Primary
End point timeframe:	
First dose date up to 113 weeks plus 30 days	

Notes:

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

End point values	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	29	26	42
Units: percentage of participants				
number (not applicable)	100.0	100.0	100.0	100.0

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Treatment-Emergent Laboratory Abnormalities

End point title	Percentage of Participants With Treatment-Emergent Laboratory Abnormalities[2]

End point description:

Treatment-emergent laboratory abnormalities were defined as values that increase at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of last dose of study drug plus 30 days and prior to the day of initiation of subsequent anti-cancer therapy. Percentages were rounded off. Analysis Population Description: Participants in the Safety Analysis Set were analyzed.

End point type	Primary

End point timeframe:

First dose date up to 113 weeks plus 30 days

Notes:

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

End point values	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	29	26	42
Units: percentage of participants				
number (not applicable)				
Any Grade	100	100	100	100
Grade 3 or Higher	77.8	82.8	92.3	78.6

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR) (Phase 2 Cohorts 1a, 1b, and 1c)

End point title	Objective Response Rate (ORR) (Phase 2 Cohorts 1a, 1b, and 1c)[3][4]

End point description:

ORR was defined as the percentage of participants who achieve a complete response (CR) or partial response (PR), as measured by RECIST version 1.1, as determined by investigator assessment. CR was

defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Clopper-Pearson method was used in outcome measure analysis. Percentages were rounded-off. Analysis Population Description: Participants in the modified intent to treat analysis set were analyzed. The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis, this endpoint was applicable only to Phase 2 cohorts. Therefore, data for cohorts of Phase 2 are reported.

End point type	Primary

End point timeframe:

Up to 90 Weeks

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis ,this endpoint was applicable only to Phase 2 arms. Therefore, data for arms of Phase 2 are reported.
[4] - 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: The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis ,this endpoint was applicable only to Phase 2 arms. Therefore, data for arms of Phase 2 are reported.

End point values	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	26	42	
Units: percentage of participants				
number (confidence interval 95%)	17.2 (5.8 to 35.8)	3.8 (0.1 to 19.6)	4.8 (0.6 to 16.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) (Phase 2 Cohorts 1a, 1b, and 1c)

End point title	Progression-free Survival (PFS) (Phase 2 Cohorts 1a, 1b, and 1c)[5]

End point description:

PFS was defined as the interval from the first dosing date of any study drug to the earlier date of the first documentation of objective disease progression (PD) by investigator assessment per RECIST, Version 1.1, or death from any cause. PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (appearance of one or more new lesions was also considered progression). Kaplan-Meier (KM) estimates were used in outcome measure analysis. Analysis Population Description: Participants in the modified Intent-to-Treat Analysis Set were analyzed. The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis, this endpoint was applicable only to Phase 2 cohorts. Therefore, data for cohorts of Phase 2 are reported.

End point type	Secondary

End point timeframe:

Up to 117 Weeks

Notes:

[5] - 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: The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis ,this endpoint was applicable only to Phase 2 arms. Therefore, data for arms of Phase 2 are reported.

End point values	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	26	42	
Units: months				
median (confidence interval 95%)	4.2 (2.0 to 8.0)	2.7 (2.1 to 4.0)	2.2 (2.0 to 3.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) (Phase 2 Cohorts 1a, 1b, and 1c)

End point title	Duration of Response (DOR) (Phase 2 Cohorts 1a, 1b, and

End point description:

DOR was defined as time from first documentation of CR or PR to the earliest date of documented PD, per RECIST, Version 1.1, or death from any cause, whichever occurs first, as determined by investigator assessment. CR and PR are defined in endpoint #3 and PD is defined in endpoint#4. KM Estimates were used in endpoint analysis. Analysis Population Description: Participants in the modified Intent-to-Treat Analysis Set who achieved CR or PR were analyzed. The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis, this endpoint was applicable only to Phase 2 cohorts. Therefore, data for cohorts of Phase 2 are reported. 0000/9999 means data is not available

End point type	Secondary

End point timeframe:

Up to 117 Weeks

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis ,this endpoint was applicable only to Phase 2 arms. Therefore, data for arms of Phase 2 are reported.

