



## 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        | <ul style="list-style-type: none"><li>• Correction of full data set Alignment with final posting on ClinicalTrials.gov after NIH review.</li></ul> |

#### 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:

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**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:

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**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:

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**Population of trial subjects**

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**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:

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**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                         |
| <b>Arm title</b>             | 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.

|                  |                             |
|------------------|-----------------------------|
| <b>Arm title</b> | 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.

|                  |                             |
|------------------|-----------------------------|
| <b>Arm title</b> | 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.  |   |
| <b>Arm title</b>  | 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                                    |
| 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.   |   |
| <b>Arm title</b>  | 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.   |   |
| <b>Arm title</b>  | 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.   |   |
| <b>Arm title</b>  | 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.  |  |
| <b>Arm title</b>   | 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.  |  |
| <b>Arm title</b>   | 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.  |  |
| <b>Arm title</b>   | 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.   |  |
| <b>Arm title</b>   | 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.

|                  |  |
|------------------|--|
| <b>Arm title</b> | 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.

|                  |  |
|------------------|--|
| <b>Arm title</b> | 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.

|                  |   |
|------------------|---|
| <b>Arm title</b> | 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.

|                  |   |
|------------------|---|
| <b>Arm title</b> | 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:<br>Ginisortamab 100<br>mg | Part A: Ginisortamab<br>250 mg | Part A:<br>Ginisortamab 500<br>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:<br>Ginisortamab 1000<br>mg | Part A: Ginisortamab<br>2000 mg | Part A1:<br>Ginisortamab 2000<br>mg Q2W (60-min),<br>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:<br>Ginisortamab 2000<br>mg Q2W (30-min),<br>28D | Part A1:<br>Ginisortamab 3000<br>mg Q3W (90-min),<br>21D | Part A1:<br>Ginisortamab 4000<br>mg Q4W (120-min),<br>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                                  | - | - | - |

| <b>Number of subjects in period 1</b>             | 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:<br>Ginisortamab 500<br>mg + mFOLFOX6<br>SoC | Part C: Ginisortamab<br>1000 mg +<br>mFOLFOX6 SoC | Part C:<br>Ginisortamab 2000<br>mg + mFOLFOX6<br>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 |

## Baseline characteristics

### Reporting groups

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

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

|  |   |   |   |
|--|---|---|---|
| Sex: Female, Male<br>Units: participants |   |   |   |
| Female                                   | 2 | 1 | 3 |
| Male                                     | 4 | 5 | 5 |

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

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

| Reporting group values                 | Part C:<br>Ginisortamab 500<br>mg + mFOLFOX6<br>SoC | Part C: Ginisortamab<br>1000 mg +<br>mFOLFOX6 SoC | Part C:<br>Ginisortamab 2000<br>mg + mFOLFOX6<br>SoC |
|--|---|---|--|
| Number of subjects                     | 5   | 3   | 7  |
| Age Categorical<br>Units: participants |   |   |  |
| 18 - <65 years                         | 3   | 2   | 5  |
| 65 - <85 years                         | 2   | 1   | 2  |
| Age Continuous<br>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 |

|                               |       |  |  |
|-------------------------------|-------|--|--|
| <b>Reporting group values</b> | 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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) <sup>[1]</sup> |
|-----------------|--|

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:<br>Ginisortamab<br>100 mg | Part A:<br>Ginisortamab<br>250 mg | Part A:<br>Ginisortamab<br>500 mg | Part A:<br>Ginisortamab<br>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:<br>Ginisortamab<br>2000 mg | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(60-min), 28D | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(30-min), 28D | Part A1:<br>Ginisortamab<br>3000 mg Q3W<br>(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:<br>Ginisortamab<br>4000 mg Q4W<br>(120-min),<br>28D | Part B:<br>Ginisortamab<br>500 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>1000 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>2000 mg +<br>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:<br>Ginisortamab<br>500 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>1000 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>2000 mg +<br>mFOLFOX6<br>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 <sup>[2]</sup> |
|-----------------|--|

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  $\geq 3$  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:<br>Ginisortamab<br>100 mg | Part A:<br>Ginisortamab<br>250 mg | Part A:<br>Ginisortamab<br>500 mg | Part A:<br>Ginisortamab<br>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 $\geq 3$ TEAEs         | 66.7                              | 40.0                              | 40.0                              | 0                                  |
| NCI CTCAE grade $\geq 3$ related TEAEs | 0                                 | 0                                 | 0                                 | 0                                  |

| End point values                       | Part A:<br>Ginisortamab<br>2000 mg | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(60-min), 28D | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(30-min), 28D | Part A1:<br>Ginisortamab<br>3000 mg Q3W<br>(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 $\geq 3$ TEAEs         | 50.0                               | 62.5   | 50.0   | 37.5   |
| NCI CTCAE grade $\geq 3$ related TEAEs | 0                                  | 0  | 0  | 0  |

| End point values                       | Part A1:<br>Ginisortamab<br>4000 mg Q4W<br>(120-min),<br>28D | Part B:<br>Ginisortamab<br>500 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>1000 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>2000 mg +<br>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 $\geq 3$ TEAEs         | 62.5   | 55.6   | 75.0  | 87.5  |
| NCI CTCAE grade $\geq 3$ related TEAEs | 12.5   | 22.2   | 0   | 25.0  |

| End point values | Part C:<br>Ginisortamab<br>500 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>1000 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>2000 mg +<br>mFOLFOX6<br>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 $\geq 3$ TEAEs         | 100             | 100             | 85.7            |  |
| NCI CTCAE grade $\geq 3$ 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) <sup>[3]</sup> |
|-----------------|--|

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  $\leq 2$  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  $\geq 3$  hematological toxicity of  $> 5$  days duration or febrile neutropenia (absolute neutrophil count [ANC]  $< 1000$ /cubic millimeter [mm<sup>3</sup>] with single temperature of  $> 38.3^\circ\text{C}$  or sustained temperature  $\geq 38^\circ\text{C}$  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 1 or 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:<br>Ginisortamab<br>100 mg | Part A:<br>Ginisortamab<br>250 mg | Part A:<br>Ginisortamab<br>500 mg | Part A:<br>Ginisortamab<br>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:<br>Ginisortamab<br>2000 mg | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(60-min), 28D | Part A1:<br>Ginisortamab<br>2000 mg Q2W<br>(30-min), 28D | Part A1:<br>Ginisortamab<br>3000 mg Q3W<br>(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:<br>Ginisortamab<br>4000 mg Q4W<br>(120-min),<br>28D | Part B:<br>Ginisortamab<br>500 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>1000 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>2000 mg +<br>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:<br>Ginisortamab<br>500 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>1000 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>2000 mg +<br>mFOLFOX6<br>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 <sup>[4]</sup> |
|-----------------|--|

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 and 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:<br>Ginisortamab<br>100 mg | Part A:<br>Ginisortamab<br>250 mg | Part A:<br>Ginisortamab<br>500 mg | Part A:<br>Ginisortamab<br>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 <sup>[5]</sup> |
|-----------------|---|

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:<br>Ginisortamab<br>500 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>1000 mg +<br>TFD/TPI SoC | Part B:<br>Ginisortamab<br>2000 mg +<br>TFD/TPI SoC | Part C:<br>Ginisortamab<br>500 mg +<br>mFOLFOX6<br>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:<br>Ginisortamab<br>1000 mg +<br>mFOLFOX6<br>SoC | Part C:<br>Ginisortamab<br>2000 mg +<br>mFOLFOX6<br>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 (±<br>99999) | 135.0042 (±<br>43.8716) |  |  |
|--|--------------------|-------------------------|--|--|

## Statistical analyses

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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.

| <b>Serious adverse events</b>                                       | Part A:<br>Ginisortamab 1000<br>mg | Part A: Ginisortamab<br>500 mg | Part A:<br>Ginisortamab 250<br>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<br>Peritonitis bacterial<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 1 / 5 (20.00%)<br>0 / 1<br>0 / 0 |
| Lower respiratory tract infection bacterial<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all          | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 1 / 5 (20.00%)<br>0 / 1<br>0 / 0 |
| Liver abscess<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all  | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  |
| Pneumonia<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all  | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  |
| Sepsis<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all   | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 1 / 5 (20.00%)<br>0 / 1<br>0 / 0 |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                              | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 1 / 5 (20.00%)<br>0 / 1<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  |
| Urosepsis<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all  | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  |
| Vascular device infection<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                            | 0 / 6 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 5 (0.00%)<br>0 / 0<br>0 / 0  | 0 / 5 (0.00%)<br>0 / 0<br>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         |

| <b>Serious adverse events</b>                                       | Part A:<br>Ginisortamab 100 mg | Part A: Ginisortamab 2000 mg | Part B:<br>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         |
| <b>Blood and lymphatic system disorders</b>     |                |               |               |
| 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         |
| <b>Gastrointestinal disorders</b>               |                |               |               |
| 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         |

| <b>Serious adverse events</b>                                       | Part B:<br>Ginisortamab 2000<br>mg + TFD/TPI SoC | Part C: Ginisortamab<br>500 mg +<br>mFOLFOX6 SoC | Part C:<br>Ginisortamab 1000<br>mg + mFOLFOX6<br>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         |

| <b>Serious adverse events</b>                                       | Part B:<br>Ginisortamab 500<br>mg + TFD/TPI SoC | Part A1:<br>Ginisortamab 4000<br>mg Q4W (120-min),<br>28D | Part C:<br>Ginisortamab 2000<br>mg + mFOLFOX6<br>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          |

|                               |          |          |          |
|-------------------------------|----------|----------|----------|
| <b>Serious adverse events</b> | Part A1: | Part A1: | Part A1: |
|-------------------------------|----------|----------|----------|

|   | Ginisortamab 2000<br>mg Q2W (30-min),<br>28D | Ginisortamab 2000<br>mg Q2W (60-min),<br>28D | Ginisortamab 3000<br>mg Q3W (90-min),<br>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 %

| <b>Non-serious adverse events</b>                                   | Part A:<br>Ginisortamab 1000<br>mg | Part A: Ginisortamab<br>500 mg | Part A:<br>Ginisortamab 250<br>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<br>occurrences (all)        | 0 / 6 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>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<br>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<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 6 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 | 0 / 5 (0.00%)<br>0  |
| Confusional state<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Anxiety<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Investigations   |                     |                     |                     |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)     | 1 / 6 (16.67%)<br>1 | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Amylase increased<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 |
| Aspartate aminotransferase<br>subjects affected / exposed<br>occurrences (all)             | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)   | 2 / 6 (33.33%)<br>2 | 1 / 5 (20.00%)<br>2 | 1 / 5 (20.00%)<br>1 |
| Blood alkaline phosphatase increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Blood bilirubin increased<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 |
| Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0  | 1 / 5 (20.00%)<br>2 | 0 / 5 (0.00%)<br>0  |
| Blood lactate dehydrogenase increased<br>subjects affected / exposed<br>occurrences (all)  | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>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             |
| Hypertransaminaemia                    |                |                |               |
| 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<br>subjects affected / exposed<br>occurrences (all)        | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 |
| Nephrolithiasis<br>subjects affected / exposed<br>occurrences (all)            | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)                | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)                | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Musculoskeletal and connective tissue disorders                                |                     |                     |                     |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                  | 3 / 6 (50.00%)<br>4 | 1 / 5 (20.00%)<br>1 | 0 / 5 (0.00%)<br>0  |
| Bone pain<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 |
| Flank pain<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Limb discomfort<br>subjects affected / exposed<br>occurrences (all)            | 0 / 6 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 | 0 / 5 (0.00%)<br>0  |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  |
| Musculoskeletal chest pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>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             |

| <b>Non-serious adverse events</b>                                   | Part A:<br>Ginisortamab 100<br>mg | Part A: Ginisortamab<br>2000 mg | Part B:<br>Ginisortamab 1000<br>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<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 | 0 / 4 (0.00%)<br>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<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 | 1 / 4 (25.00%)<br>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<br>occurrences (all) | 0 / 3 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 | 0 / 4 (0.00%)<br>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<br>subjects affected / exposed<br>occurrences (all)   | 0 / 3 (0.00%)<br>0  | 1 / 6 (16.67%)<br>1 | 1 / 4 (25.00%)<br>2 |
| Urosepsis<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 3 (33.33%)<br>1 | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Vaginal infection<br>subjects affected / exposed<br>occurrences (all)         | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Vascular device infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Metabolism and nutrition disorders  |                     |                     |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)        | 1 / 3 (33.33%)<br>1 | 2 / 6 (33.33%)<br>2 | 0 / 4 (0.00%)<br>0  |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)               | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Hypercalcaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Hypertriglyceridaemia<br>subjects affected / exposed<br>occurrences (all)     | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Hyperlipidaemia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>0  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 3 (0.00%)<br>0  | 1 / 6 (16.67%)<br>1 | 0 / 4 (0.00%)<br>0  |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 3 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0  | 0 / 4 (0.00%)<br>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             |

| <b>Non-serious adverse events</b>                                      | Part B:<br>Ginisortamab 2000<br>mg + TFD/TPI SoC | Part C: Ginisortamab<br>500 mg +<br>mFOLFOX6 SoC | Part C:<br>Ginisortamab 1000<br>mg + mFOLFOX6<br>SoC |
|--|--|--|--|
| Total subjects affected by non-serious<br>adverse events               |  |  |  |
| subjects affected / exposed  | 8 / 8 (100.00%)                                  | 5 / 5 (100.00%)                                  | 3 / 3 (100.00%)                                      |
| Neoplasms benign, malignant and<br>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<br>occurrences (all)   | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Oedema peripheral<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1 | 0 / 3 (0.00%)<br>0  |
| Mucosal inflammation<br>subjects affected / exposed<br>occurrences (all)   | 1 / 8 (12.50%)<br>1 | 1 / 5 (20.00%)<br>1 | 1 / 3 (33.33%)<br>1 |
| Immune system disorders<br>Drug hypersensitivity<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 1 / 3 (33.33%)<br>1 |
| Reproductive system and breast disorders<br>Pruritus genital<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Balanoposthitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Prostatitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders<br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0  | 1 / 5 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0  |
| Aspiration<br>subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0  |
| Cough<br>subjects affected / exposed<br>occurrences (all)  | 1 / 8 (12.50%)<br>1 | 3 / 5 (60.00%)<br>3 | 1 / 3 (33.33%)<br>2 |
| Dyspnoea exertional<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0  | 1 / 5 (20.00%)<br>2 | 1 / 3 (33.33%)<br>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<br>occurrences (all)                                     | 2 / 8 (25.00%)<br>2  | 1 / 5 (20.00%)<br>1 | 0 / 3 (0.00%)<br>0 |
| Prothrombin time prolonged<br>subjects affected / exposed<br>occurrences (all)       | 0 / 8 (0.00%)<br>0   | 1 / 5 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0 |
| Weight decreased<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0 |
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all) | 5 / 8 (62.50%)<br>11 | 1 / 5 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0 |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0 |
| Injury, poisoning and procedural complications                                       |                      |                     |                    |
| Craniofacial fracture<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0   | 1 / 5 (20.00%)<br>1 | 0 / 3 (0.00%)<br>0 |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 8 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 8 (0.00%)<br>0   | 1 / 5 (20.00%)<br>1 | 0 / 3 (0.00%)<br>0 |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)        | 1 / 8 (12.50%)<br>1  | 1 / 5 (20.00%)<br>2 | 0 / 3 (0.00%)<br>0 |
| Humerus fracture<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0   | 1 / 5 (20.00%)<br>1 | 0 / 3 (0.00%)<br>0 |
| Cardiac disorders  |                      |                     |                    |
| Palpitations<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 8 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 3 (0.00%)<br>0 |
| Arrhythmia supraventricular  |                      |                     |                    |

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

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



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

| <b>Non-serious adverse events</b>                                   | Part B:<br>Ginisortamab 500<br>mg + TFD/TPI SoC | Part A1:<br>Ginisortamab 4000<br>mg Q4W (120-min),<br>28D | Part C:<br>Ginisortamab 2000<br>mg + mFOLFOX6<br>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<br>occurrences (all)  | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Neutrophil count decreased<br>subjects affected / exposed<br>occurrences (all)                  | 2 / 9 (22.22%)<br>4 | 0 / 8 (0.00%)<br>0  | 3 / 7 (42.86%)<br>4 |
| Lymphocyte count decreased<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| International normalised ratio<br>increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Platelet count decreased<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 9 (11.11%)<br>2 | 0 / 8 (0.00%)<br>0  | 2 / 7 (28.57%)<br>2 |
| Prothrombin time prolonged<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Weight decreased<br>subjects affected / exposed<br>occurrences (all)                            | 1 / 9 (11.11%)<br>2 | 2 / 8 (25.00%)<br>2 | 2 / 7 (28.57%)<br>2 |
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all)            | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>1 |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)                            | 1 / 9 (11.11%)<br>1 | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>1 |
| Injury, poisoning and procedural<br>complications   |                     |                     |                     |
| Craniofacial fracture<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                                   | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>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<br>occurrences (all)                                  | 2 / 9 (22.22%)<br>3  | 1 / 8 (12.50%)<br>1 | 1 / 7 (14.29%)<br>2 |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Neuropathy peripheral<br>subjects affected / exposed<br>occurrences (all)         | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 2 / 7 (28.57%)<br>3 |
| Neurotoxicity<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Parosmia<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Peripheral sensory neuropathy<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>1 |
| Memory impairment<br>subjects affected / exposed<br>occurrences (all)             | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Syncope<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Taste disorder<br>subjects affected / exposed<br>occurrences (all)                | 1 / 9 (11.11%)<br>1  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Blood and lymphatic system disorders  |                      |                     |                     |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                       | 5 / 9 (55.56%)<br>12 | 2 / 8 (25.00%)<br>5 | 2 / 7 (28.57%)<br>4 |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)                   | 5 / 9 (55.56%)<br>14 | 0 / 8 (0.00%)<br>0  | 2 / 7 (28.57%)<br>3 |
| Lymphopenia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 9 (0.00%)<br>0   | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)              | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Iron deficiency anaemia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 9 (11.11%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)          | 2 / 9 (22.22%)<br>3 | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>2 |
| Eye disorders   |                     |                     |                     |
| Dry eye<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>1 |
| Eye pain<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 9 (11.11%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Gastrointestinal disorders  |                     |                     |                     |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all)      | 0 / 9 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 7 (0.00%)<br>0  |
| Abdominal discomfort<br>subjects affected / exposed<br>occurrences (all)      | 0 / 9 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 7 (0.00%)<br>0  |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)            | 2 / 9 (22.22%)<br>2 | 2 / 8 (25.00%)<br>3 | 3 / 7 (42.86%)<br>3 |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)      | 2 / 9 (22.22%)<br>2 | 1 / 8 (12.50%)<br>1 | 0 / 7 (0.00%)<br>0  |
| Abnormal faeces<br>subjects affected / exposed<br>occurrences (all)           | 1 / 9 (11.11%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Aorto-oesophageal fistula<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>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<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Metabolism and nutrition disorders  |                     |                     |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)        | 6 / 9 (66.67%)<br>7 | 2 / 8 (25.00%)<br>2 | 5 / 7 (71.43%)<br>5 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)               | 1 / 9 (11.11%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hypercalcaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hypertriglyceridaemia<br>subjects affected / exposed<br>occurrences (all)     | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 7 (14.29%)<br>1 |
| Hyperlipidaemia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)            | 2 / 9 (22.22%)<br>2 | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hypoglycaemia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hypocalcaemia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 9 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 7 (0.00%)<br>0  |
| Hypokalaemia<br>subjects affected / exposed<br>occurrences (all)              | 1 / 9 (11.11%)<br>1 | 1 / 8 (12.50%)<br>1 | 0 / 7 (0.00%)<br>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              |

| <b>Non-serious adverse events</b>                                   | Part A1:<br>Ginisortamab 2000<br>mg Q2W (30-min),<br>28D | Part A1:<br>Ginisortamab 2000<br>mg Q2W (60-min),<br>28D | Part A1:<br>Ginisortamab 3000<br>mg Q3W (90-min),<br>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<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Vena cava thrombosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| General disorders and administration site conditions                       |                     |                     |                     |
| Chest pain<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Chills<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)                | 5 / 8 (62.50%)<br>6 | 3 / 8 (37.50%)<br>4 | 0 / 8 (0.00%)<br>0  |
| Feeling cold<br>subjects affected / exposed<br>occurrences (all)           | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Influenza like illness<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                | 2 / 8 (25.00%)<br>2 | 0 / 8 (0.00%)<br>0  | 2 / 8 (25.00%)<br>2 |
| Peripheral swelling<br>subjects affected / exposed<br>occurrences (all)    | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Oedema peripheral<br>subjects affected / exposed<br>occurrences (all)      | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Mucosal inflammation<br>subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Immune system disorders  |                     |                     |                     |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| Drug hypersensitivity<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Reproductive system and breast disorders                                  |                     |                     |                     |
| Pruritus genital<br>subjects affected / exposed<br>occurrences (all)      | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Balanoposthitis<br>subjects affected / exposed<br>occurrences (all)       | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Prostatitis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                           |                     |                     |                     |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)              | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Aspiration<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Cough<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  |
| Dyspnoea exertional<br>subjects affected / exposed<br>occurrences (all)   | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Hypoxia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 |
| Haemoptysis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>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<br>occurrences (all)                                     | 0 / 8 (0.00%)<br>0 | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0 |
| White blood cell count decreased<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Injury, poisoning and procedural complications                                       |                    |                     |                    |
| Craniofacial fracture<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)        | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Humerus fracture<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Cardiac disorders  |                    |                     |                    |
| Palpitations<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Arrhythmia supraventricular<br>subjects affected / exposed<br>occurrences (all)      | 0 / 8 (0.00%)<br>0 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Nervous system disorders   |                    |                     |                    |
| Brain oedema<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 8 (0.00%)<br>0 | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>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<br>occurrences (all)                            | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Taste disorder<br>subjects affected / exposed<br>occurrences (all)          | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Blood and lymphatic system disorders  |                     |                     |                     |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 8 (12.50%)<br>1 | 1 / 8 (12.50%)<br>1 | 1 / 8 (12.50%)<br>2 |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Lymphopenia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Iron deficiency anaemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)        | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Eye disorders   |                     |                     |                     |
| Dry eye<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Eye pain<br>subjects affected / exposed<br>occurrences (all)                | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  |
| Gastrointestinal disorders  |                     |                     |                     |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all)    | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>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             |
| Hypertransaminaemia                    |                |                |               |
| 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<br>subjects affected / exposed<br>occurrences (all)               | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)           | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Urosepsis<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Vaginal infection<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Vascular device infection<br>subjects affected / exposed<br>occurrences (all)         | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Metabolism and nutrition disorders  |                     |                     |                    |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)                | 0 / 8 (0.00%)<br>0  | 1 / 8 (12.50%)<br>1 | 0 / 8 (0.00%)<br>0 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Hypercalcaemia<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Hypertriglyceridaemia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0 |
| Hyperlipidaemia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>0  | 0 / 8 (0.00%)<br>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. |

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| 11 June 2020 | <p>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.</p> <ul style="list-style-type: none"> <li>- Footnote was added to specify timing of ctDNA sampling on Cycle 3 onwards Day 1.</li> <li>- Footnote was added to specify that echocardiograms were only be assessed at evennumbered cycles from Cycle 3 onwards.</li> <li>- Footnote was added to clarify requirements for tumor assessments at Safety Follow-Up (SFU) visit.</li> <li>- