Clinical trial results:
A Phase 2 Study of Magrolimab Combination Therapy in Patients with Head and Neck Squamous Cell Carcinoma

Summary

EudraCT number	2020-005708-20
Trial protocol	ES DE PT FR PL
Global end of trial date	02 October 2024

Results information

Result version number	v1
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	GS-US-548-5916

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04854499
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	02 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goals of this clinical study are to learn about the safety, tolerability, dosing and effectiveness of the study drug, magrolimab in combination with other anticancer therapies in patients with head and neck squamous cell carcinoma (HNSCC).

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 September 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	Australia: 19
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	France: 34
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Poland: 29
Country: Number of subjects enrolled	Spain: 12
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	United States: 43
Country: Number of subjects enrolled	Portugal: 27
Worldwide total number of subjects	193
EEA total number of subjects	126

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)	112
From 65 to 84 years	81
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

279 participants were screened.

Pre-assignment

Screening details:

Participants were enrolled at study sites in Europe, North America and Asia Pacific. Optional Phase 2 Cohort 2 was never opened due to closure of the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum

Arm description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU (5-fluorouracil) intravenous (IV) infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 73 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 73 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 18.3 weeks (for carboplatin).

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

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	KEYTRUDA®
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

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	5-FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

Arm title	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU

Arm description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU IV infusions as mentioned below: Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 72 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 88 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 22 weeks for carboplatin and 23 weeks for cisplatin.

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

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

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	KEYTRUDA®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	5-FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

Arm title	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Arm description:

Participants received pembrolizumab + platinum + 5 FU IV infusions as mentioned below: Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 70 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks for carboplatin and 18 weeks for cisplatin.

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

Dosage and administration details:

Administered intravenously

Investigational medicinal product name	5-FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Administered intravenously

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

Dosage and administration details:

Administered intravenously

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

Dosage and administration details:

Administered intravenously

Arm title	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU

Arm description:

Participants with untreated metastatic or unresectable, locally recurrent HNSCC regardless of PD-L1 status received magrolimab + zimberelimab + platinum + 5 FU IV infusions as mentioned below: Magrolimab 1 mg/kg on Day 1; 30 mg/kg on Days 8 and 15 of Cycles 1 and 2 and On Day 1 of Cycle 2; 60 mg mg/kg on Day 1 of Cycle 3 for 21-day cycle each for up to 37 weeks; Zimberelimab 360 mg IV on Day 1 of Cycle 1, 2 and 3 for 21-day cycle each for up to 40 weeks; 5-FU 1000 mg/m^2/day continuous IV on Days 1 to 4 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 16 weeks.

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	
Investigational medicinal product name	Zimberelimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously	
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously	
Investigational medicinal product name	5-FU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Administered intravenously	
Arm title	Safety Run-in Cohort 2: Magrolimab + Docetaxel

Arm description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 69 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 13 weeks.

Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
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 3: Magrolimab + Docetaxel

Arm description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 42 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 34 weeks.

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

Dosage and administration details:

Administered intravenously

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

Dosage and administration details:

Administered intravenously

Number of subjects in period 1[1]	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU
Started	6	52	54
Completed	0	0	0
Not completed	6	52	54
Death	1	23	21
Study terminated by sponsor	5	27	28
Investigator's discretion	-	1	3
Withdrew consent	-	1	2
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 3: Magrolimab + Docetaxel
Started	32	7	41
Completed	0	0	0
Not completed	32	7	41

Death	7	6	24
Study terminated by sponsor	19	1	10
Investigator's discretion	4	-	5
Withdrew consent	2	-	1
Lost to follow-up	-	-	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 1 participant who was randomized but not treated was not included in the Modified Intent-to-Treat (mITT) Analysis Set in Safety Run-In 2 Cohort for Period 1 table reported above.

Baseline characteristics

Reporting groups

Reporting group title	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU (5-fluorouracil) intravenous (IV) infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 73 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 73 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 18.3 weeks (for carboplatin).

Reporting group title	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 72 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 88 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 22 weeks for carboplatin and 23 weeks for cisplatin.

Reporting group title	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Reporting group description:

Participants received pembrolizumab + platinum + 5 FU IV infusions as mentioned below:
Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 70 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks for carboplatin and 18 weeks for cisplatin.

Reporting group title	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU

Reporting group description:

Participants with untreated metastatic or unresectable, locally recurrent HNSCC regardless of PD-L1 status received magrolimab + zimberelimab + platinum + 5 FU IV infusions as mentioned below:
Magrolimab 1 mg/kg on Day 1; 30 mg/kg on Days 8 and 15 of Cycles 1 and 2 and On Day 1 of Cycle 2; 60 mg mg/kg on Day 1 of Cycle 3 for 21-day cycle each for up to 37 weeks; Zimberelimab 360 mg IV on Day 1 of Cycle 1, 2 and 3 for 21-day cycle each for up to 40 weeks; 5-FU 1000 mg/m^2/day continuous IV on Days 1 to 4 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 16 weeks.

Reporting group title	Safety Run-in Cohort 2: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 69 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 13 weeks.

Reporting group title	Phase 2 Cohort 3: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 42 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 34 weeks.

Reporting group values	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Number of subjects	6	52	54
Age categorical Units: Subjects			
< 65	1	35	33
>= 65	5	17	21
Age continuous Units: years			
arithmetic mean	69	61	61
standard deviation	± 6.2	± 7.4	± 9.5
Gender categorical Units: Subjects			
Female	0	9	11
Male	6	43	43
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	44	47
More than one race	0	6	5
Ethnicity Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	6	43	44
Unknown or Not Reported	0	7	10

Reporting group values	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 3: Magrolimab + Docetaxel
Number of subjects	32	7	41
Age categorical Units: Subjects			
< 65	16	5	22
>= 65	16	2	19
Age continuous Units: years			
arithmetic mean	63	58	63
standard deviation	± 11.4	± 15.5	± 9.9
Gender categorical Units: Subjects			
Female	5	0	4
Male	27	7	37
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0

White	26	6	30
More than one race	5	0	7
Ethnicity Units: Subjects			
Hispanic or Latino	3	1	1
Not Hispanic or Latino	22	6	32
Unknown or Not Reported	7	0	8

Reporting group values	Total		
Number of subjects	192		
Age categorical Units: Subjects			
< 65	112		
>= 65	80		
Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	29		
Male	163		
Race Units: Subjects			
American Indian or Alaska Native	0		
Asian	4		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	158		
More than one race	30		
Ethnicity Units: Subjects			
Hispanic or Latino	7		
Not Hispanic or Latino	153		
Unknown or Not Reported	32		

End points reporting groups

Reporting group title	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU (5-fluorouracil) intravenous (IV) infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 73 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 73 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 18.3 weeks (for carboplatin).

Reporting group title	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 72 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 88 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 22 weeks for carboplatin and 23 weeks for cisplatin.

Reporting group title	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Reporting group description:

Participants received pembrolizumab + platinum + 5 FU IV infusions as mentioned below:
Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 70 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks for carboplatin and 18 weeks for cisplatin.

Reporting group title	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU

Reporting group description:

Participants with untreated metastatic or unresectable, locally recurrent HNSCC regardless of PD-L1 status received magrolimab + zimberelimab + platinum + 5 FU IV infusions as mentioned below:
Magrolimab 1 mg/kg on Day 1; 30 mg/kg on Days 8 and 15 of Cycles 1 and 2 and On Day 1 of Cycle 2; 60 mg mg/kg on Day 1 of Cycle 3 for 21-day cycle each for up to 37 weeks; Zimberelimab 360 mg IV on Day 1 of Cycle 1, 2 and 3 for 21-day cycle each for up to 40 weeks; 5-FU 1000 mg/m^2/day continuous IV on Days 1 to 4 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycle 1, 2 and 3 to 6 for 21-day cycle each for up to 16 weeks.

Reporting group title	Safety Run-in Cohort 2: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 69 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 13 weeks.

Reporting group title	Phase 2 Cohort 3: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 42 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 34 weeks.

Primary: Safety Run-in Cohorts 1 and 2: Percentage of Participants Experiencing Dose Limiting Toxicities (DLTs) According to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0

End point title	Safety Run-in Cohorts 1 and 2: Percentage of Participants Experiencing Dose Limiting Toxicities (DLTs) According to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0[1][2]

End point description:

A DLT was defined as any Grade 3 or higher hematologic toxicity or Grade 3 or higher nonhematologic toxicity that had worsened in severity from pretreatment baseline during the DLT assessment period and, in the opinion of the investigator, the AE was related to magrolimab and the relationship of the AE with the combination partner regimen can be ruled out. DLT Evaluable Analysis Set was defined as all participants in the safety run-in evaluations who meet either of the following criteria during the DLT assessment period:
- The participants experienced a DLT at any time after initiation of the first infusion of magrolimab.
- The participant did not experience a DLT and completed at least 2 infusions of magrolimab and at least 1 dose of pembrolizumab, platinum, and 5-FU for Safety Run-in 1 Cohort 1; at least 1 dose of docetaxel for Safety Run-in Cohort 2.

End point type	Primary

End point timeframe:

First dose date up to 21 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.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per prespecified analysis, the data for this endpoint was collected only for Safety Run-In Arms 1 and 2. Hence the data is not reported for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C for this endpoint.

End point values	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Safety Run-in Cohort 2: Magrolimab + Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Safety Run-in Cohorts 1 and 2: Percentage of Participants Experiencing Laboratory Abnormalities According to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0

End point title	Safety Run-in Cohorts 1 and 2: Percentage of Participants Experiencing Laboratory Abnormalities According to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0[3][4]

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 last dose date of study drug plus 30 days (or last dose date of zimberelimab plus 90 days) and prior to the day of initiation of subsequent anti-cancer therapy.
Analysis Population Description : Safety Run-in Cohorts 1 and 2: 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 73 weeks plus 30 days

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: No statistical comparison was planned or performed.

[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: Per prespecified analysis, the data for this endpoint was collected only for Safety Run-In Arms 1 and 2. Hence the data is not reported for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C for this endpoint.

End point values	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Safety Run-in Cohort 2: Magrolimab + Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: percentage of participants				
number (not applicable)	83.3	71.4		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Cohort 1, Arms A and B: Progression-free Survival (PFS)

End point title	Phase 2 Cohort 1, Arms A and B: Progression-free Survival (PFS)[5]

End point description:

PFS was defined as the time from the date of randomization until the earliest date of documented disease progression, as assessed by investigator assessment, or death from any cause, whichever occurred first. Progressive disease (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 included 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. (Note: the appearance of one or more new lesions is also considered progression). Kaplan-Meier (KM) estimates were used in outcome measure analysis. Participants in Phase 2 Cohort 1, Arms A and B in the ITT analysis set were analyzed.

End point type	Primary

End point timeframe:

Up to 129 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 cohort Arms A and B. Hence the data is not reported for Phase 2 Cohort 3 and Phase 2 cohort Arm C for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	54		
Units: months				
median (confidence interval 95%)	5.5 (3.0 to 6.9)	5.6 (4.2 to 7.4)		

Statistical analyses

Statistical analysis title	Phase 2 Cohort 1 Arm A Vs Arm B
Comparison groups	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU v Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.314
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.809
upper limit	2.136

Primary: Phase 2 Cohort 3: Objective Response Rate (ORR)

End point title	Phase 2 Cohort 3: Objective Response Rate (ORR)[6][7]

End point description:

ORR was defined as the percentage of participants who achieved a complete response (CR) or partial response (PR) as measured by Response Evaluation Criteria In Solid Tumors (RECIST) v1.1 as determined by investigator assessment. CR is 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 is defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Participants in Phase 2 Cohort 3 in the mITT Analysis Set with available data were analyzed.

End point type	Primary

End point timeframe:

Up to 129 weeks

Notes:

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

[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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3. Hence the data for Phase 2 cohort Arms A, B and C is not reported for this endpoint.

End point values	Phase 2 Cohort 3: Magrolimab + Docetaxel			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: percentage of participants				
number (confidence interval 95%)	12.2 (4.1 to 26.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Safety Run-in Cohort 1 and 2, Phase 2 Cohort 1 Arm A and Phase 2 Cohort 3: Serum Concentration of Magrolimab

End point title	Safety Run-in Cohort 1 and 2, Phase 2 Cohort 1 Arm A and Phase 2 Cohort 3: Serum Concentration of Magrolimab[8]

End point description:

Participants in the Pharmacokinetic (PK) Analysis Set with available data were analyzed. The PK Analysis Set, defined as all participants who received any amount of magrolimab and have at least 1 evaluable post-treatment serum concentration of magrolimab, at the given timepoint were analyzed.
999: Data is not available as the concentrations were below the level of quantification.

End point type	Secondary

End point timeframe:

Day 8 1-Hour Postdose; Days 15, 22, 43: Predose; Day 43 1-Hour Postdose; Day 71 1-Hour Postdose; Days 85,127, 190,197, 211, 253 Predose; Day 253 1-Hour Postdose

Notes:

[8] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3, Phase 2 Cohort 1 Arm A and Safety Run-in Arms 1 and 2. Hence the data is not reported for Phase 2 Cohort 1 Arm C for this endpoint.

End point values	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+ Platinum+5-FU	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	41	6	29
Units: µg/mL				
arithmetic mean (standard deviation)				
D 8 1 HourPostdose N=5,15,5,5	305 (± 56.4)	481 (± 137)	288 (± 55.2)	459 (± 140)
D 15 Predose N=0,24,0,16	999 (± 0)	149 (± 52.8)	999 (± 0)	125 (± 49.4)
D 22 Predose N=6,41,6,29	208 (± 185)	250 (± 100)	255 (± 149)	253 (± 110)
D 43 Predose N=5,38,5,27	359 (± 253)	397 (± 195)	561 (± 514)	477 (± 219)
D 43 1-Hour Postdose N=0,24,0,19	999 (± 0)	1440 (± 306)	999 (± 0)	1330 (± 426)
D 71 1-Hour Postdose N=0,0,0,1	999 (± 0)	999 (± 0)	999 (± 0)	572 (± 0)
D 85 Predose N=4,31,2,18	138 (± 106)	308 (± 140)	813 (± 830)	272 (± 119)
D 127 Predose N=3,4,0,1	142 (± 113)	204 (± 235)	999 (± 0)	393 (± 0)
D 190 Predose N=1,12,1,4	707 (± 0)	359 (± 94.9)	999 (± 0)	270 (± 95.9)
D 211 Predose N=0,0,1,0	999 (± 0)	74.8 (± 0)	999 (± 0)	999 (± 0)
D 253 Predose N=1,1,0,0	543 (± 0)	252 (± 0)	999 (± 0)	999 (± 0)

D 253 1-Hour Postdose N=0,1,0,0	999 (± 0)	228 (± 0)	999 (± 0)	999 (± 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Safety Run-in Cohort 1 and 2, Phase 2 Cohort 1 Arm A, C and Phase 2 Cohort 3: Percentage of Participants Who Developed Antidrug Antibodies (ADAs) to Magrolimab

End point title	Safety Run-in Cohort 1 and 2, Phase 2 Cohort 1 Arm A, C and Phase 2 Cohort 3: Percentage of Participants Who Developed Antidrug Antibodies (ADAs) to Magrolimab

End point description:

Participants in the Immunogenicity Analysis Set with available data were analyzed. The Immunogenicity Analysis Set included 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 end of treatment (up to approximately 73 weeks)

End point values	Safety Run-in Cohort 1: Magrolimab + Pembrolizumab + Platinum	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+ Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	41	0[9]	32
Units: percentage of participants				
number (not applicable)				
ADA Prevalence	16.7	3.8		0
ADA Incidence	0	0		3.1

Notes:

[9] - No participants were analyzed from this group.

End point values	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 3: Magrolimab + Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	40		
Units: percentage of participants				
number (not applicable)				
ADA Prevalence	0	5.0		
ADA Incidence	0	3.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohort 1, Arms B and C: Progression-free Survival (PFS)

End point title	Phase 2 Cohort 1, Arms B and C: Progression-free Survival (PFS)[10]

End point description:

PFS was defined as the time from the date of randomization (Phase 2 Cohorts 1) or date of dose initiation (Phase 2 Cohorts 2 and 3) until the earliest date of documented disease progression as determined by investigator assessment per RECIST, version 1.1, or death from any cause, whichever occurs first. Disease progression is defined in OM#2. KM estimates were used in outcome measure analysis. Participants in Phase 2 Cohort 1 Arms B and C in the ITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Up to 129 weeks

Notes:

[10] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort Arms B and C. Hence the data is not reported for Phase 2 Cohort 3 and Phase 2 cohort Arm A for this endpoint.

End point values	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	32		
Units: months				
median (confidence interval 95%)	5.6 (4.2 to 7.4)	5.5 (3.0 to 9.2)		

Statistical analyses

Statistical analysis title	Phase 2 Cohort 1 Arm B Vs Arm C
Comparison groups	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU v Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.094
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.603
upper limit	1.985

Secondary: Phase 2 Cohort 1, Arms A, B and C: Objective Response Rate (ORR)

End point title	Phase 2 Cohort 1, Arms A, B and C: Objective Response Rate (ORR)[11]

End point description:

ORR was defined as the percentage of participants who achieved a CR or PR as determined by investigator assessment. CR and PR are defined in OM#3. Participants in Phase 2 Cohort 1, Arms A, B and C in the ITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Up to 129 weeks

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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 cohort Arms A, B and C. Hence the data for Arm Phase 2 Cohort 3 is not reported for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	54	32	
Units: percentage of participants				
number (confidence interval 95%)	38.5 (25.3 to 53.0)	38.9 (25.9 to 53.1)	37.5 (21.1 to 56.3)	

Statistical analyses

Statistical analysis title	Phase 2 Cohort 1 Arm B Vs Phase 2 Cohort 1 Arm C
Comparison groups	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU v Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.943
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.383
upper limit	2.321

Statistical analysis title	Ph 2 Cohort 1 Arm A Vs Ph 2 Cohort 1 Arm B
Comparison groups	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU v Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.982
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.449
upper limit	2.147

Secondary: All Phase 2 Cohorts: Duration of Response (DOR)

End point title	All Phase 2 Cohorts: Duration of Response (DOR)[12]

End point description:

DOR was defined as the time from first documentation of CR or PR to the earliest date of documented disease progression or death from any cause, whichever occurs first. Disease progression is defined in OM#2 and CR and PR are defined in OM#3.Participants in Phase 2 Cohort 1, Arms A, B and C in the ITT and participants in Phase 2 Cohort 3 in the mITT analysis set who achieved overall response were analyzed. 9999: Upper limit of Confidence interval (CI) was not estimable due to low number of participants with events.

End point type	Secondary

End point timeframe:

Up to 129 weeks

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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	12	5
Units: months				
median (confidence interval 95%)	5.4 (3.5 to 9.3)	6.2 (3.6 to 9999)	6.3 (2.8 to 9999)	5.0 (3.3 to 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohort 3: Progression-free Survival (PFS)

End point title	Phase 2 Cohort 3: Progression-free Survival (PFS)[13]

End point description:

PFS was defined as the time from the date of dose initiation (Phase 2 Cohort 3) until the earliest date of documented disease progression as determined by investigator assessment per RECIST, version 1.1, or

death from any cause, whichever occurs first. Disease progression is defined in OM#2. KM estimates were used in outcome measure analysis. Participants in Phase 2 Cohort 3 in the mITT Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Up to 129 weeks

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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3. Hence the data for Phase 2 cohort Arms A, B and C is not reported for this endpoint.

End point values	Phase 2 Cohort 3: Magrolimab + Docetaxel			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: months				
median (confidence interval 95%)	3.6 (2.4 to 4.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: All Phase 2 Cohorts: Overall Survival (OS)

End point title	All Phase 2 Cohorts: Overall Survival (OS)[14]

End point description:

OS was defined as the time from the date of randomization (Phase 2 Cohorts 1) or time from the date of dose initiation (Phase 2) to death from any cause. KM estimates were used in outcome measure analysis. Participants in Phase 2 Cohort 1, Arms A, B and C in the ITT and participants in Phase 2 Cohort 3 in the mITT analysis set were analyzed.

End point type	Secondary

End point timeframe:

Up to 129 weeks

Notes:

[14] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+ Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	54	32	41
Units: months				
median (confidence interval 95%)	10.8 (6.9 to 18.2)	13.3 (9.1 to 9999)	9999 (7.9 to 9999)	9.1 (6.6 to 12.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohorts: Change from Baseline (CFB) in the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core Questionnaire (EORTC QLQ-C30) Score

End point title	Phase 2 Cohorts: Change from Baseline (CFB) in the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core Questionnaire (EORTC QLQ-C30) Score[15]

End point description:

EORTC QLQ-C30 is a quality of life (QOL) questionnaire for cancer participants, that has 30 items. 5 functional scales (physical, role, emotional, cognitive, and social functioning), 1 global health status scale, 3 symptom scales (fatigue, nausea and vomiting, and pain), and 6 single items (dyspnea, insomnia, loss of appetite, constipation, diarrhea, and financial difficulties). Scoring of the QLQ-C30 was performed according to QLQ-C30 Scoring manual. All of the scales and single-item measures range in score from 0 to 100. Higher score for the functioning scales and global health status denote a better level of functioning (i.e. a better state of the participant), while higher scores on the symptom and single-item scales indicated a higher level of symptoms (i.e. a worse state of the participant). Phase 2 Cohort 1: Participants in the Intent to Treat Analysis Set with available data were analyzed. Phase 2 Cohort 3: Participants in mITT Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 3, Week 6, Week 9, Week 12, Week 15, Week 18, Week 21, Week 24, Week 27 and Week 90

Notes:

[15] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	50	28	37
Units: score on scale				
arithmetic mean (standard deviation)				
GlobalHealthStatus(GHS)/QoL,Baseline N=51,50,28,37	54.7 (± 24.9)	57.3 (± 23.2)	55.1 (± 20.8)	55.4 (± 25.6)
CFB in GHS/QoL, Week 3 N=42,43,23,29	5.0 (± 20.2)	1.9 (± 23.3)	-3.6 (± 16.1)	1.7 (± 18.1)
CFB in GHS/QoL, Week 6 N=32,36,16,26	6.0 (± 26.5)	10.2 (± 26.7)	-1.0 (± 16.9)	-1.3 (± 23.7)
CFB in GHS/QoL, Week 9 N=27,30,18,21	2.8 (± 22.2)	1.1 (± 27.6)	-4.2 (± 18.6)	2.0 (± 19.0)
CFB in GHS/QoL, Week 12 N=31,34,17,18	-4.8 (± 29.2)	6.4 (± 25.8)	2.9 (± 14.1)	-4.2 (± 20.5)

CFB in GHS/QoL, Week 15 N=30,29,13,18	-0.3 (± 27.0)	5.2 (± 25.8)	2.6 (± 22.7)	0.0 (± 24.8)
CFB in GHS/QoL, Week 18 N=28,25,11,15	5.4 (± 27.0)	10.0 (± 26.4)	-4.5 (± 23.1)	-2.8 (± 23.7)
CFB in GHS/QoL, Week 21 N=23,24,10,13	4.3 (± 28.1)	4.9 (± 22.4)	-10.8 (± 23.6)	-8.3 (± 20.7)
CFB in GHS/QoL, Week 24 N=20,18,12,9	9.2 (± 26.3)	1.9 (± 20.9)	-5.6 (± 23.9)	-10.2 (± 15.5)
CFB in GHS/QoL, Week 27 N=15,15,6,5	2.2 (± 27.7)	0.0 (± 18.6)	6.9 (± 26.0)	1.7 (± 24.6)
CFB in GHS/QoL, Week 90 N=1,0,0,0	33.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Physical Functioning(PF), Baseline N=52,50,27,37	75.0 (± 25.3)	75.4 (± 23.2)	74.9 (± 23.2)	73.7 (± 23.8)
CFB in PF, Week 3 N=43,43,22,29	-4.8 (± 15.6)	-3.6 (± 21.2)	-9.2 (± 15.7)	-2.9 (± 17.0)
CFB in PF, Week 6 N=33,36,15,27	-3.4 (± 14.4)	2.2 (± 20.2)	-6.2 (± 15.6)	-11.3 (± 21.7)
CFB in PF, Week 9 N=28,30,18,21	-1.4 (± 21.3)	-1.0 (± 18.8)	-4.3 (± 15.9)	-2.9 (± 13.9)
CFB in PF, Week 12 N=32,34,16,18	-4.5 (± 22.7)	3.8 (± 23.7)	-5.3 (± 15.7)	-10.0 (± 17.5)
CFB in PF, Week 15 N=31,29,12,18	-6.5 (± 21.0)	3.3 (± 26.2)	-13.3 (± 24.1)	-11.9 (± 19.7)
CFB in PF, Week 18 N=29,26,10,15	0.0 (± 15.5)	2.7 (± 27.7)	-4.7 (± 13.4)	-16.0 (± 20.7)
CFB in PF, Week 21 N=24,24,11,13	-5.0 (± 20.9)	-6.5 (± 21.4)	-12.1 (± 19.3)	-21.0 (± 24.2)
CFB in PF, Week 24 N=21,17,12,9	-5.1 (± 15.9)	-7.4 (± 23.6)	-8.3 (± 14.0)	-21.5 (± 10.9)
CFB in PF, Week 27 N=16,15,5,5	-7.9 (± 17.6)	0.0 (± 20.3)	-12.0 (± 14.5)	-22.7 (± 18.0)
CFB in PF, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Role Functioning (RF), Baseline N=52,49,27,37	72.8 (± 32.5)	74.5 (± 27.7)	69.8 (± 32.0)	60.8 (± 35.4)
CFB in RF, Week 3 N=43,41,22,29	-1.9 (± 21.6)	-2.4 (± 33.9)	-12.1 (± 37.2)	-5.7 (± 28.3)
CFB in RF, Week 6 N=33,35,15,26	-5.1 (± 23.4)	2.4 (± 32.6)	-10.0 (± 19.7)	-3.2 (± 26.7)
CFB in RF, Week 9 N=28,30,18,21	-3.6 (± 29.2)	-5.6 (± 35.1)	-9.3 (± 30.4)	7.9 (± 27.2)
CFB in RF, Week 12 N=32,34,16,18	-6.2 (± 35.9)	2.0 (± 38.0)	-7.3 (± 33.3)	-8.3 (± 37.6)
CFB in RF, Week 15 N=32,29,12,18	-10.4 (± 36.4)	7.5 (± 35.8)	-6.9 (± 28.8)	-4.6 (± 32.2)
CFB in RF, Week 18 N=29,26,10,15	-4.0 (± 30.7)	-1.3 (± 37.1)	-5.0 (± 19.3)	-7.8 (± 37.2)
CFB in RF, Week 21 N=24,23,11,13	-6.9 (± 38.0)	-11.6 (± 29.1)	-13.6 (± 35.6)	-14.1 (± 39.0)
CFB in RF, Week 24 N=21,18,12,9	-4.8 (± 32.6)	-2.8 (± 30.9)	0.0 (± 24.6)	-20.4 (± 21.7)
CFB in RF, Week 27 N=16,15,5,5	-16.7 (± 21.1)	-11.1 (± 37.1)	-10.0 (± 22.4)	-23.3 (± 19.0)
CFB in RF, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Emotional Functioning (EF), Baseline N=51,50,28,37	69.5 (± 25.3)	69.7 (± 27.6)	70.3 (± 28.3)	81.5 (± 16.4)
CFB in EF, Week 3 N=42,43,23,29	7.7 (± 25.1)	7.5 (± 25.2)	5.7 (± 20.9)	1.2 (± 17.5)
CFB in EF, Week 6 N=32,36,16,26	12.6 (± 23.5)	12.3 (± 25.9)	4.0 (± 24.6)	-5.7 (± 21.8)
CFB in EF, Week 9 N=27,30,18,21	7.7 (± 19.8)	6.1 (± 16.5)	11.4 (± 22.6)	0.1 (± 14.8)
CFB in EF, Week 12 N=31,34,17,18	3.8 (± 24.6)	11.8 (± 20.7)	9.6 (± 21.0)	1.5 (± 11.6)
CFB in EF, Week 15 N=30,29,13,18	0.3 (± 28.0)	11.8 (± 27.1)	3.6 (± 19.8)	-5.4 (± 19.3)
CFB in EF, Week 18 N=28,25,11,15	3.7 (± 23.8)	12.0 (± 25.8)	6.6 (± 28.6)	-4.4 (± 16.5)
CFB in EF, Week 21 N=23,24,10,13	0.8 (± 22.6)	2.0 (± 22.5)	6.7 (± 12.3)	-5.6 (± 12.7)
CFB in EF, Week 24 N=20,18,13,9	3.1 (± 20.0)	4.6 (± 22.4)	2.4 (± 19.8)	-4.3 (± 9.0)
CFB in EF, Week 27 N=15,15,6,5	0.6 (± 16.5)	9.6 (± 10.9)	6.5 (± 27.6)	-11.1 (± 18.1)
CFB in EF, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Cognitive Functioning (CF)BaselineN=51,50,28,37	84.0 (± 22.1)	84.7 (± 22.3)	85.7 (± 16.8)	83.8 (± 21.3)
CFB in CF, Week3 N=42,43,23,29	1.6 (± 16.0)	-0.4 (± 20.7)	-7.2 (± 14.1)	-4.6 (± 16.6)
CFB in CF, Week6 N=32,36,16,26	2.1 (± 15.7)	0.9 (± 25.8)	-1.0 (± 7.4)	-2.6 (± 24.4)
CFB in CF, Week9 N=27,30,18,21	1.9 (± 14.1)	-0.6 (± 14.8)	-2.8 (± 13.1)	-4.8 (± 19.1)
CFB in CF, Week12 N=31,34,17,18	-6.5 (± 23.8)	1.5 (± 18.5)	-4.9 (± 12.9)	-3.7 (± 20.3)
CFB in CF, Week15 N=31,29,13,18	-3.8 (± 22.2)	0.6 (± 19.1)	-1.3 (± 12.7)	-1.9 (± 13.9)
CFB in CF, Week18 N=28,25,11,15	-4.8 (± 22.2)	-1.3 (± 20.9)	-6.1 (± 8.4)	-3.3 (± 16.9)

CFB in CF, Week21 N=23,24,10,13	-3.6 (± 20.1)	-0.7 (± 18.7)	-6.7 (± 8.6)	-10.3 (± 26.8)
CFB in CF, Week24 N=20,18,13,9	-3.3 (± 16.8)	-3.7 (± 18.6)	-3.8 (± 12.1)	-13.0 (± 16.2)
CFB in CF, Week27 N=15,15,6,5	0.0 (± 15.4)	-4.4 (± 11.7)	-5.6 (± 8.6)	-33.3 (± 31.2)
CFB in CF, Week90 N=1,0,0,0	16.7 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Social Functioning(SF), Baseline N=51,49,28,37	75.5 (± 26.5)	73.8 (± 31.2)	76.8 (± 24.1)	68.0 (± 36.9)
CFB in SF, Week 3 N=42,43,23,29	2.4 (± 24.6)	-3.5 (± 33.6)	-12.3 (± 23.7)	-3.4 (± 30.3)
CFB in SF, Week 6 N=32,36,16,26	3.6 (± 27.7)	6.9 (± 33.4)	-7.3 (± 18.2)	1.3 (± 35.6)
CFB in SF, Week 9 N=27,30,18,21	-3.7 (± 28.6)	-3.3 (± 23.3)	-7.4 (± 21.6)	9.5 (± 34.0)
CFB in SF, Week 12 N=31,33,17,18	-2.2 (± 30.0)	0.5 (± 31.0)	-4.9 (± 19.3)	-7.4 (± 27.5)
CFB in SF, Week 15 N=31,29,13,18	-8.1 (± 34.1)	4.0 (± 27.7)	5.1 (± 23.0)	-2.8 (± 41.3)
CFB in SF, Week 18 N=28,25,11,15	1.2 (± 22.6)	2.7 (± 19.6)	-1.5 (± 15.7)	7.8 (± 36.1)
CFB in SF, Week 21 N=23,24,10,13	-5.8 (± 30.0)	-0.7 (± 24.3)	-11.7 (± 28.4)	-5.1 (± 41.6)
CFB in SF, Week 24 N=20,18,13,9	-0.8 (± 28.9)	-4.6 (± 32.7)	-1.3 (± 22.0)	-22.2 (± 25.0)
CFB in SF, Week 27 N=15,15,6,5	-2.2 (± 30.8)	-5.6 (± 12.1)	-5.6 (± 13.6)	-33.3 (± 31.2)
CFB in SF, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Fatigue, Baseline N=52,50,28,37	37.4 (± 28.9)	38.6 (± 24.3)	40.1 (± 30.3)	42.9 (± 29.9)
CFB in Fatigue, Week 3 N=43,43,23,29	1.7 (± 19.7)	2.5 (± 20.8)	7.2 (± 26.7)	8.0 (± 25.7)
CFB in Fatigue, Week 6 N=33,36,16,27	-2.7 (± 21.9)	-5.4 (± 27.3)	4.2 (± 27.5)	13.2 (± 28.9)
CFB in Fatigue, Week 9 N=28,30,19,21	0.4 (± 22.5)	-0.2 (± 31.2)	3.8 (± 29.5)	-3.2 (± 26.8)
CFB in Fatigue, Week 12 N=32,34,17,18	2.8 (± 24.1)	-4.4 (± 26.9)	2.0 (± 26.1)	8.6 (± 27.4)
CFB in Fatigue, Week 15 N=31,29,13,18	8.6 (± 28.4)	-4.4 (± 27.5)	8.5 (± 36.6)	12.3 (± 24.7)
CFB in Fatigue, Week 18 N=29,26,11,15	4.2 (± 23.8)	-2.6 (± 25.5)	7.1 (± 36.6)	18.5 (± 31.6)
CFB in Fatigue, Week 21 N=24,24,12,13	3.7 (± 27.3)	2.5 (± 23.9)	11.6 (± 40.2)	15.4 (± 30.6)
CFB in Fatigue, Week 24 N=21,18,13,9	4.8 (± 22.4)	0.9 (± 24.9)	7.7 (± 29.9)	29.6 (± 15.7)
CFB in Fatigue, Week 27 N=16,15,5,5	2.1 (± 17.8)	4.8 (± 27.8)	2.2 (± 25.3)	35.6 (± 24.1)
CFB in Fatigue, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Nausea-Vomiting, Baseline N=51,50,28,37	5.6 (± 16.6)	5.7 (± 12.4)	4.8 (± 11.9)	7.7 (± 15.5)
CFB in Nausea-Vomiting, Week3 N=42,43,23,29	6.7 (± 20.2)	5.0 (± 16.5)	15.9 (± 34.3)	2.9 (± 12.7)
CFB in Nausea-Vomiting, Week6 N=33,36,16,27	1.0 (± 13.8)	2.3 (± 21.1)	2.1 (± 16.0)	0.6 (± 16.3)
CFB in Nausea-Vomiting, Week9 N=27,30,19,21	8.6 (± 25.1)	3.9 (± 20.4)	7.9 (± 25.1)	5.6 (± 21.3)
CFB in Nausea-Vomiting, Week12N=30,34,17,18	13.3 (± 27.5)	3.9 (± 18.8)	1.0 (± 23.9)	-1.9 (± 13.9)
CFB in Nausea-Vomiting, Week15N=31,29,13,18	5.9 (± 21.8)	5.7 (± 22.8)	5.1 (± 12.5)	3.7 (± 18.6)
CFB in Nausea-Vomiting, Week18N=28,26,11,15	3.6 (± 18.9)	4.5 (± 21.9)	3.0 (± 10.1)	5.6 (± 26.5)
CFB in Nausea-Vomiting, Week21N=24,24,12,13	7.6 (± 18.4)	6.3 (± 21.3)	11.1 (± 29.6)	7.7 (± 20.0)
CFB in Nausea-Vomiting, Week24N=21,18,13,9	4.8 (± 12.0)	0.0 (± 9.9)	5.1 (± 12.5)	-1.9 (± 13.0)
CFB in Nausea-Vomiting, Week27N=6,15,5,5	2.1 (± 12.0)	4.4 (± 13.3)	13.3 (± 18.3)	-3.3 (± 18.3)
CFB in Nausea-Vomiting, Week90N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Pain,Baseline N=52,50,28,37	37.2 (± 32.1)	40.3 (± 30.9)	39.9 (± 31.5)	36.0 (± 33.2)
CFB in Pain, Week3 N=43,43,23,29	-5.8 (± 27.4)	-3.9 (± 31.0)	-2.9 (± 25.5)	-5.7 (± 27.9)
CFB in Pain, Week6 N=33,36,16,27	-12.1 (± 22.5)	-19.9 (± 36.0)	-10.4 (± 22.7)	-3.7 (± 34.1)
CFB in Pain, Week9 N=28,30,19,21	-7.7 (± 23.8)	-13.9 (± 29.1)	-8.8 (± 28.5)	-13.5 (± 28.2)
CFB in Pain, Week 12 N=32,34,17,18	-4.7 (± 28.5)	-23.0 (± 34.6)	-13.7 (± 24.5)	-3.7 (± 31.6)
CFB in Pain, Week 15 N=32,29,13,18	-2.6 (± 31.4)	-19.0 (± 36.4)	0.0 (± 30.4)	-4.6 (± 34.2)
CFB in Pain, Week 18 N=29,26,11,15	-8.0 (± 22.5)	-18.6 (± 35.4)	6.1 (± 15.4)	-2.2 (± 30.8)