End point values	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	2	
Units: months				
median (confidence interval 95%)	7.6 (3.7 to 9999)	9999 (9999 to 9999)	4.7 (4.6 to 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) (Phase 2 Cohorts 1a, 1b, and 1c)

End point title	Overall Survival (OS) (Phase 2 Cohorts 1a, 1b, and 1c)[7]

End point description:

OS is defined as time from date of dose initiation to death from any cause. KM estimates were used in endpoint analysis. Analysis Population Description: Participants in the modified Intent-to-Treat Analysis

Set were analyzed. The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis, this endpoint was applicable only to Phase 2 cohorts. Therefore, data for cohorts of Phase 2 are reported. 9999: Upper limit of confidence interval was not estimable due to low number of participants with events.

End point type	Secondary

End point timeframe:

Up to 117 Weeks

Notes:

[7] - 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: The study had 2 parts - Safety Run-in and Phase 2. Per pre-specified analysis ,this endpoint was applicable only to Phase 2 arms. Therefore, data for arms of Phase 2 are reported.

End point values	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	26	42	
Units: months				
median (confidence interval 95%)	9.8 (5.2 to 9999)	7.6 (4.7 to 13.7)	6.4 (3.9 to 8.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Magrolimab

End point title	Serum Concentration of Magrolimab

End point description:

Analysis Population Description: The participants in the Pharmacokinetic (PK) Analysis Set with available data were analyzed. The PK Analysis Set included all participants who received any amount of magrolimab and have at least 1 measurable posttreatment serum concentration of magrolimab. 9999 : Standard Deviation (SD) is not estimable for 1 participant. Here 'N' is defined as participants with available data at the given timepoint.

End point type	Secondary

End point timeframe:

Day 1, Day 8 Predose, Day 8 1-Hour Postdose, Day 22, Day 43 Predose, Day 43 1-Hour Postdose, Day 85, Day 127, Day 190 and Day 253 Predose

End point values	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	23	23	36
Units: µg/mL				
arithmetic mean (standard deviation)				
D 1 Predose	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
D 8 Predose N=5,20,22,29	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
D 8 1-Hour Postdose N=1	407 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

D 22 Predose N=4,23,23,32	460 (± 112)	302 (± 161)	260 (± 148)	334 (± 134)
D 43 Predose N=5,20,21,28	624 (± 451)	523 (± 195)	439 (± 182)	529 (± 258)
D 43 1- Hour Postdose N=2,18,18,27	1880 (± 523)	1550 (± 525)	1560 (± 492)	1730 (± 560)
D 85 Predose N=4,14,12,15	415 (± 135)	266 (± 134)	319 (± 271)	297 (± 181)
D 127 Predose N=3,11,3,10	277 (± 35.0)	281 (± 143)	393 (± 93.8)	174 (± 106)
D 190 Predose N=3,7,4	281 (± 71.1)	344 (± 104)	9999 (± 9999)	250 (± 113)
D 253 Predose N=2,6	237 (± 56.6)	363 (± 179)	9999 (± 9999)	9999 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Developed Anti-Magrolimab Antibodies

End point title	Percentage of Participants who Developed Anti-Magrolimab Antibodies

End point description:

Analysis Population Description:: Participants in the Immunogenicity Analysis Set with available data were analyzed. The Immunogenicity Analysis Set includes all participants who received any amount of magrolimab and have at least 1 evaluable anti-magrolimab antibody test result.

End point type	Secondary

End point timeframe:

Up to 113 Weeks

End point values	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	25	25	37
Units: percentage of participants				
number (not applicable)	0	4.0	8.0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Up to 117 weeks; Adverse events: Up to 113 weeks plus 30 days

Adverse event reporting additional description:

All-cause mortality: All Enrolled Analysis Set included all participants who received a study subject identification number in the study after screening. Adverse events: The Safety Analysis Set included all participants who took at least 1 dose of any study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)

Reporting group description:

Participants with solid tumors (including metastatic non small cell lung cancer (mNSCLC), metastatic urothelial cancer (mUC), and metastatic small cell lung cancer (mSCLC)) received 1 mg/kg magrolimab intravenously (IV) on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 113 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 113 weeks; each cycle length = 21 days.

Reporting group title	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)

Reporting group description:

Participants with mSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 72 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 72 weeks; each cycle length = 21 days.

Reporting group title	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)

Reporting group description:

Participants with mUC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 68 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 68 weeks; each cycle length = 21 days.

Reporting group title	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)

Reporting group description:

Participants with mNSCLC received 1 mg/kg magrolimab IV on Day 1, 30 mg/kg IV on Days 8 and 15 of cycle 1; 30 mg/kg IV on Days 1, 8 and 15 of Cycle 2; 60 mg/kg IV on Day 1 of Cycle 3 and onwards for up to 90 weeks; and 75 mg/m^2 docetaxel IV on Day 1 of each cycle for up to 69 weeks; each cycle length = 21 days.

Serious adverse events	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	18 / 42 (42.86%)	12 / 26 (46.15%)
number of deaths (all causes)	6	37	18
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary ~ disease			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			

subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Transfusion reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0

Epilepsy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	4 / 26 (15.38%)
occurrences causally related to treatment / all	0 / 0	4 / 4	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	0 / 0	6 / 6	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone ~ secretion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			

subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 29 (55.17%)		
number of deaths (all causes)	17		
number of deaths resulting from adverse events	0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary ~ disease				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonitis				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				

subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutrophil count decreased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Transfusion reaction			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Seizure			

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Neuritis				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Febrile neutropenia				
subjects affected / exposed	3 / 29 (10.34%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	3 / 29 (10.34%)			
occurrences causally related to treatment / all	4 / 4			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	2 / 29 (6.90%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				

Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic colitis				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal haemorrhage				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Inappropriate antidiuretic hormone ~ secretion				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Pneumonia				

subjects affected / exposed	4 / 29 (13.79%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Sepsis				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung abscess				

subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Encephalitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Safety Run-in Cohort 1 (Magrolimab + Docetaxel)	Phase 2 Cohort 1c, mSCLC (Magrolimab + Docetaxel)	Phase 2 Cohort 1b, mUC (Magrolimab + Docetaxel)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	41 / 42 (97.62%)	26 / 26 (100.00%)
Vascular disorders			
Superficial vein thrombosis			

subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Hypovolaemic shock			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 9 (66.67%)	11 / 42 (26.19%)	5 / 26 (19.23%)
occurrences (all)	6	14	5
Oedema peripheral			
subjects affected / exposed	3 / 9 (33.33%)	4 / 42 (9.52%)	5 / 26 (19.23%)
occurrences (all)	3	4	5
Chills			
subjects affected / exposed	1 / 9 (11.11%)	4 / 42 (9.52%)	1 / 26 (3.85%)
occurrences (all)	1	5	2
Mucosal inflammation			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	2 / 26 (7.69%)
occurrences (all)	1	2	2
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	3 / 26 (11.54%)
occurrences (all)	0	1	3
Pyrexia			
subjects affected / exposed	3 / 9 (33.33%)	8 / 42 (19.05%)	8 / 26 (30.77%)
occurrences (all)	3	10	9
Asthenia			
subjects affected / exposed	1 / 9 (11.11%)	23 / 42 (54.76%)	10 / 26 (38.46%)
occurrences (all)	1	25	18
Generalised oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Vascular device occlusion			

subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Dysphonia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences (all)	1	3	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	1 / 26 (3.85%)
occurrences (all)	0	3	2
Cough			
subjects affected / exposed	2 / 9 (22.22%)	5 / 42 (11.90%)	2 / 26 (7.69%)
occurrences (all)	4	5	2
Dyspnoea			

subjects affected / exposed	2 / 9 (22.22%)	12 / 42 (28.57%)	3 / 26 (11.54%)
occurrences (all)	2	13	3
Sneezing			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences (all)	0	3	2
Depression			
subjects affected / exposed	3 / 9 (33.33%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	3	1	0
Anxiety			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
Confusional state			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
White blood cell count decreased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	5	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences (all)	1	3	2
Weight decreased			
subjects affected / exposed	2 / 9 (22.22%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences (all)	2	3	2
Neutrophil count decreased			

subjects affected / exposed	3 / 9 (33.33%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences (all)	5	7	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Sars-cov-2 test positive			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 9 (11.11%)	5 / 42 (11.90%)	2 / 26 (7.69%)
occurrences (all)	1	8	2
Transfusion reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 9 (11.11%)	6 / 42 (14.29%)	1 / 26 (3.85%)
occurrences (all)	1	6	1
Dysgeusia			
subjects affected / exposed	1 / 9 (11.11%)	6 / 42 (14.29%)	2 / 26 (7.69%)
occurrences (all)	1	6	2
Headache			
subjects affected / exposed	2 / 9 (22.22%)	6 / 42 (14.29%)	2 / 26 (7.69%)
occurrences (all)	2	7	2
Neurotoxicity			
subjects affected / exposed	0 / 9 (0.00%)	4 / 42 (9.52%)	1 / 26 (3.85%)
occurrences (all)	0	4	1
Migraine			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Lethargy			

subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences (all)	0	3	3
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	5 / 26 (19.23%)
occurrences (all)	0	4	8
Leukopenia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 42 (9.52%)	4 / 26 (15.38%)
occurrences (all)	0	5	4
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	16 / 42 (38.10%)	13 / 26 (50.00%)
occurrences (all)	0	19	17
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Anaemia			
subjects affected / exposed	5 / 9 (55.56%)	26 / 42 (61.90%)	14 / 26 (53.85%)
occurrences (all)	7	37	21
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 9 (33.33%)	16 / 42 (38.10%)	4 / 26 (15.38%)
occurrences (all)	4	20	4
Diarrhoea			

subjects affected / exposed	2 / 9 (22.22%)	19 / 42 (45.24%)	6 / 26 (23.08%)
occurrences (all)	5	22	6
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
Dyspepsia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	2 / 26 (7.69%)
occurrences (all)	1	2	2
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	6 / 42 (14.29%)	1 / 26 (3.85%)
occurrences (all)	0	8	1
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	5 / 42 (11.90%)	3 / 26 (11.54%)
occurrences (all)	0	5	4
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	7 / 42 (16.67%)	4 / 26 (15.38%)
occurrences (all)	5	9	4
Constipation			
subjects affected / exposed	2 / 9 (22.22%)	8 / 42 (19.05%)	4 / 26 (15.38%)
occurrences (all)	3	8	4
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
Alopecia			
subjects affected / exposed	2 / 9 (22.22%)	6 / 42 (14.29%)	6 / 26 (23.08%)
occurrences (all)	2	6	6
Nail discolouration			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0

Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Nail disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	2 / 9 (22.22%)	0 / 42 (0.00%)	2 / 26 (7.69%)
occurrences (all)	3	0	2
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	3
Pollakiuria			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Urinary incontinence			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Urinary retention			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	5 / 42 (11.90%)	4 / 26 (15.38%)
occurrences (all)	1	7	4
Back pain			
subjects affected / exposed	2 / 9 (22.22%)	6 / 42 (14.29%)	2 / 26 (7.69%)
occurrences (all)	2	8	2
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	5 / 42 (11.90%)	3 / 26 (11.54%)
occurrences (all)	0	5	3
Musculoskeletal chest pain			

subjects affected / exposed	0 / 9 (0.00%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	4 / 42 (9.52%)	1 / 26 (3.85%)
occurrences (all)	0	4	1
Bone pain			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	3 / 26 (11.54%)
occurrences (all)	0	0	3
Muscular weakness			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	4 / 42 (9.52%)	1 / 26 (3.85%)
occurrences (all)	0	4	1
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	2 / 42 (4.76%)	4 / 26 (15.38%)
occurrences (all)	1	2	7
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	3 / 42 (7.14%)	1 / 26 (3.85%)
occurrences (all)	0	3	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Covid-19			
subjects affected / exposed	0 / 9 (0.00%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences (all)	0	1	2
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0

Localised infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Nail infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Osteomyelitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	2 / 9 (22.22%)	3 / 42 (7.14%)	1 / 26 (3.85%)
occurrences (all)	3	3	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 9 (22.22%)	17 / 42 (40.48%)	2 / 26 (7.69%)
occurrences (all)	2	20	2
Hyponatraemia			
subjects affected / exposed	2 / 9 (22.22%)	4 / 42 (9.52%)	1 / 26 (3.85%)
occurrences (all)	2	5	1
Hypoalbuminaemia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 42 (9.52%)	2 / 26 (7.69%)
occurrences (all)	3	5	2
Hypocalcaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences (all)	3	1	1
Dehydration			
subjects affected / exposed	1 / 9 (11.11%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			

subjects affected / exposed	2 / 9 (22.22%)	2 / 42 (4.76%)	3 / 26 (11.54%)
occurrences (all)	4	2	3
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	4 / 42 (9.52%)	0 / 26 (0.00%)
occurrences (all)	0	4	0
Hypoglycaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Iron overload			
subjects affected / exposed	1 / 9 (11.11%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Phase 2 Cohort 1a, mNSCLC (Magrolimab + Docetaxel)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 29 (100.00%)		
Vascular disorders			
Superficial vein thrombosis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Hypovolaemic shock			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	3		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 29 (20.69%)		
occurrences (all)	6		
Oedema peripheral			
subjects affected / exposed	6 / 29 (20.69%)		
occurrences (all)	7		

Chills subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Mucosal inflammation subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	11 / 29 (37.93%) 19		
Asthenia subjects affected / exposed occurrences (all)	18 / 29 (62.07%) 25		
Generalised oedema subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Malaise subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Immune system disorders Contrast media reaction subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Reproductive system and breast disorders Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			

Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Pulmonary embolism subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Hiccups subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dysphonia subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Haemoptysis subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 1		
Cough subjects affected / exposed occurrences (all)	4 / 29 (13.79%) 7		
Dyspnoea subjects affected / exposed occurrences (all)	9 / 29 (31.03%) 12		
Sneezing subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Depression subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Anxiety subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Confusional state			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Lymphocyte count decreased			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	7		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	7		
C-reactive protein increased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Sars-cov-2 test positive			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	4		
Transfusion reaction			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Neurotoxicity			
subjects affected / exposed	6 / 29 (20.69%)		
occurrences (all)	8		
Migraine			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	4		
Thrombocytopenia			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	3		
Leukopenia			

subjects affected / exposed	5 / 29 (17.24%)		
occurrences (all)	5		
Neutropenia			
subjects affected / exposed	13 / 29 (44.83%)		
occurrences (all)	17		
Febrile neutropenia			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Leukocytosis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	22 / 29 (75.86%)		
occurrences (all)	38		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	5 / 29 (17.24%)		
occurrences (all)	6		
Diarrhoea			
subjects affected / exposed	14 / 29 (48.28%)		
occurrences (all)	21		
Dysphagia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	3		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		

Stomatitis subjects affected / exposed occurrences (all)	4 / 29 (13.79%) 6		
Vomiting subjects affected / exposed occurrences (all)	4 / 29 (13.79%) 6		
Constipation subjects affected / exposed occurrences (all)	6 / 29 (20.69%) 6		
Skin and subcutaneous tissue disorders			
Pruritus subjects affected / exposed occurrences (all)	4 / 29 (13.79%) 4		
Alopecia subjects affected / exposed occurrences (all)	8 / 29 (27.59%) 8		
Nail discolouration subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Nail disorder subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Rash subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Renal and urinary disorders			
Cystitis noninfective subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dysuria subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Pollakiuria			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 29 (20.69%)		
occurrences (all)	8		
Back pain			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Musculoskeletal chest pain			
subjects affected / exposed	5 / 29 (17.24%)		
occurrences (all)	5		
Pain in extremity			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Bone pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Infections and infestations			

Respiratory tract infection subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 4			
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Candida infection subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 1			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 3			
Covid-19 subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2			
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 4			
Fungal infection subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Localised infection subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Nail infection subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Osteomyelitis subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Tooth abscess subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0			

Oral candidiasis subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	7 / 29 (24.14%) 8		
Hyponatraemia subjects affected / exposed occurrences (all)	5 / 29 (17.24%) 6		
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 2		
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dehydration subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 1		
Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 2		
Hypokalaemia subjects affected / exposed occurrences (all)	5 / 29 (17.24%) 5		
Hypoglycaemia subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Iron overload subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 March 2021	Herein is a summary of the major changes made to original protocol dated 15 December 2020 and reflected in Amendment 1 dated 03 March 2021. The protocol has been amended primarily to: - Modify various sections of the protocol to reflect the removal of the triple negative breast (TNBC) cancer cohorts, in response to initial regulatory feedback received from the FDA during the initial review of this protocol. This amendment removed the Safety Run-in Cohort 1 (Magrolimab + Nab-paclitaxel) and the Phase 2 Cohort 1a (mTNBC). The TNBC Cohorts will be a separate study under a different IND. - Other sections of the protocol also revised to address regulatory feedback from the Food and Drug Administration (FDA) include clarifying eligibility criteria for small cell lung cancer (SCLC) and the definition of dose-limiting toxicity (DLT). - In response to regulatory feedback received from International Health Authorities, language throughout the protocol has been harmonized with ongoing studies of magrolimab. - Clarification of key study procedures. - Biomarker sample collection timepoints at screening, Cycle 1, and the end of treatment have been adjusted to reflect current data needs for the characterization of the mechanism of action of magrolimab in solid tumors and for harmonization with other magrolimab solid tumor studies.
15 March 2021	Herein is a summary of the major changes made to Amendment 1 dated 03 March 2021 and reflected in Amendment 2 dated 15 March 2021. The protocol has been amended to address feedback received from the FDA. The sections revised are as follows: - Modify the exceptions to dose-limiting toxicity (DLT) definition for electrolyte abnormalities, tumor lysis, and hypomagnesemia.
14 December 2021	This amendment provides the modification of the magrolimab dosing in Cycles 3 and beyond to 60 mg/kg (every 3 weeks) and guidance on dose delays of magrolimab in case of TEAEs.
27 January 2022	The primary reason for this amendment is to provide additional guidance for enhanced anemia management. Anemia is a known and well-described risk for magrolimab that can occur in early doses and is transient. Adequate monitoring and management of anemia during the first 2 doses of magrolimab are needed to ensure patient safety, especially in patients with low baseline hemoglobin. A minimum hemoglobin threshold prior to the first 2 doses of magrolimab treatment during treatment initiation along with post magrolimab treatment hemoglobin monitoring during those treatments are included in the amended protocol.

24 October 2023	High-level summaries of the history of this study's amendments are provided in tabular form in the subsections below (from most recent amendment to oldest), with changes listed in each table in order of importance. Minor changes such as the correction of typographic errors, grammar, or formatting are not detailed. - Collection period for treatment-emergent adverse events clarified. - Collection period for incidence of treatment-emergent laboratory abnormalities - clarified. - Updates made to align with current safety recommendations. - Timing of primary analysis for Phase 2 Cohort 1 clarified. - Updated the toxicity management regarding hemoglobin monitoring to align with current recommendations. - Remove circulating tumor cell sample collection as not performed. - Sample size for urothelial cancer cohort updated. - Magrolimab administration language updated to clarify vital signs will be - assessed prior to administration. Sections 5.4 - Language added to allow local sourcing of docetaxel. Section 5.3.2 - Updated guidance provided for the management of infusion-related reactions. - New sections provided for guidance on management of severe neutropenia and serious infections. - Text added to align with EU-CTR requirements. - Text updated to clarify that 'urine or serum pregnancy tests will be conducted from Cycle 1 Day 1' with respect to pregnancy test. - Analysis sets updated. - Guidance on COVID-19 vaccination provided. Section 5.7.1.1 - Language updated to clarify that a final analysis may be conducted after the primary analysis. - Inclusion criteria were updated for clarification. Synopsis; Section 4.2 - Text was updated to replace 'participants' with 'patients' to maintain consistency. - Changes from administrative amendment 1 were added to the protocol. - Changes from administrative amendment 2 were added to the protocol. - Minor changes to correct typographic errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported