Clinical trial results:
A Phase 1/2 Open-Label, Multicenter Study to Assess the Safety, Pharmacokinetics, and Anti Tumor Activity of UCB6114 Administered Intravenously to Participants With Advanced Solid Tumors

Summary

EudraCT number	2019-002598-78
Trial protocol	GB
Global end of trial date	11 April 2024

Results information

Result version number	v2 (current)
This version publication date	11 June 2025
First version publication date	27 April 2025
Version creation reason	• Correction of full data set Alignment with final posting on ClinicalTrials.gov after NIH review.

Trial information

Trial identification

Sponsor protocol code	ONC001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04393298
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	07 June 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 April 2024
Global end of trial reached?	Yes
Global end of trial date	11 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Characterize the safety profile of UCB6114

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not applicable

Actual start date of recruitment	09 July 2020
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	United Kingdom: 70
Country: Number of subjects enrolled	United States: 23
Worldwide total number of subjects	93
EEA total number of subjects	0

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)	61
From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in July 2020 and concluded in April 2024.

Pre-assignment

Screening details:

The Participant Flow refers to the Safety Set (SS).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Ginisortamab 100 mg

Arm description:

Participants received ginisortamab monotherapy 100 milligrams (mg) as an intravenously (iv) infusion every 2 weeks (Q2W) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 100 mg at pre-specified timepoints.

Arm title	Part A: Ginisortamab 250 mg

Arm description:

Participants received ginisortamab monotherapy 250 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 250 mg at pre-specified timepoints.

Arm title	Part A: Ginisortamab 500 mg

Arm description:

Participants received ginisortamab monotherapy 500 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental

Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 500 mg at pre-specified timepoints.

Arm title	Part A: Ginisortamab 1000 mg

Arm description:

Participants received ginisortamab monotherapy 1000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
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Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 1000 mg at pre-specified timepoints.

Arm title	Part A: Ginisortamab 2000 mg

Arm description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 2000 mg at pre-specified timepoints.

Arm title	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D

Arm description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion (60-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 2000 mg at pre-specified timepoints.

Arm title	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D

Arm description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion (30-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental

Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 2000 mg at pre-specified timepoints.

Arm title	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D

Arm description:

Participants received ginisortamab monotherapy 3000 mg as an iv infusion (90-minute infusion) every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 3000 mg at pre-specified timepoints.

Arm title	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D

Arm description:

Participants received ginisortamab monotherapy 4000 mg as an iv infusion (120-minute infusion) every 4 weeks (Q4W) on Day 1 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 4000 mg at pre-specified timepoints.

Arm title	Part B: Ginisortamab 500 mg + TFD/TPI SoC

Arm description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with orally administered trifluridine/tipiracil (TFD/TPI) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 500 mg at pre-specified timepoints.

Arm title	Part B: Ginisortamab 1000 mg + TFD/TPI SoC

Arm description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental

Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 1000 mg at pre-specified timepoints.

Arm title	Part B: Ginisortamab 2000 mg + TFD/TPI SoC

Arm description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 2000 mg at pre-specified timepoints.

Arm title	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC

Arm description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 500 mg at pre-specified timepoints.

Arm title	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC

Arm description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 1000 mg at pre-specified timepoints.

Arm title	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC

Arm description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant

withdrawal.

Arm type	Experimental
Investigational medicinal product name	Ginisortamab
Investigational medicinal product code	
Other name	UCB6114
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Ginisortamab 2000 mg at pre-specified timepoints.

Number of subjects in period 1	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg
Started	3	5	5
Completed	1	1	2
Not completed	2	4	3
Clinical Progression: Not suitable for SFU return	-	-	-
Adverse event, serious fatal	-	-	-
Started a New Cancer Treatment	-	-	-
Due to symptoms (New Brain Metastases)	-	-	-
Symptomatic Cancer - Unfit to take a call	-	-	-
Consent withdrawn by participant, not due to AE	-	-	1
Passed Away on The 30 Oct 2020	1	-	-
Since no Treatment Administered at Cycle 2 Day 15	-	-	1
Disease Progression Confirmed by Scans (CT/MRI)	-	1	-
Disease Progression	-	1	-
Further Deterioration Noted at Clinic review	-	-	1
Adverse event, non-fatal	-	-	-
Progressive Disease and Subsequent Death	-	-	-
Patient Passed Away	-	-	-
Clinical Progression in Combination with AE	-	-	-
Progressive Disease (PD)	-	-	-
Progression	1	-	-
Progressive Disease - New Brain Mets on CT Head	-	-	-
Patient Discharged to Hospice	-	-	-
Clinical Progression	-	2	-
Sponsor decision- sepsis (treatment delay)	-	-	-
Patient Deceased	-	-	-

Lack of efficacy	-	-	-

Number of subjects in period 1	Part A: Ginisortamab 1000 mg	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D
Started	6	6	8
Completed	3	3	1
Not completed	3	3	7
Clinical Progression: Not suitable for SFU return	-	-	1
Adverse event, serious fatal	-	-	1
Started a New Cancer Treatment	-	1	-
Due to symptoms (New Brain Metastases)	-	-	1
Symptomatic Cancer - Unfit to take a call	-	-	-
Consent withdrawn by participant, not due to AE	-	-	-
Passed Away on The 30 Oct 2020	-	-	-
Since no Treatment Administered at Cycle 2 Day 15	-	-	-
Disease Progression Confirmed by Scans (CT/MRI)	-	-	-
Disease Progression	-	-	3
Further Deterioration Noted at Clinic review	-	-	-
Adverse event, non-fatal	-	1	-
Progressive Disease and Subsequent Death	-	-	-
Patient Passed Away	-	-	-
Clinical Progression in Combination with AE	-	-	-
Progressive Disease (PD)	3	-	-
Progression	-	-	-
Progressive Disease - New Brain Mets on CT Head	-	-	1
Patient Discharged to Hospice	-	-	-
Clinical Progression	-	-	-
Sponsor decision- sepsis (treatment delay)	-	1	-
Patient Deceased	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D
Started	8	8	8
Completed	4	5	2
Not completed	4	3	6
Clinical Progression: Not suitable for SFU return	-	-	-

Adverse event, serious fatal	1	-	1
Started a New Cancer Treatment	-	-	-
Due to symptoms (New Brain Metastases)	-	-	-
Symptomatic Cancer - Unfit to take a call	-	-	-
Consent withdrawn by participant, not due to AE	-	-	-
Passed Away on The 30 Oct 2020	-	-	-
Since no Treatment Administered at Cycle 2 Day 15	-	-	-
Disease Progression Confirmed by Scans (CT/MRI)	-	-	-
Disease Progression	2	1	2
Further Deterioration Noted at Clinic review	-	-	-
Adverse event, non-fatal	-	-	2
Progressive Disease and Subsequent Death	1	-	-
Patient Passed Away	-	1	-
Clinical Progression in Combination with AE	-	-	-
Progressive Disease (PD)	-	-	-
Progression	-	-	-
Progressive Disease - New Brain Mets on CT Head	-	-	-
Patient Discharged to Hospice	-	-	1
Clinical Progression	-	-	-
Sponsor decision- sepsis (treatment delay)	-	-	-
Patient Deceased	-	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC
Started	9	4	8
Completed	5	3	3
Not completed	4	1	5
Clinical Progression: Not suitable for SFU return	-	-	-
Adverse event, serious fatal	1	-	1
Started a New Cancer Treatment	-	-	-
Due to symptoms (New Brain Metastases)	-	-	-
Symptomatic Cancer - Unfit to take a call	1	-	-
Consent withdrawn by participant, not due to AE	-	-	-
Passed Away on The 30 Oct 2020	-	-	-
Since no Treatment Administered at Cycle 2 Day 15	-	-	-

Disease Progression Confirmed by Scans (CT/MRI)	-	-	-
Disease Progression	1	-	3
Further Deterioration Noted at Clinic review	-	-	-
Adverse event, non-fatal	-	-	-
Progressive Disease and Subsequent Death	-	-	-
Patient Passed Away	-	-	-
Clinical Progression in Combination with AE	1	-	-
Progressive Disease (PD)	-	-	-
Progression	-	1	1
Progressive Disease - New Brain Mets on CT Head	-	-	-
Patient Discharged to Hospice	-	-	-
Clinical Progression	-	-	-
Sponsor decision- sepsis (treatment delay)	-	-	-
Patient Deceased	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC
Started	5	3	7
Completed	3	2	0
Not completed	2	1	7
Clinical Progression: Not suitable for SFU return	-	-	1
Adverse event, serious fatal	1	-	1
Started a New Cancer Treatment	-	-	-
Due to symptoms (New Brain Metastases)	-	-	-
Symptomatic Cancer - Unfit to take a call	-	-	-
Consent withdrawn by participant, not due to AE	-	-	3
Passed Away on The 30 Oct 2020	-	-	-
Since no Treatment Administered at Cycle 2 Day 15	-	-	-
Disease Progression Confirmed by Scans (CT/MRI)	-	-	-
Disease Progression	-	-	1
Further Deterioration Noted at Clinic review	-	-	-
Adverse event, non-fatal	1	1	-
Progressive Disease and Subsequent Death	-	-	-
Patient Passed Away	-	-	-
Clinical Progression in Combination with AE	-	-	-

Progressive Disease (PD)	-	-	-
Progression	-	-	-
Progressive Disease - New Brain Mets on CT Head	-	-	-
Patient Discharged to Hospice	-	-	-
Clinical Progression	-	-	-
Sponsor decision- sepsis (treatment delay)	-	-	-
Patient Deceased	-	-	-
Lack of efficacy	-	-	1

Reporting groups	
Reporting group title	Part A: Ginisortamab 100 mg
Reporting group description:	
Participants received ginisortamab monotherapy 100 milligrams (mg) as an intravenously (iv) infusion every 2 weeks (Q2W) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 250 mg
Reporting group description:	
Participants received ginisortamab monotherapy 250 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 500 mg
Reporting group description:	
Participants received ginisortamab monotherapy 500 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 1000 mg
Reporting group description:	
Participants received ginisortamab monotherapy 1000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 2000 mg
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion (60-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion (30-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Reporting group description:	
Participants received ginisortamab monotherapy 3000 mg as an iv infusion (90-minute infusion) every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 4000 mg as an iv infusion (120-minute infusion) every 4 weeks (Q4W) on Day 1 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part B: Ginisortamab 500 mg + TFD/TPI SoC
Reporting group description:	
Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with orally administered trifluridine/tipiracil (TFD/TPI) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part B: Ginisortamab 1000 mg + TFD/TPI SoC
Reporting group description:	
Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of	

progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part B: Ginisortamab 2000 mg + TFD/TPI SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group values	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg
Number of subjects	3	5	5
Age Categorical Units: participants			
18 - <65 years	1	4	3
65 - <85 years	2	1	2
Age Continuous Units: Years			
arithmetic mean	65.0	54.4	58.2
standard deviation	± 1.0	± 11.0	± 12.2
Sex: Female, Male Units: participants			
Female	0	2	3
Male	3	3	2

Reporting group values	Part A: Ginisortamab 1000 mg	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D
Number of subjects	6	6	8
Age Categorical Units: participants			
18 - <65 years	3	3	7
65 - <85 years	3	3	1
Age Continuous Units: Years			
arithmetic mean	65.3	60.7	56.6
standard deviation	± 8.0	± 9.5	± 12.0

Sex: Female, Male Units: participants			
Female	2	1	3
Male	4	5	5

Reporting group values	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D
Number of subjects	8	8	8
Age Categorical Units: participants			
18 - <65 years	3	5	4
65 - <85 years	5	3	4
Age Continuous Units: Years			
arithmetic mean	67.3	60.9	60.8
standard deviation	± 6.3	± 6.7	± 17.6
Sex: Female, Male Units: participants			
Female	3	5	2
Male	5	3	6

Reporting group values	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC
Number of subjects	9	4	8
Age Categorical Units: participants			
18 - <65 years	7	4	7
65 - <85 years	2	0	1
Age Continuous Units: Years			
arithmetic mean	57.6	51.5	57.6
standard deviation	± 9.5	± 6.2	± 14.2
Sex: Female, Male Units: participants			
Female	4	2	2
Male	5	2	6

Reporting group values	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC
Number of subjects	5	3	7
Age Categorical Units: participants			
18 - <65 years	3	2	5
65 - <85 years	2	1	2
Age Continuous Units: Years			
arithmetic mean	58.6	63.0	61.1
standard deviation	± 10.7	± 13.0	± 9.1

Sex: Female, Male Units: participants			
Female	2	1	3
Male	3	2	4

Reporting group values	Total		
Number of subjects	93		
Age Categorical Units: participants			
18 - <65 years	61		
65 - <85 years	32		
Age Continuous Units: Years arithmetic mean standard deviation	- -		
Sex: Female, Male Units: participants			
Female	35		
Male	58		

End points

End points reporting groups

Reporting group title	Part A: Ginisortamab 100 mg
Reporting group description:	
Participants received ginisortamab monotherapy 100 milligrams (mg) as an intravenously (iv) infusion every 2 weeks (Q2W) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 250 mg
Reporting group description:	
Participants received ginisortamab monotherapy 250 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 500 mg
Reporting group description:	
Participants received ginisortamab monotherapy 500 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 1000 mg
Reporting group description:	
Participants received ginisortamab monotherapy 1000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A: Ginisortamab 2000 mg
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion (60-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 2000 mg as an iv infusion (30-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Reporting group description:	
Participants received ginisortamab monotherapy 3000 mg as an iv infusion (90-minute infusion) every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D
Reporting group description:	
Participants received ginisortamab monotherapy 4000 mg as an iv infusion (120-minute infusion) every 4 weeks (Q4W) on Day 1 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part B: Ginisortamab 500 mg + TFD/TPI SoC
Reporting group description:	
Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with orally administered trifluridine/tipiracil (TFD/TPI) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.	
Reporting group title	Part B: Ginisortamab 1000 mg + TFD/TPI SoC
Reporting group description:	
Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of	

progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part B: Ginisortamab 2000 mg + TFD/TPI SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Primary: Percentage of Participants with treatment-emergent adverse events (TEAEs)

End point title	Percentage of Participants with treatment-emergent adverse events (TEAEs)[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study medication, whether or not considered related to the study medication. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study medication. A treatment-emergent adverse event (TEAE) was defined as any AE with a start date on or after the first dose of UCB6114 up until the last dose of Ginisortamab (UCB6114) +30 days (i.e. up to 3.8 years). The SS consisted of all study participants who received at least 1 full or partial dose of Ginisortamab (UCB6114).

End point type	Primary

End point timeframe:

From Baseline until the End of Study (up to 3.8 years)

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	5	6
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	8	8
Units: percentage of participants				
number (not applicable)	100	87.5	100	87.5

End point values	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	8
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	3	7	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants based on severity of treatment-emergent adverse events

End point title	Percentage of participants based on severity of treatment-emergent adverse events[2]

End point description:

AE is any untoward medical occurrence in patient or clinical study participant, temporally associated with use of study medication, whether or not considered related to study medication. AE can therefore be any unfavorable and unintended sign(abnormal laboratory finding), symptom, or disease(new or exacerbated) temporally associated with use of study medication. TEAE: any AE with start date on or after first dose of UCB6114 up until last dose of Ginisortamab(UCB6114)+30 days. Event for which no Common Terminology Criteria for AE(CTCAE) severity grade was recorded by investigator but intensity was recorded instead was assigned as follows to CTCAE severity grade:Severe=Grade 3, Life Threatening (indicated on electronic case report form (eCRF) for event that is serious)=Grade 4, Death

(indicated on the eCRF for event that is serious or has outcome of death)=Grade 5. As planned, data reported for National Cancer Institute (NCI) CTCAE grade >=3 TEAEs and related TEAEs. Safety set.

End point type	Primary

End point timeframe:

From Baseline until the End of Study (up to 3.8 years)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	5	6
Units: percentage of participants				
number (not applicable)				
NCI CTCAE grade >=3 TEAEs	66.7	40.0	40.0	0
NCI CTCAE grade >=3 related TEAEs	0	0	0	0

End point values	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	8	8
Units: percentage of participants				
number (not applicable)				
NCI CTCAE grade >=3 TEAEs	50.0	62.5	50.0	37.5
NCI CTCAE grade >=3 related TEAEs	0	0	0	0

End point values	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	8
Units: percentage of participants				
number (not applicable)				
NCI CTCAE grade >=3 TEAEs	62.5	55.6	75.0	87.5
NCI CTCAE grade >=3 related TEAEs	12.5	22.2	0	25.0

End point values	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	3	7	
Units: percentage of participants				
number (not applicable)				
NCI CTCAE grade >=3 TEAEs	100	100	85.7	
NCI CTCAE grade >=3 related TEAEs	40.0	0	14.3	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with dose-limiting toxicities (DLTs)

End point title	Number of Participants with dose-limiting toxicities (DLTs)[3]

End point description:

DLT:any AE at least related to study medication that occurs during Cycle 1 and met following criteria:Grade (Gr) 3 or 4 nonhematological toxicity according to NCI CTCAE(Version 5.0) except for alopecia, or nausea, vomiting, or diarrhea that reverses to Gr ≤2 within 24 hours (hr) with appropriate medical therapy; Gr 3 or 4 biochemical abnormality that persists despite maximal supportive treatment or biochemical abnormalities that is symptomatic and nontransient; Any Gr ≥3 hematological toxicity of >5 days duration or febrile neutropenia (absolute neutrophil count [ANC]<1000/cubic millimeter[mm3] with single temperature of >38.3°C or sustained temperature ≥38°C for more than one hr), infection with Gr 3 or 4 neutropenia, thrombocytopenia with bleeding or requiring platelet transfusion, or Gr 4 thrombocytopenia; Prolonged Gr 2 diarrhea(>7 days) despite adequate antidiarrheal medication, or multiple Grade 1or 2 toxicities (eg, Gr 1 or 2 diarrhea, vomiting, rash, and fatigue). Safety set.

End point type	Primary

End point timeframe:

From Baseline throughout 28 days (Cycle 1)

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

End point values	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	5	6
Units: participants	0	0	0	0

End point values	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	8	8
Units: participants	0	0	0	0

End point values	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	8
Units: participants	0	1	0	1

End point values	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	3	7	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A and A1: UCB6114 Serum concentration by scheduled assessment and cohort

End point title	Part A and A1: UCB6114 Serum concentration by scheduled assessment and cohort[4]

End point description:

Blood samples for ginisortamab serum concentration analysis were collected at different timepoints following the first dose of ginisortamab. The data is reported for Part A and A1. Pharmacokinetic Set (PKS): all participants of SS with at least 1 evaluable PKS concentration (ie, sample above lower limit of quantitation [0.02µg/mL] and for which date, sample time, prior date an dosing time are known). n=participants evaluable at specified time points. 9999: GeoMean and GeoCV (%) were only calculated if at least 2/3 of concentrations are quantified at respective timepoint. 99999: No arms of Part A1 had data collection on Cycle 2 Day 15 Predose. 999: Dosing was only performed on Day 1 of each cycle for Part A1:Ginisortamab 3000mg Q3W(90-min) 21-day and Ginisortamab 4000mg Q4W(120-min) 28-day arms. Hence, Predose, Day 15 of Cycle 1 was not collected.

End point type	Secondary

End point timeframe:

Parts A: Cycle 1 (Day 1 end of infusion [EOI] and Day 15 Predose), Cycle 2 (Day 1 Predose and Day 15 Predose); Part A 1: Cycle 1 (Day 1 EOI and Day 15 Predose), Cycle 2 (Day 1 Predose)

Notes:

[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: UCB6114 Serum concentration for Part B and C arms are reported in the separate endpoint. Therefore, no data was reported for these arms in this endpoint.

End point values	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 250 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	5	6
Units: microgram per milliliter (ug/mL)				
geometric mean (geometric coefficient of variation)				

Cycle 1 Day 1 EOI (n=3,5,4,5,6,8,8,8,5)	18.0477 (± 10.0206)	72.5261 (± 24.1924)	130.7757 (± 14.1088)	277.5536 (± 10.8287)
Cycle 1 Day 15 Predose (n=3,5,5,6,5,7,8,0,0)	4.4210 (± 10.1288)	12.8115 (± 27.1385)	24.3743 (± 31.2011)	61.4527 (± 33.1491)
Cycle 2 Day 1 Predose (n=2,1,5,6,4,4,8,6,7)	9999 (± 9999)	9999 (± 9999)	34.6409 (± 26.9986)	67.0799 (± 37.9557)
Cycle 2 Day 15 Predose (n=1,1,4,5,4,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	42.6861 (± 38.1929)	78.2336 (± 35.0467)

End point values	Part A: Ginisortamab 2000 mg	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	8	8
Units: microgram per milliliter (ug/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 EOI (n=3,5,4,5,6,8,8,8,5)	552.3530 (± 19.5548)	592.2331 (± 26.1556)	593.1846 (± 22.2154)	946.0883 (± 19.3798)
Cycle 1 Day 15 Predose (n=3,5,5,6,5,7,8,0,0)	92.0396 (± 38.4595)	105.5277 (± 25.1756)	97.1957 (± 39.3439)	999 (± 999)
Cycle 2 Day 1 Predose (n=2,1,5,6,4,4,8,6,7)	149.3886 (± 37.0769)	193.4242 (± 34.5942)	147.2154 (± 26.4979)	124.7274 (± 44.3198)
Cycle 2 Day 15 Predose (n=1,1,4,5,4,0,0,0,0)	166.4011 (± 34.1041)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: microgram per milliliter (ug/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 EOI (n=3,5,4,5,6,8,8,8,5)	1357.6103 (± 20.4135)			
Cycle 1 Day 15 Predose (n=3,5,5,6,5,7,8,0,0)	999 (± 999)			
Cycle 2 Day 1 Predose (n=2,1,5,6,4,4,8,6,7)	98.9331 (± 33.8567)			
Cycle 2 Day 15 Predose (n=1,1,4,5,4,0,0,0,0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B and C: UCB6114 concentration by scheduled assessment and dose

level	
End point title	Part B and C: UCB6114 concentration by scheduled assessment and dose level[5]

End point description:

Blood samples for ginisortamab serum concentration analysis were collected at timepoints following the (Cycle 1 Day 1) and the (Cycle 2 Day 1) administration of ginisortamab. Data is reported for Part B and Part C. The PKS included all study participants in the SS (all study participants who received at least 1 full or partial dose of Ginisortamab [UCB6114]) who had at least 1 evaluable PKS concentration (ie, a sample which is above the lower limit of quantitation [0.02µg/mL] and for which the date and time of the sample and prior date and time of dosing are known). Here, "n" signifies participants who were evaluable at specified time points. Here, "99999" signifies GeoMean and GeoCV (%) were only calculated if at least 2/3 of the concentrations are quantified at the respective timepoint.

End point type	Secondary

End point timeframe:

Parts B and C: Cycle 1 (Day 1 EOI and Day 15 Predose), Cycle 2 (Day 1 Predose and Day 15 Predose)

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: UCB6114 Serum concentration for Part A and A1 arms are reported in the separate endpoint. Therefore, no data was reported for these arms in this endpoint.

End point values	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part B: Ginisortamab 1000 mg + TFD/TPI SoC	Part B: Ginisortamab 2000 mg + TFD/TPI SoC	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	8	5
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 EOI (n=7,4,7,5,3,7)	104.0606 (± 15.3565)	250.8708 (± 7.6032)	463.5265 (± 28.6333)	122.8221 (± 14.8778)
Cycle 1 Day 15 Predose (n=8,3,7,5,3,7)	19.7473 (± 42.6072)	37.4171 (± 14.8496)	83.4236 (± 30.8533)	16.8917 (± 33.2664)
Cycle 2 Day 1 Predose (6,3,6,5,3,5)	33.0061 (± 35.3957)	61.0398 (± 5.0117)	118.0926 (± 29.3051)	25.4863 (± 53.6347)
Cycle 2 Day 15 Predose (n=6,4,5,3,2,3)	38.3595 (± 42.1013)	55.0249 (± 39.4082)	135.5849 (± 32.8644)	24.7120 (± 83.6183)

End point values	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 EOI (n=7,4,7,5,3,7)	175.0745 (± 34.7390)	471.9576 (± 17.1727)		
Cycle 1 Day 15 Predose (n=8,3,7,5,3,7)	32.3094 (± 56.2327)	70.7026 (± 50.9842)		
Cycle 2 Day 1 Predose (6,3,6,5,3,5)	82.7657 (± 47.9648)	141.6084 (± 30.8310)		

Cycle 2 Day 15 Predose (n=6,4,5,3,2,3)	99999 (± 99999)	135.0042 (± 43.8716)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to End of the Study (up to 3.8 years)

Adverse event reporting additional description:

A TEAE was defined as any AE with a start date on or after the first dose of UCB6114 until the last dose of Ginisortamab (UCB6114) +30 days. A pre-treatment AE which increased in severity on or after the first dose of study treatment was also counted as a TEAE. Analysis set: safety set.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Part A: Ginisortamab 1000 mg

Reporting group description:

Participants received ginisortamab monotherapy 1000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A: Ginisortamab 500 mg

Reporting group description:

Participants received ginisortamab monotherapy 500 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A: Ginisortamab 250 mg

Reporting group description:

Participants received ginisortamab monotherapy 250 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A: Ginisortamab 100 mg

Reporting group description:

Participants received ginisortamab monotherapy 100 milligrams (mg) as an intravenously (iv) infusion every 2 weeks (Q2W) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A: Ginisortamab 2000 mg

Reporting group description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part B: Ginisortamab 1000 mg + TFD/TPI SoC

Reporting group description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part B: Ginisortamab 2000 mg + TFD/TPI SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with orally administered TFD/TPI on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 1000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part B: Ginisortamab 500 mg + TFD/TPI SoC

Reporting group description:

Participants received ginisortamab 500 mg as an iv infusion Q2W in combination with orally administered trifluridine/tipiracil (TFD/TPI) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D

Reporting group description:

Participants received ginisortamab monotherapy 4000 mg as an iv infusion (120-minute infusion) every 4 weeks (Q4W) on Day 1 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC

Reporting group description:

Participants received ginisortamab 2000 mg as an iv infusion Q2W in combination with mFOLFOX6 chemotherapy (oxaliplatin, leucovorin, and 5-fluorouracil) on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D

Reporting group description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion (30-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D

Reporting group description:

Participants received ginisortamab monotherapy 2000 mg as an iv infusion (60-minute infusion) Q2W on Day 1 and Day 15 of each 28-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Reporting group title	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D

Reporting group description:

Participants received ginisortamab monotherapy 3000 mg as an iv infusion (90-minute infusion) every 3 weeks (Q3W) on Day 1 of each 21-day treatment cycle until the occurrence of progressive disease, unacceptable toxicity, or participant withdrawal.

Serious adverse events	Part A: Ginisortamab 1000 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 250 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	3 / 5 (60.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 hypertension			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Overdose			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Toxicity to various agents			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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

Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Large intestine perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Urogenital fistula			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
Peritonitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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 bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (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	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 2000 mg	Part B: Ginisortamab 1000 mg + TFD/TPI SoC
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	2 / 4 (50.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Overdose			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (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
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Cerebrovascular accident			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Large intestine perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Biliary obstruction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urogenital fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			
Peritonitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 bacterial			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (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
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (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
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (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
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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 bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (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	Part B: Ginisortamab 2000 mg + TFD/TPI SoC	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 8 (50.00%)	5 / 5 (100.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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			
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (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
Catheter site thrombosis			

subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (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

Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Toxicity to various agents			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (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
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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			
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Large intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Large intestinal obstruction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (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
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (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
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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			

Urogenital fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Sacral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Back pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Peritonitis bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (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
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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 sepsis			

subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (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	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 9 (44.44%)	5 / 8 (62.50%)	2 / 7 (28.57%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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			
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (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
Catheter site thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
Overdose			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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

Toxicity to various agents			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Humerus fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Febrile neutropenia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (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
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 lower			

subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (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
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Intestinal obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Renal and urinary disorders			
Urogenital fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Sacral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
Peritonitis bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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

Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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 infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (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			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (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
Neutropenic sepsis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A1:	Part A1:	Part A1:

	Ginisortamab 2000 mg Q2W (30-min), 28D	Ginisortamab 2000 mg Q2W (60-min), 28D	Ginisortamab 3000 mg Q3W (90-min), 21D
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	1 / 8 (12.50%)	2 / 8 (25.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Hypoxia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Toxicity to various agents			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Myocardial infarction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (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
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Nausea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Large intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Intestinal obstruction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Urogenital fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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

Sacral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
Peritonitis bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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

Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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 bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (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

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

Non-serious adverse events	Part A: Ginisortamab 1000 mg	Part A: Ginisortamab 500 mg	Part A: Ginisortamab 250 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	5 / 5 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 6 (50.00%)	3 / 5 (60.00%)	1 / 5 (20.00%)
occurrences (all)	8	3	1
Feeling cold			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Balanoposthitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dyspnoea exertional			

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood triglycerides increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
International normalised ratio increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Craniofacial fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Palpitations			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cold dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abnormal faeces			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aorto-oesophageal fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dry mouth			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Obstruction gastric			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 6 (16.67%)	2 / 5 (40.00%)	2 / 5 (40.00%)
occurrences (all)	3	2	2
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophageal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hydroureter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	3 / 6 (50.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	4	1	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Dehydration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: Ginisortamab 100 mg	Part A: Ginisortamab 2000 mg	Part B: Ginisortamab 1000 mg + TFD/TPI SoC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	2	4	2
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Aspiration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	1	3
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	2	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	4
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ejection fraction decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	1	5
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Prothrombin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Craniofacial fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cold dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	3 / 4 (75.00%)
occurrences (all)	2	0	17
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	2 / 4 (50.00%)
occurrences (all)	0	4	4
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aorto-oesophageal fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	4 / 6 (66.67%)	2 / 4 (50.00%)
occurrences (all)	0	7	2
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Obstruction gastric			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	4 / 6 (66.67%)	2 / 4 (50.00%)
occurrences (all)	2	4	3
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	2	2
Hepatobiliary disorders			

Hepatomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hydroureter			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Back pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Sinusitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Urosepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B: Ginisortamab 2000 mg + TFD/TPI SoC	Part C: Ginisortamab 500 mg + mFOLFOX6 SoC	Part C: Ginisortamab 1000 mg + mFOLFOX6 SoC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	5 / 5 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Embolism			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vena cava thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 8 (25.00%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	3	3	2
Feeling cold			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Peripheral swelling			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 8 (12.50%)	3 / 5 (60.00%)	1 / 3 (33.33%)
occurrences (all)	1	3	2
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Epistaxis			

subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Amylase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood triglycerides increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased			
subjects affected / exposed	4 / 8 (50.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	7	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			

subjects affected / exposed	2 / 8 (25.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	5 / 8 (62.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	11	2	0
Lipase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Craniofacial fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arrhythmia supraventricular			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 8 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Parosmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Memory impairment			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 8 (75.00%)	3 / 5 (60.00%)	1 / 3 (33.33%)
occurrences (all)	14	11	5
Neutropenia			
subjects affected / exposed	3 / 8 (37.50%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	8	1	3
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	2	3	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Abdominal discomfort			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aorto-oesophageal fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	4 / 8 (50.00%)	3 / 5 (60.00%)	2 / 3 (66.67%)
occurrences (all)	4	3	2
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	3 / 5 (60.00%)	2 / 3 (66.67%)
occurrences (all)	2	4	3
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0

Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Epigastric discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obstruction gastric			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 8 (50.00%)	5 / 5 (100.00%)	0 / 3 (0.00%)
occurrences (all)	6	5	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oesophageal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	4 / 5 (80.00%)	0 / 3 (0.00%)
occurrences (all)	1	7	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Alopecia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	2 / 8 (25.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hydroureter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	1 / 8 (12.50%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	2	3	2
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Limb discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pathological fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Candida infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Urosepsis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 8 (37.50%)	3 / 5 (60.00%)	0 / 3 (0.00%)
occurrences (all)	3	3	0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 8 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B: Ginisortamab 500 mg + TFD/TPI SoC	Part A1: Ginisortamab 4000 mg Q4W (120-min), 28D	Part C: Ginisortamab 2000 mg + mFOLFOX6 SoC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	8 / 8 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fatigue			

subjects affected / exposed	5 / 9 (55.56%)	3 / 8 (37.50%)	5 / 7 (71.43%)
occurrences (all)	8	3	6
Feeling cold			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 9 (33.33%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Prostatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aspiration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Amylase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 9 (33.33%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	3	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Blood bilirubin increased			

subjects affected / exposed	3 / 9 (33.33%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Gamma-glutamyltransferase			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	3 / 7 (42.86%)
occurrences (all)	4	0	4
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Prothrombin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	2	2	2
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Craniofacial fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Humerus fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Arrhythmia supraventricular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cold dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lethargy			

subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	3	1	2
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Neurotoxicity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 9 (55.56%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	12	5	4
Neutropenia			
subjects affected / exposed	5 / 9 (55.56%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	14	0	3
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	2
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	2 / 9 (22.22%)	2 / 8 (25.00%)	3 / 7 (42.86%)
occurrences (all)	2	3	3
Abdominal pain upper			
subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Abnormal faeces			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aorto-oesophageal fistula			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Ascites			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	2
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	6	1	2
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Obstruction gastric			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	6 / 9 (66.67%)	1 / 8 (12.50%)	4 / 7 (57.14%)
occurrences (all)	12	2	4
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 9 (55.56%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	6	1	1
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Alopecia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hydroureter			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Osteoporosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 9 (22.22%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Synovial cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0

Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	1	1	2
Urosepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vascular device infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 9 (66.67%)	2 / 8 (25.00%)	5 / 7 (71.43%)
occurrences (all)	7	2	5
Dehydration			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part A1: Ginisortamab 2000 mg Q2W (30-min), 28D	Part A1: Ginisortamab 2000 mg Q2W (60-min), 28D	Part A1: Ginisortamab 3000 mg Q3W (90-min), 21D
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	7 / 8 (87.50%)	7 / 8 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 8 (62.50%)	3 / 8 (37.50%)	0 / 8 (0.00%)
occurrences (all)	6	4	0
Feeling cold			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 8 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	2
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Drug hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pruritus genital			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	3 / 8 (37.50%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 8 (37.50%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Electrocardiogram T wave amplitude decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Craniofacial fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Balance disorder			

subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cold dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	1	1	2
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Abnormal faeces			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aorto-oesophageal fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	4	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eructation			

subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Obstruction gastric			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 8 (25.00%)	1 / 8 (12.50%)	2 / 8 (25.00%)
occurrences (all)	3	1	3
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 8 (25.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hydroureter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Limb discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Sinusitis bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	1
Hypophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2020	Protocol Amendment 1 was dated 11-Jun-2020: - Sponsor name was updated. - Number of participants statement updated. - Timing of SFU visit updated and allowance for Final Visit was conducted by phone. - Footnote to the schema was updated. - Cycle 2 Day 2 column and Cycle 3 onwards Day 8 column deleted as all assessments on those days was deleted. - Blood collection for PK analysis row – samples deleted from Cycle 2 Day 2 and Final Visit. - Blood collection immunogenicity (ADA) row – samples deleted from Cycle 2 Day 15, Cycle 3 onwards Day 15, and Final Visit. - Added new row for blood collection for circulating tumor deoxyribonucleic acid (ctDNA) analysis. - Added new row for survival census. - Added new row for coagulation. - Footnote a was corrected to delete reference to Day 2 of Cycle 2. - Footnote was deleted. - Footnote was corrected to delete reference to Day 8 of Cycle 3 and Cycle 4 onwards. - Footnote was added to the headings for columns Cycle 1 (Days 1 and 15), Cycle 2 (Day 15), and Cycle 3 onwards (Days 1 and 15) to specify timing of predose and postdose safety assessments at these visits. - Footnote was revised to include coagulation. - Footnote was revised to specify timing of electrocardiogram (ECG) assessments due to reduction in number of assessments. - Footnote was revised to clarify use of urine vs serum pregnancy assessments. -Footnote was revised to correct a grammatical error. - Footnote was added to the Cycle 1 Day 1 for the urinalysis, hematology, blood chemistry, and coagulation rows. - Footnote was revised to add coagulation, Clarification of timing of Day 1 predose sample collection was added. Clarified that laboratory tests may be obtained 24h prior to the scheduled visit. - Footnote was revised to specify timing of vital sign assessments on Cycle 1 Day 1. - Footnote was revised to specify types of urine abnormalities that require microscopic analysis. - Footnote was revised to specify collection windows for end of infusion samples.

11 June 2020	Protocol Amendment 1 was dated 11-Jun-2020: - Footnote was revised to clarify collection of antidrug antibody (ADA) samples. -Footnote was revised to add use of samples for assay verification. - Footnote was revised to clarify timing of tumor assessments prior to starting study medication and to specify exception for prior computed tomography (CT) or magnetic resonance imaging (MRI) scan. - Footnote was added to specify which procedures were assessed Day 15 only of Cycle 1. - Footnote was added to specify timing of ctDNA sampling on Cycle 3 onwards Day 1. - Footnote was added to specify that echocardiograms were only be assessed at evennumbered cycles from Cycle 3 onwards. - Footnote was added to clarify requirements for tumor assessments at Safety Follow-Up (SFU) visit. - Footnote was added to clarify when tumor assessment is not required at SFU Visit. - Footnote was added to specify predose eligibility assessment at Cycle 1 Day 1. - Footnote was added to clarify liver laboratory assessments in the case of bone metastases. - Footnote was added to specify completion of survival census. - Footnote was added to clarify timing of complete and symptom-directed physical examinations. - Row for Part B: colorectal carcinoma changed to colorectal adenocarcinoma. - Sentence “Higher or lower doses may be considered based on emerging data.” was deleted. - Pancreatic carcinoma changed to pancreatic adenocarcinoma. - Specified 16-day observation for participants who enroll after sentinel participant experiences a dose limiting toxicity (DLT). - Clarification of design choices with expanded explanatory text. - Clarified Safety Monitoring Committee (SMC) role in dose decisions and role in adding additional dose levels. Clarified that doses above 2000mg require an amendment. - Row Part A: Term pancreatic carcinoma corrected to term pancreatic adenocarcinoma Rows Part B, Part D, and Part F: Term colorectal carcinoma corrected to colorectal adenocarcinoma.
11 June 2020	Protocol Amendment 1 was dated 11-Jun-2020: - Inclusion criterion was renumbered; terms pancreatic carcinoma and colorectal carcinoma corrected pancreatic adenocarcinoma and colorectal adenocarcinoma, respectively. - Inclusion criterion was renumbered and was changed from “or” to “and”. - Exclusion criterion was deleted. Exclusion criterion was renumbered; and was modified to add history of biliary stent. - Exclusion criterion was renumbered and was modified to remove “or any other type of medical research”. - New criterion: Exclusion criterion was added to specify criterion for renal function. - New criterion: Exclusion criterion was added to exclude major surgery prior to study drug initiation. - New criterion: Exclusion criterion was added to specify criteria for coagulation parameters. - Drug accountability procedure changed to use of drug accountability logs instead of electronic case report form (eCRF). - Term “concomitant” was deleted from (redundant with sentence preceding bulleted list) - Footnote was changed to spell out pharmacokinetics (PK) terms. - List of abbreviations for table was updated. - Footnote was deleted as any doses higher than 2000mg would be subject to a substantial protocol amendment. - Text was added to specify the maximum amount of blood collected from participants during each part of the study. - Coagulation added to sample types; number and volumes of samples updated, total blood volumes updated. - Clarified timing of complete and symptomdirected physical examinations. Clarified that height were only be recorded at Screening. - Coagulation added to types of laboratory assessments. - Text was updated to reflect use of serum or urine pregnancy tests. - AUCtau changed to AUC0-336h. - Footnote was updated to reflect reporting. - Deleted PK sample collection from Final Visit.

11 June 2020	Protocol Amendment 1 was dated 11-Jun-2020:- Cycle 1, Day 15 (samples 9 and 10), Day 16 (sample 11), and Day 22 (sample 12) sampling times and predose/postdose timepoints updated. - Cycle 2, Day 1 (samples 13, 14, and 15) sampling times and predose/postdose timepoints updated. - First note in footnotes updated to reflect number of samples and blood volumes. - New note added to footnotes to specify predose sample summarization in statistical analysis. - Footnote added to specify collection of Cycle 3 Day 1 PK sample in subjects who were not continuing treatment. - Specified exception for prior CT or MRI scan. Moved tumor assessments from Final Visit to SFU visit. - Blood volumes updated. - New section added. - Blood volume corrected. - Sentence regarding laboratory manual deleted. - Text updated to reflect reduction in total number of samples taken during Cycles 2, 3, and 4. - Blood sample timepoints for ADA analysis: Deletion of Day 15 samples for Cycles 2, 3, and 4. Clarification of timing of sampling at SFU Visit. Comment column removed. - Updated definitions of analysis sets, including deletion of Full Analysis Set (FAS) and addition of Anti-drug Antibody Set (ADAS). - Added text omitted in error from original version of protocol. - Updated planned analyses. Updated vital signs information. - Clarification of study parts. - Updated planned analyses. - Updated terminology. - Clarification of definitions. - Noted that further details were provided in statistical analysis plan (SAP). - Clarified text for addition of dose level based on emerging data. - Added coagulation parameters as a row. Deleted coagulation tests from other Screening tests row. Changed "Other Screening Tests" to "Other Tests). Blood urea nitrogen (BUN) or urea creatinine changed to BUN or urea Added serum creatinine. - Added coagulation to abnormal laboratory test results bullet for events meeting the AE definition.
11 June 2020	Protocol Amendment 1 was dated 11-Jun-2020: - Aligned text to be consistent with Response Evaluation Criteria in Solid Tumors v1.1 (RECIST v1.1) guidelines and to the eCRF mapping of terms. - Added activated partial thromboplastin time (aPTT), international normalized ratio (INR), and prothrombin time (PT) to list of abbreviations. - Correction of spelling, grammar, or typographical errors.
12 October 2020	Protocol Amendment 2 was dated 12-Oct-2020: - Separated the terms "phosphorus or phosphate" and "albumin". - Section was restructured to clarify situations of: • participant discontinuation • treatment discontinuation • study/site discontinuation by sponsor. - Added language to Criterion clarifying that the presence of liver metastases must be recorded in the eCRF. - • Added language allowing palliative bone-directed radiotherapy as concomitant treatment • Defined taking prohibited medications as defined elsewhere in the protocol as a criterion for discontinuation of study medication. - Overall survival (OS) was originally measured from date of study enrollment to date of death. Revised to measure OS from the date of first dosing to date of death. - Excepted palliative bone-directed radiotherapy from criteria for discontinuation Added Criterion. - Added language allowing temporary suspension of study medication for up to 3 weeks. – Added clarification that site was attempt to contact participants who withdraw from the study to complete the SFU and Final Visits. - Added a section on Coronavirus Disease 2019 (COVID-19) Pandemic. - Added language regarding collection of AEs and SAEs related to COVID-19. - Replaced "early discontinuation visit" with "Safety Follow-up Visit" when specifying follow-up for positive pregnancy test. - Added language regarding missing doses due to the COVID-19 Pandemic. - In Amendment 1, the Summary of Changes table footnote reference to Cycle 1 Day 15/16 was deleted. - Footnote was added to the coagulation and ECOG assessments on Cycle 1 Day 15/16.
12 October 2020	Protocol Amendment 2 was dated 12-Oct-2020: - Flexibility in assessment collection for PK sampling and Screening procedures to accommodate potential impacts of the COVID-19 pandemic. - Added survival census to SFU Visit. - Added language to footnote clarifying survival census at SFU Visit. Added language to Footnote allowing collection of laboratory tests from local laboratories. - Added language to footnote expanding window of PK assessments scheduled for Day 16 to Day 21 in context of COVID-19. - Language added to define screen failures due to impacts of the COVID-19 pandemic. - Language added to define screen failures due to impacts of the COVID-19 pandemic. Exclusion Criterion was modified to remove separate conditions for study participants with bone metastases.

07 January 2021	Protocol Amendment 3 was dated 07-Jan-2021: - Corrected 24h Rapid Response Helpline phone number. - Added text pertaining to dose escalation (combination therapy) modules Part B and Part C throughout the document,including the synopsis, objectives and endpoints, schema, schedules of activities, background, design, benefi t-risk assessment, dose selection, selection and withdrawal criteria, treatments administered, concomitant medications, dose modifi cations, and statistical analyses. - Clarifi cation of available literature on expression data in tumors. - For better clarity, separated objectives and endpoints for Part A, A1, B, and C to 2 separate tables,one for Parts A and A1, and a second for Part B and C. Updated objectives and endpoints for Parts A and A1, and Parts B and C. Updated objectives and endpoints for Parts D, E, F, and G. - Updated Figure to reflect changes to terminology in overall design. - Added text clarifying types of tumors selected for Part A. - Exclusion criterion renumbered. Text was corrected from: "In the presence of therapeutic intent to anticoagulate the participant:INR or PT and aPTT…" to "In the presence of therapeutic intent to anticoagulate the participant: INR or PT or aPTT…" - Updated dose formulation row to clarify formulation. - Moved text and table pertaining to PK analyses. -Added text specifying which PK concentrations disclosed on public registries for Part A, Part B, and Part C. - Correction of spelling, grammar, or typographical errors.
17 June 2021	Protocol Amendment 4 was dated 17-Jun-2021: - Addition of the IND number. - Pharmacodynamic endpoint related to protein marker levels was updated as follows: "Change in protein marker levels in blood by scheduled assessment and dose level". - Update of the definition of DLTs to confirm that they include any AE at least possibly related to the study medication and fulfilling the specified criteria. - Revision of the DLT definition for Part A (update of the febrile neutropenia definition as per CTCAE v5.0 and addition of Grade 4 thrombocytopenia). - Revision of the DLT definition for Part B and Part C (addition of any Grade 4 thrombocytopenia). - Revision of the eligibility criteria such that participants with locally advanced disease must also had unresectable disease (definition of the study population; Part A: inclusion criterion; Part B and Part C: inclusion criterion. The precision was also added throughout the text when relevant. The sentence at the end, which mentioned that inclusion criteria for Parts A1, B, C, D, E, F, and G defined in a protocol amendment, was moved at the end; reference to Parts B and C was deleted. - Inclusion of ramucirumab as an option in the prior treatment regimen in Part B. Revision of the eligibility criteria to provide a single QTc cutoff , irrespective of the participant's sex (Part A: exclusion criterion, Part B: exclusion criterion, Part C: inclusion criterion). The sentence at the end, which mentioned that exclusion criteria for Parts A1, B, C, D, E, F, and G was defined in a protocol amendment, was moved at the end of; reference to Parts B and C was deleted. - Clarification that all participants with known hypersensitivity to any of the study medications excluded from the study.
17 June 2021	Protocol Amendment 4 was dated 17-Jun-2021: - Alignment with the UK prescribing information for oxaliplatin regarding the threshold for neutrophil count in exclusion criterion. Alignment with the UK prescribing information for calcium folinate regarding known or suspected pernicious anemia or other anemias due to vitamin B12 deficiency. - Clarification that the following should be avoided in Part C: • Concomitant administration of medicinal product with a known potential to prolong the QT interval • Concurrent administration of 5-fluorouracil and Cytochrome P450 2C9 (CYP2C9) substrates • Co-administration of medicinal products known to be nephrotoxic. Title and text modified to remove the information pertaining only to Part C of the study. All the information applying to Part C was copied or moved to a new section Prohibited concomitant treatments (medications and therapies) during Part C. - Text was corrected as follows: "Administration of live (including attenuated) vaccines was not allowed during the conduct of the study and for up to 3 months after the final dose of IMP. Administration of inactivated non-live vaccines was allowed during the study at the discretion of the Investigator." - Deletion of the following sentence: "For participants who experience a DLT, dose adjustments were permitted if it was considered in the best interest of the participant to continue therapy at the discretion of the investigator, in consultation with the Sponsor." - Addition of any Grade 4 nonhematologic toxicity, including diarrhea and mucositis, which was at least possibly related to UCB6114 in the list of events leading to treatment discontinuation. - Clarification that prior approval of a substantial amendment by the regulatory authorities was required for any study restart after defined stopping criteria was met.

17 June 2021	Protocol Amendment 4 was dated 17-Jun-2021: - Revision of the maximum amount of blood collected from each participant at Screening, during Cycle 1 and Cycle 2, and at SFU. Blood sample for pregnancy test was moved to the footnote of the table. - Update of the text to specify that liver specific alkaline phosphatase (ALP) must be separated and used to assess the liver function instead of total ALP in participants with bone metastases and liver abnormalities considered as potential Hy's low cases. Update of Footnote. - Text pertaining to immunogenicity sampling was moved from Pharmacokinetics to the Immunogenicity. - Deletion of the following sentence: "Samples for analysis of circulating markers of bone turnover was not obtained in Part B or Part C" which was incorrect. Deletion of the related footnote in the Schedule of Activities' tables. - Addition of the echocardiogram assessments in the study procedures for Part B and Part C to be in line with the assessments planned. Addition of collection time-windows for blood PK sampling for Part B and Part C. Update in the time schedule of the vital sign measurements on Day 1 (2h [+1h] and 5h+ [1h] after the end of infusion). - Update the contraceptive requirements for males in Parts B and C in relation to sperm donation and pregnant or breastfeeding partners (6months compared to 3 months in Part A). Addition of the recommendation to use a barrier contraceptive in addition to the use of hormonal contraceptive for woman of childbearing potential receiving Lonsurf® in the body text. Clarification that effective contraceptive method should be utilized for at last 6 months for participant in Parts B and C (compared to 3 months in Part A).
17 June 2021	Protocol Amendment 4 was dated 17-Jun-2021: - Correction of a few typographical and formatting errors, deletion of footnote which was not applicable for a specific assessment [Part A], footnote for "Blood collection for genetic analysis"), and addition of an existing footnote to 2 of the current procedures [Part B] and [Part C] footnote added to Eligibility criteria and Medical history as they were not assessed in Cycle 2). - Clarification in the use of "cohort" and "dose level" for Part B and Part C. - Clarification in the schematic representation of the dose escalation/DLT assessment period: • "Cohort" replaced by "dose level", • Addition of the possibility of dose de-escalation • Clarification that each dose level could include more than one cohort of participants. - The wording "Health Authorities" was replaced by "regulatory authorities". Correction of a few typographical and formatting errors.
14 January 2022	Protocol Amendment 5 was dated 14-Jan-2022: - Addition of text pertaining to dose optimization module Part A1 throughout the document, including the synopsis, objectives and endpoints, schema, schedules of activities, background, design, benefit-risk assessment, dose selection, selection and withdrawal criteria, treatments administered, concomitant medications, dose modifications, study assessments and procedures, statistical analyses, and appendices. When applicable, sections, tables and figures was renumbered. - Part A1 'dose adaptation module' was renamed 'dose optimization module' for clarity. - In secondary and tertiary endpoints, the wording 'dose level' was replaced by 'cohort' to cover both dose level in Part A and dosing schedule in Part A1. The changes were also applied throughout the document, where relevant. - The description of the Safety Monitoring Committee (SMC) and Study Steering Committee (SSC) were applicable for all study parts; thus, the information was moved up in a separate section. Subsequent sections was renumbered. Treatment duration text was updated to include "criteria for discontinuation were met", in line with the text provided in the study synopsis (new text in bold). - The rationale for indication for Part B and Part C was the same as for Part A1 and the corresponding text was moved. It was clarified that Ab7326mIgG1 is the murinized version of UCB6114. - A correction was made in the exclusion criteria for Part A, Part B and Part C: "Screening of asymptomatic participants without history of central nervous system (CNS) metastases was not required". - Clarification that death due to disease progression was not be recorded as a SAE but was recorded in a survival electronic case report form (eCRF). -Clarifications of the procedures to be performed in case an infusion-related reaction occurs. - Clarification that a SAP were developed for each module.
14 January 2022	Protocol Amendment 5 was dated 14-Jan-2022: - Timepoints at which the duration of responses and Progression-free survival (PFS) was derived was corrected to be in line with the statistical analysis plan. - Correction of spelling, grammar, or typographical errors. - Type of amendment for protocol amendment 3.1 was changed from 'substantial' to 'Not applicable' as the substantial/non substantial classification was irrelevant in United States (US).

26 June 2023	Protocol Amendment 6 was dated 26-Jun-2023: - Clarification that either the entire study or an individual Study Part could be suspended. Clarification of the process for study/individual Study Part hold/potential restart when criteria for study/individual Study Part suspension were met. - Footnotes of (Part A1, Cohort 3) was updated to clarify when blood sample for PK and Gremlin should be collected with regards to biopsy. Footnotes (Part B) and (Part C) was updated to clarify when blood samples for ADA, circulating gremlin-1 and ctDNA analysis to be collected. In line with this change, footnote was added. - Correction of typographical errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
10 May 2023	A temporary hold was implemented in ONC001 Study Part C to investigate a fatal serious adverse event (SAE) reported in one study participant enrolled in Part C of the Phase 1/2 first-in-human (FIH) study ONC001, where ginisortamab (UCB6114) is administered in combination with modified FOLFOX6 (mFOLFOX6; 5 fluorouracil [5-FU], leucovorin, and oxaliplatin). Investigation and new information did not support a role of ginisortamab (UCB6114) in cause of death. Health authorities were notified on 26 June 2023 to restart enrollment and dosing of ginisortamab in ONC001 Part C.	11 July 2023

Notes:

Limitations and caveats

None reported