CFB in Pain, Week 21 N=24,24,12,13	-1.4 (± 28.6)	-10.4 (± 31.8)	-1.4 (± 35.9)	-6.4 (± 35.7)
CFB in Pain, Week24 N=21,18,13,9	-0.8 (± 22.0)	-12.0 (± 29.6)	0.0 (± 31.2)	9.3 (± 16.9)
CFB in Pain, Week 27 N=16,15,6,5	9.4 (± 28.5)	-8.9 (± 39.3)	8.3 (± 17.5)	16.7 (± 39.1)
CFB in Pain, Week 90 N=1,0,0,0	-16.7 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Dyspnoea,Baseline N=51,50,28,37	17.0 (± 25.3)	15.3 (± 24.5)	22.6 (± 31.5)	24.3 (± 32.1)
CFB in Dyspnoea,Week 3 N=42,43,23,29	0.8 (± 20.1)	2.3 (± 28.5)	1.4 (± 18.7)	9.2 (± 23.4)
CFB in Dyspnoea,Week 6 N=32,35,16,27	2.1 (± 20.6)	-1.9 (± 27.9)	6.3 (± 18.1)	13.6 (± 34.9)
CFB in Dyspnoea,Week 9 N=28,30,19,21	0.0 (± 22.2)	10.0 (± 34.1)	-5.3 (± 20.1)	11.1 (± 21.9)
CFB in Dyspnoea,Week12 N=32,34,17,18	3.1 (± 23.0)	5.9 (± 32.3)	3.9 (± 20.0)	0.0 (± 19.8)
CFB in Dyspnoea,Week15 N=31,29,13,18	10.8 (± 29.0)	3.4 (± 32.5)	5.1 (± 26.7)	13.0 (± 25.9)
CFB in Dyspnoea,Week18 N=29,26,11,15	4.6 (± 21.3)	7.7 (± 30.3)	9.1 (± 15.6)	24.4 (± 29.5)
CFB in Dyspnoea,Week21 N=24,24,12,13	5.6 (± 21.2)	16.7 (± 32.6)	11.1 (± 35.8)	20.5 (± 29.0)
CFB in Dyspnoea,Week 24 N=21,18,13,9	1.6 (± 22.3)	5.6 (± 32.8)	7.7 (± 24.2)	11.1 (± 28.9)
CFB in Dyspnoea,Week 27 N=16,15,5,5	2.1 (± 14.8)	4.4 (± 24.8)	6.7 (± 14.9)	13.3 (± 38.0)
CFB in Dyspnoea,Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Symptom Scales Insomnia: Baseline N=52,50,28,37	39.1 (± 27.0)	34.7 (± 30.1)	34.5 (± 35.7)	34.2 (± 33.8)
CFB in Insomnia,Week 3 N=43,43,23,29	-17.8 (± 26.6)	0.0 (± 32.5)	2.9 (± 26.4)	-2.3 (± 23.5)
CFB in Insomnia,Week 6 N=33,36,16,26	-15.2 (± 31.3)	-11.1 (± 39.0)	14.6 (± 32.1)	1.3 (± 31.9)
CFB in Insomnia,Week 9 N=28,30,19,21	-11.9 (± 35.4)	-20.0 (± 38.8)	-8.8 (± 21.8)	-9.5 (± 23.9)
CFB in Insomnia,Week 12 N=32,34,17,18	-15.6 (± 40.6)	-16.7 (± 34.1)	-7.8 (± 30.1)	-3.7 (± 25.3)
CFB in Insomnia,Week 15 N=31,29,13,18	-11.8 (± 36.1)	-13.8 (± 33.9)	-5.1 (± 23.0)	-7.4 (± 31.4)
CFB in Insomnia,Week 18 N=29,26,11,15	-11.5 (± 27.1)	-7.7 (± 40.3)	-3.0 (± 37.9)	6.7 (± 28.7)
CFB in Insomnia,Week 21 N=24,24,12,13	-2.8 (± 27.7)	-6.9 (± 42.8)	-2.8 (± 17.2)	-2.6 (± 41.9)
CFB in Insomnia,Week 24 N=21,18,13,9	-4.8 (± 30.3)	-11.1 (± 37.9)	-10.3 (± 34.4)	11.1 (± 33.3)
CFB in Insomnia,Week N=16,15,5,5	0.0 (± 36.5)	2.2 (± 44.5)	6.7 (± 27.9)	13.3 (± 50.6)
CFB in Insomnia,Week90 N=1,0,0,0	-33.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Appetite Loss,Baseline N=52,50,27,36	29.5 (± 37.7)	20.7 (± 24.2)	29.6 (± 31.1)	32.4 (± 36.1)
CFB in Apettite Loss,Week 3N=43,43,22,28	6.2 (± 29.3)	7.0 (± 27.8)	13.6 (± 33.6)	2.4 (± 33.9)
CFB in Apettite Loss,Week 6N=33,35,16,27	-5.1 (± 29.0)	0.0 (± 37.0)	-4.2 (± 16.7)	-3.7 (± 36.2)
CFB in Apettite Loss,Week 9N=28,30,18,21	3.6 (± 36.7)	2.2 (± 38.1)	1.9 (± 37.0)	-4.8 (± 33.8)
CFB in Apettite Loss,Week 12 N=31,33,16,18	5.4 (± 44.8)	-1.0 (± 32.8)	-2.1 (± 22.7)	7.4 (± 50.6)
CFB in Apettite Loss,Week 15 N=31,29,12,17	6.5 (± 37.9)	2.3 (± 36.7)	8.3 (± 28.9)	5.9 (± 29.4)
CFB in Apettite Loss,Week 18N=28,26,11,15	1.2 (± 32.1)	2.6 (± 37.6)	3.0 (± 37.9)	0.0 (± 39.8)
CFB in Apettite Loss,Week 21N=24,24,12,13	6.9 (± 42.8)	9.7 (± 39.9)	13.9 (± 38.8)	2.6 (± 39.6)
CFB in Apettite Loss,Week 24 N=21,18,13,9	3.2 (± 27.7)	1.9 (± 33.3)	5.1 (± 32.9)	7.4 (± 36.4)
CFB in Apettite Loss,Week 27N=16,15,5,5	14.6 (± 34.4)	4.4 (± 30.5)	6.7 (± 14.9)	13.3 (± 38.0)
CFB in Apettite Loss,Week 90N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

Constipation,Baseline N=51,50,28,37	23.5 (± 30.0)	27.3 (± 30.6)	25.0 (± 29.6)	21.6 (± 28.6)
CFB inConstipation,Week 3 N=42,43,23,29	0.8 (± 23.8)	-3.1 (± 33.2)	5.8 (± 32.8)	2.3 (± 21.7)
CFB inConstipation,Week 6 N=32,36,16,27	-6.3 (± 33.3)	-1.9 (± 33.8)	0.0 (± 32.2)	0.0 (± 20.7)
CFB inConstipation,Week 9 N=27,30,19,21	3.7 (± 32.5)	-2.2 (± 38.1)	-7.0 (± 23.8)	1.6 (± 26.8)
CFB inConstipation,Week 12 N=30,34,17,18	-2.2 (± 36.0)	-1.0 (± 32.3)	-2.0 (± 27.6)	3.7 (± 27.7)
CFB inConstipation,Week 15 N=31,29,13,18	-2.2 (± 31.0)	-2.3 (± 39.8)	0.0 (± 36.0)	11.1 (± 36.2)
CFB inConstipation,Week 18 N=28,26,11,15	-7.1 (± 31.9)	-3.8 (± 38.1)	0.0 (± 14.9)	6.7 (± 31.4)
CFB inConstipation,Week 21 N=23,24,12,13	-7.2 (± 31.7)	1.4 (± 39.9)	-8.3 (± 25.1)	5.1 (± 23.0)
CFB inConstipation,Week 24 N=20,18,13,9	-10.0 (± 40.6)	1.9 (± 47.8)	-5.1 (± 23.0)	0.0 (± 23.6)
CFB inConstipation,Week 27 N=15,15,5,5	-6.7 (± 42.2)	4.4 (± 41.5)	-6.7 (± 14.9)	0.0 (± 23.6)
CFB inConstipation,Week 90 N=1,0,0,0	-33.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Diarrhoea,BaselineN=51,50,28,37	5.2 (± 12.2)	8.7 (± 20.0)	2.4 (± 8.7)	7.2 (± 17.8)
CFB in Diarrhoea,Week 3 N=42,43,23,29	4.0 (± 16.8)	0.8 (± 21.2)	10.1 (± 23.4)	5.7 (± 33.4)
CFB in Diarrhoea,Week 6 N=32,36,16,26	0.0 (± 14.7)	-1.9 (± 17.7)	4.2 (± 11.4)	3.8 (± 35.7)
CFB in Diarrhoea,Week 9 N=27,30,18,21	6.2 (± 26.2)	-1.1 (± 22.3)	9.3 (± 25.1)	-1.6 (± 19.7)
CFB in Diarrhoea,Week N=31,33,17,18	4.3 (± 20.6)	0.0 (± 18.6)	5.9 (± 13.1)	7.4 (± 21.6)
CFB in Diarrhoea,Week15 N=30,29,13,18	8.9 (± 26.2)	-3.4 (± 24.1)	10.3 (± 21.0)	11.1 (± 32.3)
CFB in Diarrhoea,Week18 N=28,25,11,15	0.0 (± 15.7)	-4.0 (± 20.0)	6.1 (± 13.5)	11.1 (± 24.1)
CFB in Diarrhoea,Week21 N=23,24,10,13	0.0 (± 10.1)	4.2 (± 22.7)	6.7 (± 14.1)	17.9 (± 22.0)
CFB in Diarrhoea,Week 24 N=20,18,13,9	1.7 (± 13.1)	-7.4 (± 18.3)	10.3 (± 21.0)	14.8 (± 37.7)
CFB in Diarrhoea,Week at Wk 27 N=15,15,6,5	6.7 (± 13.8)	-4.4 (± 27.8)	11.1 (± 17.2)	13.3 (± 38.0)
CFB in Diarrhoea,Week at Wk 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Financial Difficulties:BaselineN=51,48,28,34	16.3 (± 26.1)	22.2 (± 32.5)	17.9 (± 29.4)	14.7 (± 29.8)
CFBinFinancialDifficulties,Week 3 N=42,42,23,26	-2.4 (± 26.9)	1.6 (± 32.9)	5.8 (± 21.7)	-2.6 (± 20.9)
CFBinFinancialDifficulties,Week 6 N=32,35,16,24	-2.1 (± 18.8)	2.9 (± 31.7)	6.3 (± 25.0)	1.4 (± 20.8)
CFBinFinancialDifficulties,Week 9 N=27,29,18,19	-1.2 (± 29.9)	3.4 (± 25.7)	-1.9 (± 13.9)	-7.0 (± 30.6)
CFBinFinancialDifficulties,Week 12 N=31,33,17,16	3.2 (± 32.6)	8.1 (± 28.9)	0.0 (± 16.7)	6.3 (± 32.7)
CFBinFinancialDifficulties,Week 15 N=30,28,13,17	8.9 (± 30.2)	1.2 (± 32.1)	-5.1 (± 18.5)	0.0 (± 23.6)
CFBinFinancialDifficulties,Week 18 N=28,24,11,13	0.0 (± 24.0)	2.8 (± 16.8)	-3.0 (± 10.1)	-5.1 (± 35.6)
CFBinFinancialDifficulties,Week 21 N=23,23,10,11	0.0 (± 22.5)	0.0 (± 28.4)	-3.3 (± 10.5)	-3.0 (± 31.5)
CFBinFinancialDifficulties,Week 24 N=20,17,13,7	5.0 (± 12.2)	5.9 (± 21.2)	0.0 (± 13.6)	19.0 (± 32.5)
CFBinFinancialDifficulties,Week 27 N=15,14,6,4	8.9 (± 15.3)	4.8 (± 17.8)	0.0 (± 21.1)	9999 (± 9999)

CFBinFinancialDifficulties,Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohorts: Change from Baseline in the European Organisation for Research and Treatment of Cancer Quality of Life - Head and Neck Module (EORTC QLQ-H and N35)

End point title	Phase 2 Cohorts: Change from Baseline in the European Organisation for Research and Treatment of Cancer Quality of Life - Head and Neck Module (EORTC QLQ-H and N35)[16]

End point description:

The H and N cancer is a 35-item questionnaire for participants with H and N cancer. It includes 7 multi-item scales that assess pain (4 items), swallowing (4 items), senses (2 items), speech (3 items), social eating (4 items), social contact (5 items), and sexuality (2 items). There are also 11 single items: teeth, opening mouth, dry mouth, sticky saliva, coughing, felt ill, pain killers, nutritional supplements, feeding tube, weight loss, weight gain. Using a 4-point Likert scale, participants indicate the degree to which they have experienced symptoms. For all items and scales, high scores indicate more problems. Phase 2 Cohort 1: Participants in the ITT Analysis Set with available data were analyzed. Phase 2 Cohort 3: Participants in the mITT Analysis Set with available data were analyzed. '999'means Standard Deviation cannot be calculated for 1 participant. '9999' means data was not available as no participants were analyzed at specified timepoint..

End point type	Secondary

End point timeframe:

Baseline, Week 3, Week 6, Week 9, Week 12, Week 15, Week 18, Week 21, Week 24, Week 27 and Week 90

Notes:

[16] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+ Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	28	37
Units: score on scale				
arithmetic mean (standard deviation)				
Pain, Baseline N=52,49,28,37	27.1 (± 30.6)	26.7 (± 24.8)	28.7 (± 25.2)	25.0 (± 25.4)
CFB in Pain, Week3 N=42,42,23,29	-2.8 (± 27.3)	3.0 (± 22.8)	6.0 (± 15.3)	-5.7 (± 21.9)
CFB in Pain, Week6 N=32,36,16,27	-4.7 (± 22.7)	-2.9 (± 31.8)	0.0 (± 23.6)	-4.6 (± 23.7)
CFB in Pain, Week9 N=28,29,19,21	-2.1 (± 24.5)	-3.2 (± 22.4)	2.3 (± 33.1)	-6.0 (± 29.1)
CFB in Pain, Week 12 N=32,33,17,19	-5.2 (± 24.7)	-7.9 (± 29.1)	-4.6 (± 26.5)	3.9 (± 21.2)
CFB in Pain, Week 15 N=31,28,13,18	2.4 (± 25.6)	-5.7 (± 30.6)	-5.8 (± 24.9)	-7.4 (± 28.9)
CFB in Pain, Week 18 N=28,26,11,14	-2.1 (± 21.7)	-10.3 (± 29.1)	6.8 (± 16.2)	-1.2 (± 15.3)
CFB in Pain, Week 21 N=24,24,11,13	2.1 (± 27.6)	-1.7 (± 34.6)	-6.8 (± 19.3)	-4.5 (± 31.1)
CFB in Pain, Week24 N=21,17,13,9	-3.6 (± 21.8)	-11.8 (± 37.6)	-4.5 (± 15.1)	2.2 (± 24.6)

CFB in Pain, Week 27 N=16,15,6,5	-4.2 (± 24.7)	-10.6 (± 36.1)	-6.9 (± 24.4)	5.0 (± 22.5)
CFB in Pain, Week 90 N=1,0,0,0	-58.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Swallowing, Baseline N=51,49,28,36	30.1 (± 33.2)	33.6 (± 34.8)	31.0 (± 26.1)	36.3 (± 31.9)
CFBinSwallowing,Week 3 N=41,40,23,28	-4.3 (± 24.6)	2.3 (± 24.5)	4.1 (± 21.3)	-3.4 (± 20.9)
CFBinSwallowing,Week 6 N=30,35,16,26	-9.7 (± 22.5)	-8.3 (± 29.7)	-3.1 (± 22.1)	-7.7 (± 24.5)
CFBinSwallowing,Week 9 N=28,29,19,21	-5.9 (± 24.0)	-6.6 (± 24.9)	0.4 (± 25.5)	-9.0 (± 31.1)
CFBinSwallowing,Week 12 N=31,32,17,19	-6.9 (± 25.0)	-3.3 (± 21.5)	-5.4 (± 15.9)	-3.5 (± 20.8)
CFBinSwallowing,Week 15 N=31,28,13,18	-3.0 (± 29.2)	-0.3 (± 23.0)	-8.3 (± 19.2)	-8.3 (± 23.7)
CFBinSwallowing,Week 18 N=28,26,11,14	-5.1 (± 28.9)	0.0 (± 32.8)	-2.3 (± 10.6)	-3.6 (± 15.6)
CFBinSwallowing,Week 21 N=23,24,11,13	-2.2 (± 25.0)	5.7 (± 33.3)	-3.8 (± 13.6)	-15.0 (± 29.8)
CFBinSwallowing,Week 24 N=20,17,13,9	-3.3 (± 23.0)	-1.0 (± 8.1)	-2.6 (± 18.4)	0.0 (± 20.4)
CFBinSwallowing,Week at Wk 27 N=16,15,6,5	5.7 (± 22.7)	-5.6 (± 21.1)	-13.9 (± 11.4)	-1.7 (± 12.4)
CFBinSwallowing,Week at Wk 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Senses Problems, Baseline N=52,49,28,36	16.0 (± 25.8)	23.5 (± 30.6)	18.5 (± 26.2)	29.2 (± 29.4)
CFB in Senses Problems, Week 3 N=42,42,23,29	-0.4 (± 21.0)	-1.2 (± 21.3)	0.7 (± 19.8)	-4.0 (± 25.8)
CFB in Senses Problems, Week 6 N=32,36,16,27	-4.2 (± 21.2)	2.8 (± 30.5)	9.4 (± 14.9)	1.9 (± 22.3)
CFB in Senses Problems, Week 9 N=28,29,19,21	-3.6 (± 21.4)	0.6 (± 22.9)	3.5 (± 28.1)	0.8 (± 18.6)
CFB in Senses Problems, Week 12 N=32,33,17,19	2.1 (± 14.5)	-2.5 (± 24.3)	-4.9 (± 28.1)	3.5 (± 27.5)
CFB in Senses Problems, Week 15 N=32,28,13,18	1.0 (± 25.4)	0.6 (± 25.0)	-2.6 (± 16.5)	3.7 (± 16.7)
CFB in Senses Problems, Week 18 N=28,26,11,14	4.2 (± 27.8)	-7.1 (± 17.1)	-1.5 (± 11.7)	6.0 (± 26.6)
CFB in Senses Problems, Week 21 N=24,24,11,13	3.5 (± 26.5)	4.9 (± 31.3)	1.5 (± 13.9)	-1.3 (± 19.8)
CFB in Senses Problems, Week 24 N=21,17,13,9	2.4 (± 29.0)	3.9 (± 25.4)	-1.3 (± 12.7)	-3.7 (± 27.4)
CFB in Senses Problems, Week 27 N=16,15,6,5	8.3 (± 40.4)	-2.2 (± 17.7)	-5.6 (± 13.6)	13.3 (± 13.9)
CFB in Senses Problems, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Speech Problems, Baseline N=51,48,28,36	36.2 (± 32.7)	32.1 (± 31.0)	32.1 (± 27.8)	29.3 (± 30.8)
CFB in Speech Problems, Week 3 N=40,40,23,28	-6.7 (± 22.2)	-1.1 (± 19.9)	0.5 (± 19.1)	4.2 (± 26.0)
CFB in Speech Problems, Week 6 N=29,35,16,25	-11.9 (± 21.4)	-6.3 (± 29.6)	-2.1 (± 20.8)	-1.3 (± 27.1)
CFB in Speech Problems, Week 9 N=26,29,19,20	-9.0 (± 27.9)	1.0 (± 20.6)	4.7 (± 20.7)	-1.7 (± 22.3)
CFB in Speech Problems, Week 12 N=28,33,17,18	-10.7 (± 23.5)	-7.4 (± 22.0)	-7.2 (± 21.1)	4.3 (± 19.9)
CFB in Speech Problems, Week 15 N=29,28,13,17	-3.8 (± 27.7)	-0.6 (± 22.0)	-12.8 (± 14.9)	4.6 (± 24.9)
CFB in Speech Problems, Week 18 N=27,24,11,14	-7.0 (± 24.1)	-8.3 (± 19.2)	-4.0 (± 13.4)	5.6 (± 19.4)
CFB in Speech Problems, Week 21 N=22,24,12,12	-3.5 (± 20.7)	3.0 (± 18.9)	-5.1 (± 18.0)	6.5 (± 30.9)

CFB in Speech Problems, Week 24 N=19,17,13,8	-10.5 (± 20.1)	0.7 (± 17.3)	-7.7 (± 16.0)	4.2 (± 22.2)
CFB in Speech Problems, Week 27 N=14,15,6,4	-6.3 (± 24.2)	-1.9 (± 17.3)	-9.3 (± 14.8)	22.2 (± 24.0)
CFB in Speech Problems, Week 90 N=1,0,0,0	-22.2 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
TroublewithSocialEating,BaselineN=50,48,28,36	33.8 (± 32.8)	34.2 (± 28.5)	28.3 (± 26.7)	24.8 (± 26.7)
CFB in SocialEating, Week3 N=40,38,22,28	0.7 (± 31.5)	0.2 (± 24.8)	7.4 (± 20.0)	3.9 (± 14.1)
CFB in SocialEating, Week6 N=29,34,16,26	-9.2 (± 18.0)	-6.9 (± 33.0)	3.0 (± 16.8)	2.4 (± 25.8)
CFB in SocialEating, Week9 N=25,27,19,21	-8.2 (± 23.9)	1.2 (± 24.4)	4.4 (± 28.8)	-3.6 (± 17.4)
CFB in SocialEating, Week12 N=29,32,17,19	-4.9 (± 27.5)	-9.4 (± 24.2)	2.5 (± 24.2)	6.1 (± 15.4)
CFB in SocialEating, Week15 N=30,28,13,18	-3.0 (± 23.3)	-1.4 (± 32.9)	-3.4 (± 22.5)	8.3 (± 20.0)
CFB in SocialEating, Week18 N=28,25,11,15	-9.2 (± 21.4)	0.0 (± 30.8)	3.5 (± 25.2)	6.1 (± 24.7)
CFB in SocialEating, Week21 N=23,23,12,13	-8.0 (± 27.7)	7.6 (± 28.7)	4.6 (± 23.8)	-3.8 (± 20.0)
CFB in SocialEating, Week24 N=20,16,13,9	-17.1 (± 24.0)	-1.0 (± 20.4)	1.7 (± 26.7)	9.9 (± 23.3)
CFB in SocialEating, Week27 N=14,14,6,5	-3.6 (± 24.8)	-1.2 (± 13.8)	0.5 (± 16.3)	20.0 (± 19.2)
CFB in SocialEating, Week90 N=1,0,0,0	-8.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
SocialContact,Baseline N=51,49,28,37	21.4 (± 24.6)	21.7 (± 28.0)	15.5 (± 22.2)	13.4 (± 19.6)
CFB in SocialContact, Week3 N=40,41,23,29	-3.5 (± 24.4)	5.4 (± 21.6)	5.2 (± 19.9)	6.9 (± 15.0)
CFB in SocialContact, Week6 N=31,35,16,26	-9.2 (± 13.9)	-2.7 (± 28.1)	2.9 (± 22.4)	10.0 (± 21.5)
CFB in SocialContact, Week9 N=27,29,19,21	-8.0 (± 17.6)	1.4 (± 18.5)	6.8 (± 24.8)	-0.6 (± 11.7)
CFB in SocialContact, Week12 N=29,33,17,19	-1.7 (± 18.0)	-5.4 (± 22.4)	-2.8 (± 19.0)	2.5 (± 20.4)
CFB in SocialContact, Week15 N=30,28,13,18	1.4 (± 28.6)	-2.1 (± 24.0)	-5.1 (± 15.7)	7.0 (± 19.1)
CFB in SocialContact, Week18 N=28,25,11,15	-1.8 (± 24.6)	-1.6 (± 22.2)	-2.4 (± 18.7)	0.4 (± 15.0)
CFB in SocialContact, Week21 N=23,24,12,13	-1.9 (± 26.9)	9.3 (± 18.0)	-2.2 (± 20.4)	9.2 (± 23.0)
CFB in SocialContact, Week24 N=20,17,13,9	-5.1 (± 22.3)	2.7 (± 11.6)	0.5 (± 23.2)	5.2 (± 9.9)
CFB in SocialContact, Week27 N=14,15,6,5	-4.3 (± 25.8)	-0.9 (± 19.5)	-4.4 (± 15.6)	17.3 (± 28.5)
CFB in SocialContact, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Less Sexuality, Baseline N=51,45,27,34	34.0 (± 34.8)	38.9 (± 41.0)	30.9 (± 29.1)	40.2 (± 37.9)
CFB in Less Sexuality, Week 3 N=39,36,21,26	4.3 (± 23.5)	7.4 (± 37.9)	9.5 (± 38.6)	4.5 (± 23.8)
CFB in Less Sexuality, Week 6 N=28,29,14,23	4.2 (± 28.9)	16.1 (± 43.3)	3.6 (± 39.9)	-3.6 (± 32.6)
CFB in Less Sexuality, Week 9 N=26,26,16,19	7.1 (± 42.2)	5.1 (± 39.4)	18.7 (± 43.4)	1.8 (± 31.4)
CFB in Less Sexuality, Week 12 N=27,28,15,17	0.6 (± 32.2)	5.4 (± 36.3)	22.2 (± 40.7)	2.9 (± 30.2)
CFB in Less Sexuality, Week 15 N=28,24,12,16	9.5 (± 43.4)	9.0 (± 42.3)	2.8 (± 48.6)	2.1 (± 30.4)
CFB in Less Sexuality, Week 18 N=26,20,9,12	-3.2 (± 33.7)	2.5 (± 39.5)	5.6 (± 39.1)	-5.6 (± 32.0)

CFB in Less Sexuality, Week 21 N=23,20,10,11	-2.9 (± 42.8)	0.8 (± 39.2)	21.7 (± 36.9)	3.0 (± 38.6)
CFB in Less Sexuality, Week 24 N=19,13,10,7	-0.9 (± 23.9)	7.7 (± 47.4)	11.7 (± 27.3)	-9.5 (± 41.8)
CFB in Less Sexuality, Week 27 N=13,12,4,3	9.0 (± 23.2)	6.9 (± 47.9)	-25.0 (± 50.0)	-33.3 (± 57.7)
CFB in Less Sexuality, Week 90 N=1,0,0,0	-33.3 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Teeth, Baseline N=50,46,28,36	21.3 (± 33.5)	16.7 (± 28.8)	14.3 (± 32.0)	30.6 (± 37.7)
CFB in Teeth, Week3 N=41,38,23,29	-11.4 (± 36.2)	-0.9 (± 26.3)	7.2 (± 24.5)	-11.5 (± 27.1)
CFB in Teeth, Week6 N=29,32,16,27	-5.7 (± 25.3)	-8.3 (± 36.9)	2.1 (± 14.8)	-17.3 (± 33.8)
CFB in Teeth, Week9 N=28,27,19,21	6.0 (± 28.8)	-2.5 (± 22.5)	-1.8 (± 36.0)	-17.5 (± 34.3)
CFB in Teeth, Week9 12 N=30,29,17,19	6.7 (± 34.4)	1.1 (± 33.9)	5.9 (± 29.4)	-8.8 (± 38.2)
CFB in Teeth, Week9 15 N=30,25,13,18	0.0 (± 31.6)	5.3 (± 39.3)	-12.8 (± 29.0)	-9.3 (± 35.8)
CFB in Teeth, Week9 18 N=27,24,11,14	0.0 (± 29.2)	-1.4 (± 45.6)	0.0 (± 14.9)	-16.7 (± 36.4)
CFB in Teeth, Week9 21 N=24,20,11,13	4.2 (± 30.0)	10.0 (± 42.0)	6.1 (± 13.5)	-5.1 (± 26.7)
CFB in Teeth, Week24 N=20,14,13,9	3.3 (± 37.3)	4.8 (± 43.1)	7.7 (± 20.0)	-22.2 (± 44.1)
CFB in Teeth, Week27 N=14,11,6,5	2.4 (± 24.3)	-6.1 (± 13.5)	0.0 (± 21.1)	-20.0 (± 50.6)
CFB in Teeth, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Opening Mouth, Baseline N=50,48,28,37	32.7 (± 40.7)	39.6 (± 41.1)	22.6 (± 32.8)	37.8 (± 41.7)
CFB in Opening Mouth, Week3 N=41,41,23,29	-2.4 (± 34.5)	3.3 (± 30.6)	11.6 (± 21.6)	-4.6 (± 19.4)
CFB in Opening Mouth, Week6 N=31,34,16,27	-6.5 (± 33.8)	-11.8 (± 24.5)	10.4 (± 26.4)	-6.2 (± 29.3)
CFB in Opening Mouth, Week9 N=27,27,19,21	2.5 (± 34.5)	-6.2 (± 32.1)	8.8 (± 36.6)	-4.8 (± 24.2)
CFB in Opening Mouth, Week12 N=30,32,17,19	-3.3 (± 35.4)	-9.4 (± 39.0)	11.8 (± 23.4)	0.0 (± 24.8)
CFB in Opening Mouth, Week15 N=31,27,13,18	0.0 (± 38.5)	-8.6 (± 45.8)	7.7 (± 14.6)	1.9 (± 35.2)
CFB in Opening Mouth, Week18 N=28,25,11,14	3.6 (± 26.2)	-6.7 (± 36.0)	12.1 (± 16.8)	2.4 (± 27.6)
CFB in Opening Mouth, Week21 N=23,23,11,13	2.9 (± 26.4)	1.4 (± 38.2)	3.0 (± 10.1)	0.0 (± 27.2)
CFB in Opening Mouth, Week24 N=20,16,13,9	10.0 (± 28.8)	-2.1 (± 39.4)	10.3 (± 21.0)	-3.7 (± 20.0)
CFB in Opening Mouth, Week27 N=15,14,6,5	8.9 (± 23.5)	-16.7 (± 31.4)	5.6 (± 13.6)	20.0 (± 29.8)
CFB in Opening Mouth, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Dry Mouth, Baseline N=52,49,28,37	42.3 (± 35.6)	38.1 (± 36.0)	34.5 (± 33.3)	49.5 (± 37.4)
CFB in Dry Mouth, Week 3 N=42,42,23,29	-9.5 (± 36.3)	-0.8 (± 26.0)	0.0 (± 24.6)	-12.6 (± 32.6)
CFB in Dry Mouth, Week 6 N=32,36,16,27	-9.4 (± 30.8)	0.9 (± 34.3)	2.1 (± 33.3)	-13.6 (± 29.6)
CFB in Dry Mouth, Week 9 N=28,29,19,21	-7.1 (± 43.8)	-2.3 (± 28.1)	1.8 (± 32.3)	-9.5 (± 39.6)
CFB in Dry Mouth, Week 12 N=32,33,17,19	-3.1 (± 37.3)	5.1 (± 40.9)	-3.9 (± 33.1)	-7.0 (± 17.8)
CFB in Dry Mouth, Week 15 N=31,28,13,18	-5.4 (± 40.5)	-1.2 (± 41.1)	2.6 (± 37.2)	-1.9 (± 31.3)
CFB in Dry Mouth, Week 18 N=28,26,11,14	-8.3 (± 35.9)	-2.6 (± 38.8)	6.1 (± 46.7)	-11.9 (± 21.1)
CFB in Dry Mouth, Week 21 N=24,24,11,13	-4.2 (± 37.2)	1.4 (± 44.5)	-3.0 (± 48.2)	-15.4 (± 29.2)
CFB in Dry Mouth, Week 24 N=21,17,13,9	-4.8 (± 38.4)	-11.8 (± 37.2)	-10.3 (± 37.0)	-14.8 (± 29.4)
CFB in Dry Mouth, Week 27 N=16,15,6,5	0.0 (± 42.2)	-20.0 (± 32.9)	0.0 (± 51.6)	6.7 (± 36.5)

CFB in Dry Mouth, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Sticky Saliva,Baseline N=52,49,28,36	41.0 (± 35.9)	44.9 (± 36.4)	38.1 (± 36.0)	45.4 (± 41.5)
CFB in Sticky Saliva, Week3 N=42,42,23,28	-7.1 (± 35.7)	-5.6 (± 36.0)	1.4 (± 40.8)	-1.2 (± 27.9)
CFB in Sticky Saliva, Week6 N=32,36,16,27	-7.3 (± 23.5)	-8.3 (± 38.5)	0.0 (± 29.8)	-1.2 (± 25.3)
CFB in Sticky Saliva, Week9 N=27,29,19,21	-1.2 (± 38.7)	10.3 (± 29.7)	-10.5 (± 35.2)	3.2 (± 36.4)
CFB in Sticky Saliva, Week12 N=32,33,17,19	-1.0 (± 35.4)	-10.1 (± 30.6)	-15.7 (± 41.0)	7.0 (± 23.8)
CFB in Sticky Saliva, Week15 N=32,28,12,18	-1.0 (± 26.1)	-11.9 (± 39.8)	-11.1 (± 35.8)	0.0 (± 30.2)
CFB in Sticky Saliva, Week18 N=28,26,11,14	-3.6 (± 33.1)	-10.3 (± 33.7)	-12.1 (± 45.4)	2.4 (± 27.6)
CFB in Sticky Saliva, Week21 N=24,24,11,13	1.4 (± 31.8)	-12.5 (± 40.3)	-6.1 (± 41.7)	5.1 (± 42.7)
CFB in Sticky Saliva, Week24 N=21,17,13,9	-3.2 (± 29.6)	-13.7 (± 33.5)	-7.7 (± 45.4)	3.7 (± 20.0)
CFB in Sticky Saliva, Week27 N=16,15,6,5	0.0 (± 24.3)	-26.7 (± 22.5)	-5.6 (± 49.1)	20.0 (± 29.8)
CFB in Sticky Saliva, Week90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Coughing,Baseline N=52,49,28,37	31.4 (± 28.3)	32.7 (± 35.7)	41.7 (± 33.5)	36.9 (± 30.2)
CFB in Coughing, Week 3 N=42,41,23,29	0.0 (± 27.5)	0.0 (± 26.9)	2.9 (± 22.3)	0.0 (± 34.5)
CFB in Coughing, Week 6 N=32,36,16,27	0.0 (± 25.4)	-4.6 (± 40.0)	-6.3 (± 21.8)	1.2 (± 31.3)
CFB in Coughing, Week 9 N=28,29,19,21	3.6 (± 35.5)	0.0 (± 33.3)	-1.8 (± 28.3)	-1.6 (± 24.7)
CFB in Coughing, Week 12 N=32,33,17,19	-5.2 (± 26.9)	-1.0 (± 38.6)	-7.8 (± 36.4)	8.8 (± 31.1)
CFB in Coughing, Week 15 N=31,28,13,18	4.3 (± 30.7)	-3.6 (± 38.9)	-2.6 (± 34.6)	-9.3 (± 25.1)
CFB in Coughing, Week 18 N=28,26,11,14	-4.8 (± 31.1)	2.6 (± 37.6)	0.0 (± 21.1)	7.1 (± 26.7)
CFB in Coughing, Week 21 N=24,24,11,13	-1.4 (± 20.8)	4.2 (± 31.6)	-6.1 (± 25.0)	2.6 (± 34.6)
CFB in Coughing, Week 24 N=21,17,13,9	-1.6 (± 28.8)	0.0 (± 16.7)	-17.9 (± 29.2)	3.7 (± 26.1)
CFB in Coughing, Week 27 N=16,15,6,5	-2.1 (± 25.7)	-6.7 (± 36.1)	0.0 (± 21.1)	13.3 (± 38.0)
CFB in Coughing, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Felt Ill, Baseline N=52,47,28,37	24.4 (± 31.0)	31.9 (± 35.4)	27.4 (± 27.3)	22.5 (± 28.4)
CFB in Felt Ill, Week N=42,41,23,29	1.6 (± 30.3)	-2.4 (± 28.3)	11.6 (± 25.8)	5.7 (± 28.3)
CFB in Felt Ill, Week 6 N=32,36,16,27	-8.3 (± 29.3)	-13.0 (± 36.8)	2.1 (± 19.1)	-1.2 (± 29.9)
CFB in Felt Ill, Week 9 N=27,28,18,21	4.9 (± 30.2)	-10.7 (± 39.6)	-3.7 (± 22.5)	0.0 (± 23.6)
CFB in Felt Ill, Week 12 N=32,32,17,19	1.0 (± 28.7)	-9.4 (± 31.9)	-2.0 (± 30.0)	-1.8 (± 28.3)
CFB in Felt Ill, Week 15 N=31,28,13,18	5.4 (± 31.1)	-15.5 (± 36.8)	2.6 (± 28.7)	5.6 (± 34.8)
CFB in Felt Ill, Week 18 N=28,25,11,14	3.6 (± 24.6)	-10.7 (± 36.9)	9.1 (± 15.6)	0.0 (± 29.2)
CFB in Felt Ill, Week 21 N=24,24,11,13	4.2 (± 17.9)	5.6 (± 32.1)	12.1 (± 27.0)	10.3 (± 41.7)
CFB in Felt Ill, Week 24 N=21,17,13,9	3.2 (± 20.8)	-2.0 (± 27.6)	7.7 (± 20.0)	11.1 (± 37.3)
CFB in Felt Ill, Week 27 N=16,15,6,5	10.4 (± 31.5)	-4.4 (± 27.8)	5.6 (± 13.6)	-13.3 (± 38.0)
CFB in Felt Ill, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Pain Killers, Baseline N=51,49,28,37	78.4 (± 41.5)	75.5 (± 43.4)	78.6 (± 41.8)	78.4 (± 41.7)
CFB in Pain killers, Week 3 N=41,42,23,28	7.3 (± 34.6)	7.1 (± 46.3)	0.0 (± 52.2)	3.6 (± 42.9)
CFB in Pain killers, Week 6 N=31,36,16,26	-12.9 (± 42.8)	-8.3 (± 55.4)	6.3 (± 68.0)	-11.5 (± 58.8)
CFB in Pain killers, Week 9 N=27,29,19,21	-14.8 (± 45.6)	3.4 (± 32.5)	-10.5 (± 56.7)	-14.3 (± 47.8)

CFB in Pain killers, Week 12 N=30,33,17,19	-20.0 (± 48.4)	-9.1 (± 52.2)	-17.6 (± 52.9)	0.0 (± 33.3)
CFB in Pain killers, Week 15 N=30,28,13,18	-16.7 (± 64.8)	-7.1 (± 46.6)	-30.8 (± 75.1)	-11.1 (± 47.1)
CFB in Pain killers, Week 18 N=28,25,11,15	-21.4 (± 63.0)	-4.0 (± 45.5)	0.0 (± 77.5)	-13.3 (± 51.6)
CFB in Pain killers, Week 21 N=23,24,12,13	-30.4 (± 63.5)	-12.5 (± 53.7)	-33.3 (± 65.1)	-15.4 (± 37.6)
CFB in Pain killers, Week 24 N=20,16,13,9	-30.0 (± 57.1)	-25.0 (± 44.7)	-23.1 (± 59.9)	-22.2 (± 44.1)
CFB in Pain killers, Week 27 N=14,15,6,5	-35.7 (± 63.3)	-13.3 (± 51.6)	-33.3 (± 51.6)	-20.0 (± 44.7)
CFB in Pain killers, Week 90 N=1,0,0,0	-100.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
NutritionalSupplements(NS),BaselineN= 50,48,28,37	34.0 (± 47.9)	47.9 (± 50.5)	42.9 (± 50.4)	48.6 (± 50.7)
CFB in NS, Week 3 N=41,41,23,29	4.9 (± 44.4)	12.2 (± 51.0)	13.0 (± 45.8)	0.0 (± 53.5)
CFB in NS, Week 6 N=31,36,16,25	-9.7 (± 53.9)	-5.6 (± 58.3)	6.3 (± 57.4)	-12.0 (± 52.6)
CFB in NS, Week 9 N=27,28,19,20	3.7 (± 64.9)	-7.1 (± 66.3)	0.0 (± 57.7)	5.0 (± 60.5)
CFB in NS, Week 12 N=29,32,17,19	17.2 (± 65.8)	-6.3 (± 56.4)	0.0 (± 50.0)	-15.8 (± 50.1)
CFB in NS, Week 15 N=30,27,13,18	3.3 (± 61.5)	-3.7 (± 58.7)	-15.4 (± 55.5)	-11.1 (± 47.1)
CFB in NS, Week 18 N=28,24,11,15	-7.1 (± 60.4)	-4.2 (± 62.4)	0.0 (± 44.7)	6.7 (± 59.4)
CFB in NS, Week 21 N=23,23,12,13	4.3 (± 63.8)	4.3 (± 63.8)	16.7 (± 57.7)	23.1 (± 59.9)
CFB in NS, Week 24 N=20,17,13,9	15.0 (± 48.9)	11.8 (± 69.7)	-15.4 (± 55.5)	-11.1 (± 60.1)
CFB in NS, Week 27 N=14,14,6,5	14.3 (± 36.3)	7.1 (± 82.9)	-16.7 (± 40.8)	0.0 (± 70.7)
CFB in NS, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Feeding Tube,Baseline N=50,48,28,37	28.0 (± 45.4)	27.1 (± 44.9)	28.6 (± 46.0)	32.4 (± 47.5)
CFBinFeedingTube,Week 3 N=41,41,23,29	4.9 (± 38.4)	4.9 (± 21.8)	4.3 (± 20.9)	-6.9 (± 25.8)
CFBinFeedingTube,Week 6 N=31,35,15,26	0.0 (± 25.8)	-5.7 (± 33.8)	-6.7 (± 25.8)	-7.7 (± 39.2)
CFBinFeedingTube,Week 9 N=27,28,19,21	-11.1 (± 32.0)	7.1 (± 26.2)	5.3 (± 40.5)	-4.8 (± 38.4)
CFBinFeedingTube,Week 12 N=29,33,17,19	-3.4 (± 32.5)	6.1 (± 34.8)	-5.9 (± 42.9)	0.0 (± 33.3)
CFBinFeedingTube,Week 15 N=30,27,13,18	3.3 (± 32.0)	0.0 (± 27.7)	-7.7 (± 49.4)	5.6 (± 23.6)
CFBinFeedingTube,Week 18 N=28,23,11,15	-3.6 (± 33.1)	4.3 (± 20.9)	-9.1 (± 30.2)	0.0 (± 37.8)
CFBinFeedingTube,Week 21 N=23,23,12,13	-4.3 (± 36.7)	4.3 (± 20.9)	-16.7 (± 38.9)	7.7 (± 27.7)
CFBinFeedingTube,Week 24 N=20,17,13,9	0.0 (± 32.4)	5.9 (± 24.3)	-15.4 (± 37.6)	0.0 (± 0.0)
CFBinFeedingTube,Week 27 N=14,13,6,5	0.0 (± 0.0)	7.7 (± 27.7)	-16.7 (± 40.8)	0.0 (± 0.0)
CFBinFeedingTube,Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Weight Loss,Baseline N=50,49,28,37	32.0 (± 47.1)	44.9 (± 50.3)	28.6 (± 46.0)	29.7 (± 46.3)
CFB in WeightLoss, Week 3 N=39,41,23,29	23.1 (± 62.7)	-4.9 (± 59.0)	30.4 (± 55.9)	10.3 (± 61.8)
CFB in WeightLoss, Week 6 N=30,36,16,26	-6.7 (± 74.0)	-13.9 (± 59.3)	12.5 (± 50.0)	19.2 (± 63.4)
CFB in WeightLoss, Week 9 N=27,29,19,21	3.7 (± 70.6)	-17.2 (± 60.2)	0.0 (± 57.7)	-9.5 (± 53.9)
CFB in WeightLoss, Week 12 N=29,33,17,19	-17.2 (± 46.8)	-18.2 (± 58.4)	11.8 (± 33.2)	-5.3 (± 52.4)
CFB in WeightLoss, Week 15 N=30,28,13,17	13.3 (± 73.0)	-10.7 (± 73.7)	15.4 (± 37.6)	-5.9 (± 65.9)
CFB in WeightLoss, Week 18 N=28,25,11,15	0.0 (± 60.9)	-20.0 (± 57.7)	0.0 (± 44.7)	6.7 (± 59.4)

CFB in WeightLoss, Week 21 N=23,24,12,13	4.3 (± 47.5)	-4.2 (± 75.1)	25.0 (± 45.2)	7.7 (± 76.0)
CFB in WeightLoss, Week 24 N=20,17,13,9	-5.0 (± 39.4)	-5.9 (± 65.9)	7.7 (± 49.4)	33.3 (± 50.0)
CFB in WeightLoss, Week 27 N=14,15,6,5	0.0 (± 55.5)	-13.3 (± 74.3)	0.0 (± 0.0)	40.0 (± 54.8)
CFB in WeightLoss, Week 90 N=1,0,0,0	0.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Weight Gain; Baseline N=49,49,28,37	14.3 (± 35.4)	8.2 (± 27.7)	21.4 (± 41.8)	18.9 (± 39.7)
CFB in WeightGain, Week3 N=39,40,23,29	7.7 (± 53.2)	27.5 (± 55.4)	4.3 (± 36.7)	-6.9 (± 53.0)
CFB in WeightGain, Week6 N=30,36,16,26	10.0 (± 54.8)	25.0 (± 43.9)	0.0 (± 63.2)	7.7 (± 48.4)
CFB in WeightGain, Week9 N=26,28,18,21	3.8 (± 59.9)	14.3 (± 44.8)	5.6 (± 63.9)	19.0 (± 60.2)
CFB in WeightGain, Week12 N=28,32,17,19	14.3 (± 52.5)	6.3 (± 50.4)	23.5 (± 43.7)	26.3 (± 56.2)
CFB in WeightGain, Week15 N=30,28,13,18	6.7 (± 58.3)	25.0 (± 64.5)	0.0 (± 40.8)	11.1 (± 47.1)
CFB in WeightGain, Week18 N=27,24,11,15	7.4 (± 38.5)	16.7 (± 56.5)	-18.2 (± 60.3)	6.7 (± 59.4)
CFB in WeightGain, Week21 N=22,24,12,13	18.2 (± 39.5)	4.2 (± 55.0)	0.0 (± 73.9)	15.4 (± 68.9)
CFB in WeightGain, Week24 N=19,17,13,9	21.1 (± 63.1)	17.6 (± 52.9)	0.0 (± 40.8)	11.1 (± 60.1)
CFB in WeightGain, Week27 N=14,15,6,5	28.6 (± 61.1)	33.3 (± 61.7)	-16.7 (± 40.8)	20.0 (± 44.7)
CFB in WeightGain, Week90 N=1,0,0,0	-100.0 (± 999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohorts: Number of Participants with 5-level EuroQol 5 Dimensions Questionnaire (EQ-5D-5L) Score

End point title	Phase 2 Cohorts: Number of Participants with 5-level EuroQol 5 Dimensions Questionnaire (EQ-5D-5L) Score[17]

End point description:

EQ-5D-5L was an instrument for use as a measure of health outcome. The EQ-5D-5L consisted of 2 sections: EuroQoL (5 dimensions) (EQ-5D) descriptive system and the EuroQoL visual analogue scale (EQ-VAS). EQ-5D comprised the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension had 5 levels: No Probs, Slight Probs, Moderate Probs, Severe Probs, and Extreme Probs. Number of participants per category are reported. Phase 2 Cohort 1: Participants in the Intent-to-Treat Analysis Set with available data were analyzed. Phase 2 Cohort 3: Participants in the Modified Intent-to-Treat Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 3, Week 6, Week 9, Week 12, Week 15, Week 18, Week 21, Week 24, Week 27 and Week 90

Notes:

[17] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	50	27	36
Units: participants				
Mobility:Baseline:NoProblems(Probs)N=51,50,27,36	35	31	19	18
Mobility: Baseline:SlightProbsN=51,50,27,36	9	10	4	7
Mobility Baseline: Moderate Probs N=51,50,27,36	5	7	2	9
Mobility: Baseline:SevereProbsN=51,50,27,36	2	1	2	2
Mob Baseline:ExtremeProbsN=51,50,27,36	0	1	0	0
Mobility: Wk 3 :NoProbsN=42,43,23,30	29	28	13	16
Mobility: Wk 3:SlightProbsN=42,43,23,30	7	10	5	6
Mobility: Wk 3:ModerateProbsN=42,43,23,30	4	3	3	5
Mobility: Wk 3:SevereProbsN=42,43,23,30	2	2	2	2
Mobility: Wk 3:ExtremeProbsN=42,43,23,30	0	0	0	1
Mobility: Wk 6 :NoProbsN=30,40,16,27	17	28	11	12
Mobility: Wk 6:SlightProbsN=30,40,16,27	7	9	3	8
Mobility: Wk 6:ModerateProbsN=30,40,16,27	3	1	2	4
Mobility: Wk 6:SevereProbsN=30,40,16,27	1	1	0	2
Mobility: Wk 6:ExtremeProbsN=30,40,16,27	2	1	0	1
Mobility: Wk 9 :NoProbsN=29,30,19,21	19	21	12	12
Mobility: Wk 9:SlightProbsN=29,30,19,21	5	5	5	4
Mobility: Wk 9:ModerateProbsN=29,30,19,21	4	2	1	4
Mobility: Wk 9:SevereProbsN=29,30,19,21	1	1	1	1
Mobility: Wk 9:ExtremeProbsN=29,30,19,21	0	1	0	0
Mobility: Wk 12 :NoProbsN=31,34,18,19	18	22	12	11
Mobility: Wk 12:SlightProbsN=31,34,18,19	9	6	4	4
Mobility: Wk 12:ModerateProbsN=31,34,18,19	2	4	2	3
Mobility: Wk 12:SevereProbsN=31,34,18,19	1	1	0	0
Mobility: Wk 12:ExtremeProbsN=31,34,18,19	1	1	0	1
Mobility: Wk 15 :NoProbsN=31,31,12,18	22	17	9	9
Mobility: Wk 15:SlightProbsN=31,31,12,18	5	7	2	5
Mobility: Wk 15:ModerateProbsN=31,31,12,18	1	5	0	2

Mobility: Wk 15:SevereProbsN=31,31,12,18	3	1	1	2
Mobility: Wk 15:ExtremeProbsN=31,31,12,18	0	1	0	0
Mobility: Wk 18 :NoProbsN=29,24,11,16	19	18	10	5
Mobility: Wk 18:SlightProbsN=29,24,11,16	5	3	1	7
Mobility: Wk 18:ModerateProbsN=29,24,11,16	2	1	0	2
Mobility: Wk 18:SevereProbsN=29,24,11,16	3	2	0	2
Mobility: Wk 18:ExtremeProbsN=29,24,11,16	0	0	0	0
Mobility: Wk 21 :NoProbsN=24,24,13,12	15	11	9	2
Mobility: Wk 21:SlightProbsN=24,24,13,12	6	8	1	6
Mobility: Wk 21:ModerateProbsN=24,24,13,12	2	3	1	3
Mobility: Wk 21:SevereProbsN=24,24,13,12	1	0	1	1
Mobility: Wk 21:ExtremeProbsN=24,24,13,12	0	2	1	0
Mobility: Wk 24 :NoProbsN=21,18,13,8	15	5	11	3
Mobility: Wk 24:SlightProbsN=21,18,13,8	4	8	0	0
Mobility: Wk 24:ModerateProbsN=21,18,13,8	1	4	2	4
Mobility: Wk 24:SevereProbsN=21,18,13,8	1	1	0	1
Mobility: Wk 24:ExtremeProbsN=21,18,13,8	0	0	0	0
Mobility: Wk 27 :NoProbsN=15,14,6,5	9	7	5	1
Mobility: Wk 27:SlightProbsN=15,14,6,5	4	5	1	0
Mobility: Wk 27:ModerateProbsN=15,14,6,5	2	0	0	3
Mobility: Wk 27:SevereProbsN=15,14,6,5	0	2	0	1
Mobility: Wk 27:ExtremeProbsN=15,14,6,5	0	0	0	0
Mobility: Wk 90 :NoProbsN=1,0,0,0	1	0	0	0
Mobility: Wk 90:SlightProbsN=1,0,0,0	0	0	0	0
Mobility: Wk 90:ModerateProbsN=1,0,0,0	0	0	0	0
Mobility: Wk 90:SevereProbsN=1,0,0,0	0	0	0	0
Mobility: Wk 90:ExtremeProbsN=1,0,0,0	0	0	0	0
Self-Care: Baseline :NoProbsN=50,49,27,36	38	38	23	30
Self-care Baseline:SlightProbsN=50,49,27,36	6	8	3	3
Self-care Baseline:ModerateProbsN=50,49,27,36	3	2	0	2
Self-care Baseline:SevereProbsN=50,49,27,36	3	0	1	1
Self-care Baseline:ExtremeProbsN=50,49,27,36	0	1	0	0
Self-Care: Wk 3 :NoProbsN=42,43,23,30	31	32	16	21
Self-Care: Wk 3:SlightProbsN=42,43,23,30	5	7	5	5

Self-Care: Wk 3:ModerateProbsN=42,43,23,30	5	4	0	2
Self-Care: Wk 3:SevereProbsN=42,43,23,30	1	0	2	2
Self-Care: Wk 3:ExtremeProbsN=42,43,23,30	0	0	0	0
Self-Care: Wk 6 :NoProbsN=30,40,16,27	25	34	13	19
Self-Care: Wk 6:SlightProbsN=30,40,16,27	3	3	3	6
Self-Care: Wk 6:ModerateProbsN=30,40,16,27	1	1	0	0
Self-Care: Wk 6:SevereProbsN=30,40,16,27	0	2	0	2
Self-Care: Wk 6:ExtremeProbsN=30,40,16,27	1	0	0	0
Self-Care: Wk 9 :NoProbsN=29,30,19,21	22	24	16	17
Self-Care: Wk 9:SlightProbsN=29,30,19,21	5	4	2	3
Self-Care: Wk 9:ModerateProbsN=29,30,19,21	2	1	0	1
Self-Care: Wk 9:SevereProbsN=29,30,19,21	0	1	1	0
Self-Care: Wk 9:ExtremeProbsN=29,30,19,21	0	0	0	0
Self-Care: Wk 12 :NoProbsN=31,34,18,19	24	27	15	17
Self-Care: Wk 12:SlightProbsN=31,34,18,19	5	3	2	1
Self-Care: Wk 12:ModerateProbsN=31,34,18,19	0	4	1	0
Self-Care: Wk 12:SevereProbsN=31,34,18,19	2	0	0	1
Self-Care: Wk 12:ExtremeProbsN=31,34,18,19	0	0	0	0
Self-Care: Wk 15 :NoProbsN=31,31,12,18	24	25	10	13
Self-Care: Wk 15:SlightProbsN=31,31,12,18	4	4	1	5
Self-Care: Wk 15:ModerateProbsN=31,31,12,18	2	1	1	0
Self-Care: Wk 15:SevereProbsN=31,31,12,18	1	1	0	0
Self-Care: Wk 15:ExtremeProbsN=31,31,12,18	0	0	0	0
Self-Care: Wk 18 :NoProbsN=29,24,11,16	22	21	10	13
Self-Care: Wk 18:SlightProbsN=29,24,11,16	4	2	1	2
Self-Care: Wk 18:ModerateProbsN=29,24,11,16	1	0	0	1
Self-Care: Wk 18:SevereProbsN=29,24,11,16	2	1	0	0
Self-Care: Wk 18:ExtremeProbsN=29,24,11,16	0	0	0	0
Self-Care: Wk 21 :NoProbsN=24,24,13,12	18	17	12	8
Self-Care: Wk 21:SlightProbsN=24,24,13,12	4	5	1	2
Self-Care: Wk 21:ModerateProbsN=24,24,13,12	1	1	0	2

Self-Care: Wk 21:SevereProbsN=24,24,13,12	0	0	0	0
Self-Care: Wk 21:ExtremeProbsN=24,24,13,12	1	1	0	0
Self-Care: Wk 24 :NoProbsN=21,18,13,8	17	15	11	6
Self-Care: Wk 24:SlightProbsN=21,18,13,8	2	0	1	0
Self-Care: Wk 24:ModerateProbsN=21,18,13,8	2	2	1	2
Self-Care: Wk 24:SevereProbsN=21,18,13,8	0	1	0	0
Self-Care: Wk 24:ExtremeProbsN=21,18,13,8	0	0	0	0
Self-Care: Wk 27 :NoProbsN=15,14,6,5	12	12	6	3
Self-Care: Wk 27:SlightProbsN=15,14,6,5	1	1	0	1
Self-Care: Wk 27:ModerateProbsN=15,14,6,5	2	0	0	1
Self-Care: Wk 27:SevereProbsN=15,14,6,5	0	1	0	0
Self-Care: Wk 27:ExtremeProbsN=15,14,6,5	0	0	0	0
Self-Care: Wk 90 :NoProbsN=1,0,0,0	1	0	0	0
Self-Care: Wk 90:SlightProbsN=1,0,0,0	0	0	0	0
Self-Care: Wk 90:ModerateProbsN=1,0,0,0	0	0	0	0
Self-Care: Wk 90:SevereProbsN=1,0,0,0	0	0	0	0
Self-Care: Wk 90:ExtremeProbsN=1,0,0,0	0	0	0	0
UsualActivitiesBaseline:No Probs N=51,49,26,36	25	24	14	15
UsualActivitiesBaseline:SlightProbsN=51,49,26,36	13	14	9	12
UsualActivitiesBaseline:ModerateProbsN=51,49,26,36	8	7	1	3
UsualActivitiesBaseline:SevereProbsN=51,49,26,36	4	1	2	2
UsualActivitiesBaseline:ExtremeProbsN=51,49,26,36	1	3	0	4
Usual ActivitiesWk Wk 3 :NoProbsN=42,42,23,30	16	19	8	10
UsualActivitiesWk 3:SlightProbsN=42,42,23,30	17	15	9	11
UsualActivitiesWk 3:ModerateProbsN=42,42,23,30	5	6	4	7
UsualActivitiesWk 3:SevereProbsN=42,42,23,30	3	2	1	1
UsualActivitiesWk 3:ExtremeProbsN=42,42,23,30	1	0	1	1
UsualActivitiesWk Wk 6 :NoProbsN=30,40,16,27	16	21	8	12
UsualActivitiesWk 6:SlightProbsN=30,40,16,27	10	12	3	4
UsualActivitiesWk 6:ModerateProbsN=30,40,16,27	2	5	5	5
UsualActivitiesWk 6:SevereProbsN=30,40,16,27	1	1	0	4
UsualActivitiesWk 6:ExtremeProbsN=30,40,16,27	1	1	0	2

UsualActivitiesWk 9 :NoProbsN=29,30,19,21	14	19	10	11
UsualActivitiesWk 9:SlightProbsN=29,30,19,21	11	4	3	7
UsualActivitiesWk 9:ModerateProbsN=29,30,19,21	4	5	6	1
UsualActivitiesWk 9:SevereProbsN=29,30,19,21	0	2	0	2
UsualActivitiesWk 9:ExtremeProbsN=29,30,19,21	0	0	0	0
Usu ActivitiesWk Wk 12 :NoProbsN=31,33,18,19	16	21	13	9
UsualActivitiesWk 12:SlightProbsN=31,33,18,19	10	8	3	7
UsualActivitiesWk 12:ModerateProbsN=31,33,18,19	1	3	2	2
UsualActivitiesWk12:SevereProbsN=31,33,18,19	2	0	0	1
UsualActivitiesWk12:ExtremeProbsN=31,33,18,19	2	1	0	0
UsualActivitiesWk15:NoProbsN=30,30,12,18	15	15	6	7
UsualActivitiesWk15:SlightProbsN=30,30,12,18	8	8	4	7
UsualActivitiesWk 15:ModerateProbsN=30,30,12,18	5	5	2	2
UsualActivitiesWk 15:SevereProbsN=30,30,12,18	2	1	0	0
UsualActivitiesWk 15:ExtremeProbsN=30,30,12,18	0	1	0	2
UsualActivitiesWk 18 :NoProbsN=29,24,11,16	18	15	7	5
UsualActivitiesWk 18:SlightProbsN=29,24,11,16	6	7	4	8
UsualActivitiesWk 18:ModerateProbsN=29,24,11,16	2	2	0	1
UsualActivitiesWk 18:SevereProbsN=29,24,11,16	2	0	0	2
UsualActivitiesWk 18:ExtremeProbsN=29,24,11,16	1	0	0	0
UsualActivitiesWk 21 :NoProbsN=24,23,13,12	15	11	8	2
UsualActivitiesWk 21:SlightProbsN=24,23,13,12	9	9	1	4
UsualActivitiesWk 21:ModerateProbsN=24,23,13,12	0	2	2	5
UsualActivitiesWk 21:SevereProbsN=24,23,13,12	0	0	1	0
UsualActivitiesWk 21:ExtremeProbsN=24,23,13,12	0	1	1	1
Usual ActivitiesWk Wk 24 :NoProbsN=21,17,13,7	12	10	7	2
UsualActivitiesWk 24:SlightProbsN=21,17,13,7	5	4	3	2
UsualActivitiesWk 24:ModerateProbsN=21,17,13,7	2	1	3	3
UsualActivitiesWk 24:SevereProbsN=21,17,13,7	1	2	0	0
UsualActivitiesWk 24:ExtremeProbsN=21,17,13,7	1	0	0	0
Usual ActivitiesWk Wk 27 :NoProbsN=15,14,6,5	8	8	4	1

UsualActivitiesWk 27:SlightProbsN=15,14,6,5	4	3	2	0
UsualActivitiesWk 27:ModerateProbsN=15,14,6,5	3	1	0	3
UsualActivitiesWk 27:SevereProbsN=15,14,6,5	0	2	0	1
UsualActivitiesWk 27:ExtremeProbsN=15,14,6,5	0	0	0	0
Usual ActivitiesWk 90 :NoProbsN=1,0,0,0	1	0	0	0
Usu ActivitiesWk 90:SlightProbsN=1,0,0,0	0	0	0	0
UsualActivitiesWk 90:ModerateProbsN=1,0,0,0	0	0	0	0
UsualActivitiesWk 90:SevereProbsN=1,0,0,0	0	0	0	0
UsualActivitiesWk 90:ExtremeProbsN=1,0,0,0	0	0	0	0
Pain/Discomfort Baseline:NoProbsN=51,50,27,36	9	10	4	7
Pain/DiscomfortBaseline:SlightProbsN=51,50,27,36	19	16	8	12
Pain/DiscomfortBaseline:ModerateProbsN=51,50,27,36	15	15	11	12
Pain/DiscomfortBaseline:SevereProbsN=51,50,27,36	6	8	2	5
Pain/DiscomfortBaseline:ExtremeProbsN=51,50,27,36	2	1	2	0
Pain/Discomfort:Wk 3 :NoProbsN=42,43,23,30	12	12	5	7
Pain/Discomfort:Wk 3:SlightProbsN=42,43,23,30	17	12	5	9
Pain/Discomfort:Wk 3:ModerateProbsN=42,43,23,30	10	15	7	10
Pain/Discomfort:Wk 3:SevereProbsN=42,43,23,30	3	4	5	4
Pain/Discomfort:Wk 3:ExtremeProbsN=42,43,23,30	0	0	1	0
Pain/Discomfort:Wk 6 :NoProbsN=30,40,16,27	10	16	4	6
Pain/Discomfort:Wk 6:SlightProbsN=30,40,16,27	15	10	7	10
Pain/Discomfort:Wk 6:ModerateProbsN=30,40,16,27	5	11	4	8
Pain/Discomfort:Wk 6:SevereProbsN=30,40,16,27	0	3	1	3
Pain/Discomfort:Wk 6:ExtremeProbsN=30,40,16,27	0	0	0	0
Pain/Discomfort:Wk 9 :NoProbsN=29,30,19,21	10	10	6	7
Pain/Discomfort:Wk 9:SlightProbsN=29,30,19,21	9	9	7	5
Pain/Discomfort:Wk 9:ModerateProbsN=29,30,19,21	8	8	5	8
Pain/Discomfort:Wk 9:SevereProbsN=29,30,19,21	2	3	1	0
Pain/Discomfort:Wk 9:ExtremeProbsN=29,30,19,21	0	0	0	1
Pain/Discomfort:Wk 12 :NoProbsN=31,34,18,19	11	11	10	6
Pain/Discomfort:Wk 12:SlightProbsN=31,34,18,19	11	15	4	4

Pain/Discomfort:Wk 12:ModerateProbsN=31,34,18,19	5	6	3	8
Pain/Discomfort:Wk 12:SevereProbsN=31,34,18,19	3	1	1	0
Pain/Discomfort:Wk 12:ExtremeProbsN=31,34,18,19	1	1	0	1
Pain/Discomfort:Wk 15 :NoProbsN=31,31,12,18	10	11	4	4
Pain/Discomfort:Wk 15:SlightProbsN=31,31,12,18	13	7	5	6
Pain/Discomfort:Wk 15:ModerateProbsN=31,31,12,18	5	9	3	8
Pain/Discomfort:Wk 15:SevereProbsN=31,31,12,18	3	3	0	0
Pain/Discomfort:Wk 15:ExtremeProbsN=31,31,12,18	0	1	0	0
Pain/Discomfort:Wk 18 :NoProbsN=29,24,11,16	10	11	4	5
Pain/Discomfort:Wk 18:SlightProbsN=29,24,11,16	11	8	3	7
Pain/Discomfort:Wk 18:ModerateProbsN=29,24,11,16	8	5	4	2
Pain/Discomfort:Wk 18:SevereProbsN=29,24,11,16	0	0	0	2
Pain/Discomfort:Wk 18:ExtremeProbsN=29,24,11,16	0	0	0	0
Pain/Discomfort:Wk 21 :NoProbsN=24,24,13,12	9	11	8	3
Pain/Discomfort:Wk 21:SlightProbsN=24,24,13,12	7	4	2	3
Pain/Discomfort:Wk 21:ModerateProbsN=24,24,13,12	5	6	3	5
Pain/Discomfort:Wk 21:SevereProbsN=24,24,13,12	3	3	0	1
Pain/Discomfort:Wk 21:ExtremeProbsN=24,24,13,12	0	0	0	0
Pain/Discomfort:Wk 24 :NoProbsN=21,18,13,8	7	7	5	3
Pain/Discomfort:Wk 24:SlightProbsN=21,18,13,8	7	4	6	1
Pain/Discomfort:Wk 24:ModerateProbsN=21,18,13,8	7	6	1	3
Pain/Discomfort:Wk 24:SevereProbsN=21,18,13,8	0	0	0	1
Pain/Discomfort:Wk 24:ExtremeProbsN=21,18,13,8	0	1	1	0
Pain/Discomfort:Wk 27 :NoProbsN=15,14,6,5	9	9	4	1
Pain/Discomfort:Wk 27:SlightProbsN=15,14,6,5	1	0	2	1
Pain/Discomfort:Wk 27:ModerateProbsN=15,14,6,5	4	2	0	2
Pain/Discomfort:Wk 27:SevereProbsN=15,14,6,5	1	3	0	0
Pain/Discomfort:Wk 27:ExtremeProbsN=15,14,6,5	0	0	0	1
Pain/Discomfort:Wk 90 :NoProbsN=1,0,0,0	0	0	0	0
Pain/Discomfort:Wk 90:SlightProbsN=1,0,0,0	1	0	0	0
Pain/Discomfort:Wk 90:ModerateProbsN=1,0,0,0	0	0	0	0

Pain/Discomfort:Wk 90:SevereProbsN=1,0,0,0	0	0	0	0
Pain/Discomfort:Wk 90:ExtremeProbsN=1,0,0,0	0	0	0	0
Anxiety/DepressionBaseline:No Probs N=51,50,27,36	20	21	9	22
Anxiety/DepressionBaselineSlightProbsN=51,50,27,36	20	15	12	9
AnxietyDepressionBaselineModerateProbN=51,50,27,36	6	8	5	5
Anxiety/DepressionBaselineSevereProbsN=51,50,27,36	4	3	1	0
AnxietyDepressionBaselineExtremeProbsN=51,50,27,36	1	3	0	0
Anxiety/DepressionWk 3:No Probs N=42,43,23,30	21	23	8	16
Anxiety/DepressionWk3:Slight Probs N=42,43,23,30	15	7	11	10
Anxiety/DepressionWk3:Moderate Probs N=42,43,23,30	3	9	3	3
Anxiety/DepressionWk3:Severe Probs N=42,43,23,30	3	4	1	1
Anxiety/DepressionWk3:Extreme Probs N=42,43,23,30	0	0	0	0
Anxiety/DepressionWk6 :NoProbsN=30,40,16,27	16	19	8	13
Anxiety/DepressionWk6:SlightProbsN=30,40,16,27	13	10	5	8
Anxiety/DepressionWk6:ModerateProbsN=30,40,16,27	1	7	3	5
Anxiety/DepressionWk6:SevereProbsN=30,40,16,27	0	3	0	1
Anxiety/DepressionWk6:ExtremeProbsN=30,40,16,27	0	1	0	0
Anxiety/DepressionWk9 :NoProbsN=29,30,19,21	8	18	8	11
Anxiety/DepressionWk9:SlightProbsN=29,30,19,21	15	8	9	8
Anxiety/DepressionWk9:ModerateProbsN=29,30,19,21	6	3	2	2
Anxiety/DepressionWk9:SevereProbsN=29,30,19,21	0	0	0	0
Anxiety/DepressionWk9:ExtremeProbsN=29,30,19,21	0	1	0	0
Anxiety/DepressionWk12 :NoProbsN=31,34,18,19	14	15	9	9
Anxiety/DepressionWk12:SlightProbsN=31,34,18,19	14	15	9	9
Anxiety/DepressionWk12:ModerateProbsN=31,34,18,19	0	4	0	1
Anxiety/DepressionWk12:SevereProbsN=31,34,18,19	1	0	0	0
Anxiety/DepressionWk12:ExtremeProbsN=31,34,18,19	2	0	0	0
Anxiety/DepressionWk15 :NoProbsN=31,31,12,18	15	14	6	10
Anxiety/DepressionWk15:SlightProbsN=31,31,12,18	11	6	5	4
Anxiety/DepressionWk15:ModerateProbsN=31,31,12,18	3	8	1	4
Anxiety/DepressionWk15:SevereProbsN=31,31,12,18	1	3	0	0

Anxiety/DepressionWk15:ExtremeProbs N=31,31,12,18	1	0	0	0
Anxiety/DepressionWk18 :NoProbsN=29,24,10,15	14	13	4	10
Anxiety/DepressionWk18:SlightProbsN= 29,24,10,15	9	6	5	2
Anxiety/DepressionWk18:ModerateProbs N=29,24,10,15	4	5	1	3
Anxiety/DepressionWk18:SevereProbsN =29,24,10,15	2	0	0	0
Anxiety/DepressionWk18:ExtremeProbs N=29,24,10,15	0	0	0	0
Anxiety/DepressionWk21 :NoProbsN=24,24,13,12	12	12	8	2
Anxiety/DepressionWk21:SlightProbsN= 24,24,13,12	7	4	4	6
Anxiety/DepressionWk21:ModerateProbs N=24,24,13,12	4	7	1	4
Anxiety/DepressionWk21:SevereProbsN =24,24,13,12	0	1	0	0
Anxiety/DepressionWk21:ExtremeProbs N=24,24,13,12	1	0	0	0
Anxiety/DepressionWk24 :NoProbsN=21,18,13,8	10	10	8	3
Anxiety/DepressionWk24:SlightProbsN= 21,18,13,8	8	3	5	2
Anxiety/DepressionWk24:ModerateProbs N=21,18,13,8	2	4	0	3
Anxiety/DepressionWk24:SevereProbsN =21,18,13,8	1	1	0	0
Anxiety/DepressionWk24:ExtremeProbs N=21,18,13,8	0	0	0	0
Anxiety/DepressionWk27 :NoProbsN=15,14,6,5	7	7	4	1
Anxiety/DepressionWk27:SlightProbsN= 15,14,6,5	4	4	2	1
Anxiety/DepressionWk27:ModerateProbs N=15,14,6,5	3	1	0	3
Anxiety/DepressionWk27:SevereProbsN =15,14,6,5	1	2	0	0
Anxiety/DepressionWk27:ExtremeProbs N=15,14,6,5	0	0	0	0
Anxiety/Depression:Wk90:No Probs N=1,0,0,0	1	0	0	0
Anxiety/DepressionWk90:Slight Probs N=1,0,0,0	0	0	0	0
Anxiety/DepressionWk90:Moderate Probs N=1,0,0,0	0	0	0	0
Anxiety/DepressionWk90:Severe Probs N=1,0,0,0	0	0	0	0
Anxiety/DepressionWk90:Extreme Probs N=1,0,0,0	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 Cohorts: Change From Baseline in the EuroQol Visual Analogue

Scale (EQ-VAS) Score

End point title	Phase 2 Cohorts: Change From Baseline in the EuroQol Visual Analogue Scale (EQ-VAS) Score[18]

End point description:

The EQ-VAS records the participant's self-rated health on a vertical VAS, where the end points are labeled "the best health you can imagine" and "the worst health you can imagine." The EQ-VAS can be used as a quantitative measure of health outcome that reflects the participant's own judgment.
Analysis Population Description : Phase 2 Cohort 1: Participants in the Intent-to-Treat Analysis Set with available data were analyzed. Phase 2 Cohort 3: Participants in the Modified Intent-to-Treat Analysis Set with available data were analyzed. '9999' signifies that data was not available since no participants were analyzed at the specified timepoint. 1111 : Standard Deviation can not be estimated for one participant.

End point type	Secondary

End point timeframe:

Baseline, Week 3, Week 6, Week 9, Week 12, Week 15, Week 18, Week 21, Week 24, Week 27 and Week 90

Notes:

[18] - 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: Per prespecified analysis, the data for this endpoint was collected only for Phase 2 Cohort 3 and Phase 2 Cohort Arms A, B and C. Hence the data is not reported for Safety Run-In Arms 1 and 2 for this endpoint.

End point values	Ph 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+ Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU	Ph 2 Cohort 1 Arm C: Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	52	32	41
Units: score on scale				
arithmetic mean (standard deviation)				
Baseline N = 52,50,27,36	61.9 (± 20.96)	64.0 (± 23.15)	59.8 (± 24.86)	62.0 (± 22.21)
Change at Week 3 N = 41,42,23,27	-3.7 (± 20.80)	4.3 (± 20.72)	4.1 (± 17.88)	-0.3 (± 16.20)
Change at Week 6 N = 30,38,14,26	2.2 (± 14.82)	5.7 (± 24.75)	1.1 (± 15.71)	-2.1 (± 16.37)
Change at Week 9 N = 29,29,16,20	-1.0 (± 18.19)	2.5 (± 16.89)	6.6 (± 18.50)	4.4 (± 20.74)
Change at Week 12 N = 31,32,16,18	4.5 (± 18.65)	7.9 (± 23.02)	5.9 (± 19.60)	-4.5 (± 4.55)
Change at Week 15 N = 31,29,11,18	0.1 (± 18.79)	10.5 (± 23.60)	3.2 (± 15.05)	-1.1 (± 12.86)
Change at Week 18 N = 29,25,11,15	-1.2 (± 9.34)	7.4 (± 23.33)	3.8 (± 20.11)	-8.1 (± 17.77)
Change at Week 21 N = 24,24,11,11	0.5 (± 18.59)	1.1 (± 21.12)	4.0 (± 20.15)	-8.5 (± 16.71)
Change at Week 24 N = 21,17,12,7	0.2 (± 22.05)	6.0 (± 22.45)	2.1 (± 20.72)	-13.9 (± 19.17)
Change at Week 27 N = 14,13,6,5	-10.0 (± 19.32)	-0.9 (± 22.46)	10.0 (± 1.45)	-9.0 (± 23.56)
Change at Week 90 N = 1,0,0,0	25.0 (± 1111)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-Cause Mortality: Up to 129 weeks; Adverse Events: Up to 73 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	Phase 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU IV infusions as mentioned below: Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 72 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 88 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 22 weeks for carboplatin and 23 weeks for cisplatin.

Reporting group title	Safety Run-in Cohort 1:Magrolimab+Pembrolizumab+Platinum+5-FU

Reporting group description:

Participants received magrolimab + pembrolizumab + platinum + 5 FU (5-fluorouracil) intravenous (IV) infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 73 weeks; Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 73 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 18.3 weeks (for carboplatin).

Reporting group title	Phase 2 Cohort 3: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 42 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 34 weeks.

Reporting group title	Safety Run-in Cohort 2: Magrolimab + Docetaxel

Reporting group description:

Participants received magrolimab + docetaxel IV infusions as mentioned below:
Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 69 weeks; Docetaxel 75 mg/m^2 IV on Day 1 of every 21-day cycle for up to 13 weeks.

Reporting group title	Phase 2 Cohort 1 Arm C:Magrolimab+Zimberelimab+Platinum+5-FU

Reporting group description:

Participants received magrolimab + zimberelimab + platinum + 5 FU IV infusions as mentioned below: Magrolimab 1 mg/kg on Cycle 1 Day 1; 30 mg/kg, beginning at Day 8 and for the next 5 doses (Cycle 1 Days 8, 15, and Cycle 2 Days 1, 8 and 15); 60 mg/kg, starting Cycle 3 Day 1 onwards for every 21-day cycle for up to 37 weeks; Zimberelimab 360 mg IV on Day 1 of every 21-day cycle for up to 40 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 19 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 18 weeks for carboplatin and 16 weeks for cisplatin.

Reporting group title	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU

Reporting group description:

Participants received pembrolizumab + platinum + 5 FU IV infusions as mentioned below: Pembrolizumab 200 mg IV on Day 1 of every 21-day cycle for up to 70 weeks; 5-FU 1000 mg/m^2/day continuous IV On Day 1 to 4 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks; Cisplatin 100 mg/m^2 IV or Carboplatin AUC 5 IV on Day 1 of Cycles 1 to 6 for 21-day cycle each for up to 24 weeks for carboplatin and 18 weeks for cisplatin.

Serious adverse events	Phase 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Safety Run-in Cohort 1:Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 52 (50.00%)	4 / 6 (66.67%)	24 / 41 (58.54%)
number of deaths (all causes)	25	1	24
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Tumour pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Peripheral ischaemia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Peripheral embolism			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Hypotension			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
General disorders and administration site conditions			
Mucosal inflammation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Hyperthermia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Fatigue			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Pyrexia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Pharyngeal haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired tracheo-oesophageal fistula			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (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
Epistaxis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Psychiatric disorders			
Disorientation			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Delirium			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Platelet count decreased			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site discharge			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Femur fracture			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Wound haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Post procedural haematoma			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Craniocerebral injury			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Infusion related reaction			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Cardiac tamponade			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Cardiac arrest			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Cardio-respiratory arrest			

subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Myocardial infarction			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Nervous system disorders			
Seizure			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	0 / 41 (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
Middle cerebral artery stroke			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Neutropenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Pancytopenia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Anaemia			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	4 / 41 (9.76%)
occurrences causally related to treatment / all	3 / 3	1 / 1	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	8 / 41 (19.51%)
occurrences causally related to treatment / all	2 / 2	1 / 1	8 / 8
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Splenic haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Abdominal pain upper			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Ascites			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Dysphagia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Neutropenic colitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Mouth haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Oral cavity fistula			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Stomatitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Aphthous ulcer			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Cholecystitis acute			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin haemorrhage			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Toxic skin eruption			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Acute kidney injury			
subjects affected / exposed	4 / 52 (7.69%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Infections and infestations			
Epididymitis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Gastroenteritis cryptosporidial			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Erysipelas			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Cellulitis staphylococcal			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Lung abscess			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Covid-19			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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

Localised infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 52 (1.92%)	4 / 6 (66.67%)	6 / 41 (14.63%)
occurrences causally related to treatment / all	1 / 1	2 / 4	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumonia aspiration			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection ~ viral			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Oral infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital herpes simplex			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (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
Wound infection			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Oral fungal infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Pneumonia necrotising			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Tracheitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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
Metabolism and nutrition disorders			
Hypercalcaemia			

subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	0 / 41 (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
Hyperglycaemia			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (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
Dehydration			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (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	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 1 Arm C:Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	15 / 29 (51.72%)	24 / 53 (45.28%)
number of deaths (all causes)	6	9	22
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Cancer pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Vascular disorders			
Peripheral ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Thrombophlebitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
General disorders and administration site conditions			
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired tracheo-oesophageal fistula			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	2 / 53 (3.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disorientation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Stoma site discharge			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Femur fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Wound haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Clavicle fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Cardiac disorders			
Atrial fibrillation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Middle cerebral artery stroke			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Syncope			

subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Anaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 29 (3.45%)	5 / 53 (9.43%)
occurrences causally related to treatment / all	3 / 3	1 / 1	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Gastric ulcer perforation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Dysphagia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Neutropenic colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Mouth haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral cavity fistula			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Cholecystitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Skin haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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			
Epididymitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Gastroenteritis cryptosporidial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Bronchitis viral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (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
Cellulitis staphylococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Lung abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	2 / 53 (3.77%)
occurrences causally related to treatment / all	0 / 1	1 / 4	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Sepsis			

subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Lower respiratory tract infection ~ viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Anal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Hepatic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	2 / 53 (3.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Genital herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Tongue abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Wound infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Subcutaneous abscess			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Tracheitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (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
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Phase 2 Cohort 1 Arm A: Magrolimab+Pembrolizumab+Platinum+5-FU	Safety Run-in Cohort 1:Magrolimab+Pembrolizumab+Platinum+5-FU	Phase 2 Cohort 3: Magrolimab + Docetaxel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 52 (94.23%)	6 / 6 (100.00%)	40 / 41 (97.56%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	3 / 41 (7.32%)
occurrences (all)	3	0	3
Embolism			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	6 / 52 (11.54%)	3 / 6 (50.00%)	5 / 41 (12.20%)
occurrences (all)	8	4	5
Oedema peripheral			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	5 / 41 (12.20%)
occurrences (all)	3	0	5
Non-cardiac chest pain			

subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	3	1	1
Mucosal inflammation			
subjects affected / exposed	5 / 52 (9.62%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	6	0	0
Fatigue			
subjects affected / exposed	12 / 52 (23.08%)	5 / 6 (83.33%)	14 / 41 (34.15%)
occurrences (all)	16	5	21
Pain			
subjects affected / exposed	4 / 52 (7.69%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Asthenia			
subjects affected / exposed	16 / 52 (30.77%)	1 / 6 (16.67%)	7 / 41 (17.07%)
occurrences (all)	17	1	9
Influenza like illness			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	0 / 52 (0.00%)	2 / 6 (33.33%)	2 / 41 (4.88%)
occurrences (all)	0	2	2
Haemoptysis			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Cough			
subjects affected / exposed	5 / 52 (9.62%)	1 / 6 (16.67%)	5 / 41 (12.20%)
occurrences (all)	6	1	5
Dysphonia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Dyspnoea exertional			

subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	8 / 52 (15.38%)	0 / 6 (0.00%)	10 / 41 (24.39%)
occurrences (all)	8	0	13
Tracheal inflammation			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	4 / 52 (7.69%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	5 / 52 (9.62%)	1 / 6 (16.67%)	3 / 41 (7.32%)
occurrences (all)	5	1	3
Anxiety			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	1	1	1

Depression			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
Investigations			
Neutrophil count decreased			
subjects affected / exposed	11 / 52 (21.15%)	2 / 6 (33.33%)	9 / 41 (21.95%)
occurrences (all)	18	2	14
Weight decreased			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	3	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 52 (7.69%)	2 / 6 (33.33%)	2 / 41 (4.88%)
occurrences (all)	5	2	2
Platelet count decreased			
subjects affected / exposed	8 / 52 (15.38%)	5 / 6 (83.33%)	1 / 41 (2.44%)
occurrences (all)	18	7	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	4 / 52 (7.69%)	3 / 6 (50.00%)	1 / 41 (2.44%)
occurrences (all)	4	3	2
Blood iron decreased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	5 / 52 (9.62%)	1 / 6 (16.67%)	4 / 41 (9.76%)
occurrences (all)	5	2	4
Haemoglobin decreased			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
Blood creatinine increased			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	4	1	0
Lymphocyte count decreased			
subjects affected / exposed	6 / 52 (11.54%)	1 / 6 (16.67%)	4 / 41 (9.76%)
occurrences (all)	6	1	4
White blood cell count decreased			

subjects affected / exposed	11 / 52 (21.15%)	4 / 6 (66.67%)	8 / 41 (19.51%)
occurrences (all)	18	6	13
Blood alkaline phosphatase increased			
subjects affected / exposed	7 / 52 (13.46%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	11	1	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Stoma site pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	3 / 41 (7.32%)
occurrences (all)	3	1	3
Cardiac disorders			
Ventricular hypokinesia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Headache			
subjects affected / exposed	10 / 52 (19.23%)	1 / 6 (16.67%)	7 / 41 (17.07%)
occurrences (all)	12	1	8
Polyneuropathy			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
Dizziness			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	6	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	2	1	2
Disturbance in attention			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Brain fog			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 52 (1.92%)	3 / 6 (50.00%)	4 / 41 (9.76%)
occurrences (all)	2	4	5
Presyncope			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	3	2	0
Dysgeusia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	9 / 52 (17.31%)	0 / 6 (0.00%)	5 / 41 (12.20%)
occurrences (all)	19	0	8
Leukopenia			
subjects affected / exposed	4 / 52 (7.69%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	8	0	5
Thrombocytopenia			

subjects affected / exposed	16 / 52 (30.77%)	1 / 6 (16.67%)	4 / 41 (9.76%)
occurrences (all)	27	1	6
Anaemia			
subjects affected / exposed	43 / 52 (82.69%)	5 / 6 (83.33%)	28 / 41 (68.29%)
occurrences (all)	66	10	38
Haemolysis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
Neutropenia			
subjects affected / exposed	16 / 52 (30.77%)	1 / 6 (16.67%)	8 / 41 (19.51%)
occurrences (all)	28	2	12
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	3	0	1
Vertigo			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Ear pain			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
Tinnitus			
subjects affected / exposed	6 / 52 (11.54%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	7	0	1
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	11 / 52 (21.15%)	3 / 6 (50.00%)	14 / 41 (34.15%)
occurrences (all)	12	4	19
Dry mouth			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Nausea			
subjects affected / exposed	19 / 52 (36.54%)	4 / 6 (66.67%)	15 / 41 (36.59%)
occurrences (all)	27	6	18
Stomatitis			
subjects affected / exposed	7 / 52 (13.46%)	5 / 6 (83.33%)	10 / 41 (24.39%)
occurrences (all)	9	12	12
Abdominal pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	4 / 41 (9.76%)
occurrences (all)	1	0	4
Abdominal pain upper			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Oral dysaesthesia			
subjects affected / exposed	0 / 52 (0.00%)	2 / 6 (33.33%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Dysphagia			
subjects affected / exposed	4 / 52 (7.69%)	0 / 6 (0.00%)	5 / 41 (12.20%)
occurrences (all)	4	0	5
Constipation			
subjects affected / exposed	18 / 52 (34.62%)	3 / 6 (50.00%)	7 / 41 (17.07%)
occurrences (all)	22	4	8
Glossodynia			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	3 / 41 (7.32%)
occurrences (all)	2	0	3

Vomiting			
subjects affected / exposed	6 / 52 (11.54%)	1 / 6 (16.67%)	6 / 41 (14.63%)
occurrences (all)	13	2	8
Oral pain			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	1	1	2
Dyspepsia			
subjects affected / exposed	4 / 52 (7.69%)	1 / 6 (16.67%)	3 / 41 (7.32%)
occurrences (all)	4	1	3
Skin and subcutaneous tissue disorders			
Rash pruritic			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Alopecia			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	9 / 41 (21.95%)
occurrences (all)	0	0	9
Rash			
subjects affected / exposed	5 / 52 (9.62%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	5	1	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	4 / 52 (7.69%)	3 / 6 (50.00%)	0 / 41 (0.00%)
occurrences (all)	4	3	0
Skin hypopigmentation			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Actinic keratosis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Skin fissures			

subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Pruritus			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	3 / 41 (7.32%)
occurrences (all)	3	1	3
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Proteinuria			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	3 / 52 (5.77%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	3	1	5
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
Pain in jaw			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Myalgia			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Neck pain			

subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
Back pain			
subjects affected / exposed	5 / 52 (9.62%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	5	0	0
Pain in extremity			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	3	0	2
Musculoskeletal chest pain			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	3 / 41 (7.32%)
occurrences (all)	6	0	3
Respiratory tract infection			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
Candida infection			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
Covid-19			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	1	1	2
Cellulitis			
subjects affected / exposed	1 / 52 (1.92%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	2 / 41 (4.88%)
occurrences (all)	0	1	2

Bronchitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Localised infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	2 / 52 (3.85%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
Nasopharyngitis			
subjects affected / exposed	2 / 52 (3.85%)	1 / 6 (16.67%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Stoma site infection			
subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 52 (0.00%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	5 / 52 (9.62%)	0 / 6 (0.00%)	2 / 41 (4.88%)
occurrences (all)	5	0	2
Hypercalcaemia			
subjects affected / exposed	5 / 52 (9.62%)	0 / 6 (0.00%)	1 / 41 (2.44%)
occurrences (all)	6	0	2
Hypomagnesaemia			
subjects affected / exposed	10 / 52 (19.23%)	1 / 6 (16.67%)	4 / 41 (9.76%)
occurrences (all)	12	1	7
Hypoalbuminaemia			

subjects affected / exposed	3 / 52 (5.77%)	0 / 6 (0.00%)	5 / 41 (12.20%)
occurrences (all)	3	0	5
Decreased appetite			
subjects affected / exposed	14 / 52 (26.92%)	3 / 6 (50.00%)	10 / 41 (24.39%)
occurrences (all)	15	3	12
Hypophosphataemia			
subjects affected / exposed	6 / 52 (11.54%)	3 / 6 (50.00%)	5 / 41 (12.20%)
occurrences (all)	6	3	5
Hypokalaemia			
subjects affected / exposed	7 / 52 (13.46%)	1 / 6 (16.67%)	6 / 41 (14.63%)
occurrences (all)	9	1	6
Dehydration			
subjects affected / exposed	0 / 52 (0.00%)	2 / 6 (33.33%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	7 / 52 (13.46%)	2 / 6 (33.33%)	6 / 41 (14.63%)
occurrences (all)	10	3	8
Hyperglycaemia			
subjects affected / exposed	1 / 52 (1.92%)	2 / 6 (33.33%)	6 / 41 (14.63%)
occurrences (all)	2	2	6
Failure to thrive			
subjects affected / exposed	0 / 52 (0.00%)	1 / 6 (16.67%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	1 / 52 (1.92%)	0 / 6 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Safety Run-in Cohort 2: Magrolimab + Docetaxel	Phase 2 Cohort 1 Arm C:Magrolimab+Zimberelimab+Platinum+5-FU	Phase 2 Cohort 1 Arm B: Pembrolizumab + Platinum + 5-FU
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	28 / 29 (96.55%)	53 / 53 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	0	3	0

Cancer pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	1	1	2
Hypotension			
subjects affected / exposed	2 / 7 (28.57%)	0 / 29 (0.00%)	3 / 53 (5.66%)
occurrences (all)	3	0	3
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	3 / 53 (5.66%)
occurrences (all)	2	4	4
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	1	2	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	1 / 53 (1.89%)
occurrences (all)	1	3	1
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	4 / 53 (7.55%)
occurrences (all)	0	4	4
Fatigue			
subjects affected / exposed	4 / 7 (57.14%)	9 / 29 (31.03%)	11 / 53 (20.75%)
occurrences (all)	5	12	13
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	2
Asthenia			

subjects affected / exposed	0 / 7 (0.00%)	10 / 29 (34.48%)	15 / 53 (28.30%)
occurrences (all)	0	10	17
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	1	1	2
Cough			
subjects affected / exposed	1 / 7 (14.29%)	5 / 29 (17.24%)	7 / 53 (13.21%)
occurrences (all)	1	5	9
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 7 (14.29%)	5 / 29 (17.24%)	6 / 53 (11.32%)
occurrences (all)	1	6	6
Tracheal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences (all)	1	1	3
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	2
Pneumonitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Laryngeal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Increased bronchial secretion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	1 / 53 (1.89%)
occurrences (all)	1	3	1
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	2
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	4 / 53 (7.55%)
occurrences (all)	1	3	4
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Investigations			
Neutrophil count decreased			
subjects affected / exposed	4 / 7 (57.14%)	4 / 29 (13.79%)	2 / 53 (3.77%)
occurrences (all)	8	15	2
Weight decreased			
subjects affected / exposed	2 / 7 (28.57%)	5 / 29 (17.24%)	7 / 53 (13.21%)
occurrences (all)	2	5	7
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	5 / 53 (9.43%)
occurrences (all)	0	4	5
Platelet count decreased			

subjects affected / exposed	3 / 7 (42.86%)	8 / 29 (27.59%)	8 / 53 (15.09%)
occurrences (all)	6	22	13
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	2	4
Blood iron decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	3 / 29 (10.34%)	5 / 53 (9.43%)
occurrences (all)	1	5	5
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	3 / 53 (5.66%)
occurrences (all)	0	1	3
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	4 / 29 (13.79%)	2 / 53 (3.77%)
occurrences (all)	0	4	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	0	3	0
White blood cell count decreased			
subjects affected / exposed	2 / 7 (28.57%)	4 / 29 (13.79%)	4 / 53 (7.55%)
occurrences (all)	5	7	5
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	1	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	3
C-reactive protein increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Stoma site pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	1 / 7 (14.29%)	6 / 29 (20.69%)	1 / 53 (1.89%)
occurrences (all)	1	6	1
Cardiac disorders			
Ventricular hypokinesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Atrial flutter			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Cardiac failure congestive			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 7 (28.57%)	8 / 29 (27.59%)	5 / 53 (9.43%)
occurrences (all)	3	11	7
Polyneuropathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	5 / 53 (9.43%)
occurrences (all)	1	1	6
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Disturbance in attention			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Brain fog			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 29 (10.34%)	1 / 53 (1.89%)
occurrences (all)	2	3	1
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	6 / 53 (11.32%)
occurrences (all)	0	2	7
Leukopenia			
subjects affected / exposed	1 / 7 (14.29%)	4 / 29 (13.79%)	7 / 53 (13.21%)
occurrences (all)	1	5	10
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 29 (17.24%)	20 / 53 (37.74%)
occurrences (all)	0	6	27
Anaemia			
subjects affected / exposed	5 / 7 (71.43%)	21 / 29 (72.41%)	37 / 53 (69.81%)
occurrences (all)	10	28	45
Haemolysis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	7 / 29 (24.14%)	12 / 53 (22.64%)
occurrences (all)	1	8	17

Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	2 / 53 (3.77%)
occurrences (all)	0	2	2
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Eye disorders			
Blindness unilateral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 7 (28.57%)	7 / 29 (24.14%)	13 / 53 (24.53%)
occurrences (all)	4	9	19
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	1	2
Nausea			
subjects affected / exposed	2 / 7 (28.57%)	11 / 29 (37.93%)	23 / 53 (43.40%)
occurrences (all)	3	15	27
Stomatitis			
subjects affected / exposed	2 / 7 (28.57%)	9 / 29 (31.03%)	18 / 53 (33.96%)
occurrences (all)	2	15	25
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Abdominal pain upper			

subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	3 / 53 (5.66%)
occurrences (all)	0	1	5
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	1 / 53 (1.89%)
occurrences (all)	0	2	1
Oral dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	5 / 53 (9.43%)
occurrences (all)	0	1	5
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	4 / 29 (13.79%)	16 / 53 (30.19%)
occurrences (all)	1	5	17
Glossodynia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	5 / 53 (9.43%)
occurrences (all)	0	1	5
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	7 / 29 (24.14%)	7 / 53 (13.21%)
occurrences (all)	0	8	7
Oral pain			
subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	3 / 53 (5.66%)
occurrences (all)	0	3	3
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	3 / 53 (5.66%)
occurrences (all)	0	5	3
Skin and subcutaneous tissue disorders			
Rash pruritic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	1	2

Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 29 (10.34%)	1 / 53 (1.89%)
occurrences (all)	0	3	1
Rash			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	3 / 53 (5.66%)
occurrences (all)	0	1	3
Skin hypopigmentation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	1	2
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Pollakiuria			

subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	4 / 53 (7.55%)
occurrences (all)	0	1	4
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Muscle tightness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	4 / 53 (7.55%)
occurrences (all)	0	0	4
Arthralgia			
subjects affected / exposed	1 / 7 (14.29%)	4 / 29 (13.79%)	4 / 53 (7.55%)
occurrences (all)	1	4	5
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	4 / 29 (13.79%)	0 / 53 (0.00%)
occurrences (all)	1	4	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	4 / 53 (7.55%)
occurrences (all)	0	0	4
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	3 / 53 (5.66%)
occurrences (all)	0	1	3
Candida infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	2 / 53 (3.77%)
occurrences (all)	1	0	2
Covid-19			
subjects affected / exposed	1 / 7 (14.29%)	1 / 29 (3.45%)	3 / 53 (5.66%)
occurrences (all)	1	1	3
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	1 / 53 (1.89%)
occurrences (all)	0	2	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	2 / 29 (6.90%)	3 / 53 (5.66%)
occurrences (all)	1	2	4
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	3
Localised infection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 29 (6.90%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	4 / 53 (7.55%)
occurrences (all)	0	1	5
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1

Lower respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Furuncle			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	2 / 53 (3.77%)
occurrences (all)	0	3	2
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	2 / 7 (28.57%)	8 / 29 (27.59%)	8 / 53 (15.09%)
occurrences (all)	2	15	12
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 29 (13.79%)	4 / 53 (7.55%)
occurrences (all)	0	7	7
Decreased appetite			
subjects affected / exposed	3 / 7 (42.86%)	3 / 29 (10.34%)	10 / 53 (18.87%)
occurrences (all)	3	3	11
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	8 / 29 (27.59%)	2 / 53 (3.77%)
occurrences (all)	0	10	2
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	6 / 29 (20.69%)	10 / 53 (18.87%)
occurrences (all)	0	13	11
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			

subjects affected / exposed	1 / 7 (14.29%)	8 / 29 (27.59%)	9 / 53 (16.98%)
occurrences (all)	2	11	13
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 29 (3.45%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	1 / 7 (14.29%)	0 / 29 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 March 2021	Herein is a summary of the major changes made to the original protocol dated 22 January 2021 and reflected in Amendment 1 dated 12 March 2021. The protocol has been amended to address feedback received from the FDA. The sections revised are as follows: For all safety run-in cohorts, modify the exceptions to dose-limiting toxicity (DLT) definition for neutropenia, thrombocytopenia, electrolyte abnormalities, nausea, vomiting, diarrhea, tumor flare phenomenon, tumor lysis and hypomagnesemia. For all safety run-in cohorts, incorporate Hy's law criteria in the DLT definition for liver enzymes. Add criteria for dose delay and permanent discontinuation for magrolimab. Modify SAE reporting requirements after the protocol-defined follow-up period.
17 March 2021	Herein is a summary of the major changes made to Amendment 1 dated 12 March 2021 and reflected in Amendment 2 dated 17 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 transaminase elevations for all safety run-in cohorts. Modify and provide additional guidance for dose modifications and delays for magrolimab.
16 December 2021	The major update(s) to the protocol and related rationale are as follows: An additional Phase 2 treatment arm was added that includes zimberelimab to allow the assessment of the efficacy and safety of magrolimab in combination with pembrolizumab +platinum + 5-FU (Cohort 1 Arm A) versus pembrolizumab + platinum + 5-FU (Cohort 1 Arm B) versus zimberelimab + platinum + 5-FU (Cohort 1 Arm C). Arm C was added to provide a comparison of zimberelimab with pembrolizumab in combination with magrolimab and chemotherapeutics in the treatment of head and neck squamous cell carcinoma (HNSCC).)
26 January 2022	The major updates to the protocol and related rationale are as follows: Inclusion Criteria was revised to update the hemoglobin level requirement from ≥ 9.5 g/dL at screening to ≥ 9 g/dL within 24 hours prior to dosing. This is supplemented with hemoglobin monitoring after magrolimab infusion to ensure adequate hemoglobin levels and transfusion guidelines for all patients. Dosage and Administration of Magrolimab and Safety Assessments were updated to link to postinfusion hemoglobin reporting requirements detailed in . Type and Screen and Direct Antiglobulin Test was updated to emphasize that the results must be available before the first dose of magrolimab. Type and Screen and Direct Antiglobulin Test was added to support the instructions for toxicity management related to anemia. Anemia management described in was updated to clarify the risk of anemia in the first 2 weeks of treatment and to provide additional guidance for enhanced anemia management. The pregnancy reporting period for patients who receive treatment with zimberelimab has been updated to 120 days from 90 days in response to input from the FDA on a different study.

20 September 2022	The major updates to the protocol and related rationale are as follows: Inclusion criteria (IC) and exclusion criteria (EC) were updated to add IC 16c (clarification to prior therapy requirements for Safety Run-in 2 and Phase 2 Cohort 3) and EC 8a (recommendation for testing of dihydropyrimidine dehydrogenase activity for patients in Phase 2 Cohort 1) Dosing instructions were updated. Clarifications to safety monitoring and laboratory assessments were made. Changes were made to Appendix 2 Schedule of Assessments. Appendix Table 2 was updated to clarify that visit may be conducted by telephone or in person. Appendix 5 was updated to update contraceptive requirements. Appendix 12 (Country-specific Considerations for France) was added to summarize updates made in the protocol to incorporate feedback received from the France health authority.
01 November 2023	Nonclinical and clinical experience with zimberelimab was added to provide a rationale for the use of zimberelimab in Cohort 1 Arm C. Objectives and endpoints were modified to indicate that disease progression will be determined by investigator assessment instead of independent central review. Instructions outlining the duration of postinfusion monitoring of patients after zimberelimab infusion have been added to align with the pharmacy instructions for zimberelimab. Instructions on the administration of docetaxel have been added to allow for the infusion duration to follow local practice. The benefit/risk assessment of the study was updated with potential overlapping toxicities and their mitigation per the current clinical experience with magrolimab. New sections for management of severe neutropenia and serious infections have been added. Cross-references to these sections have been added for further clarity on magrolimab dose delays with regards to these adverse events.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported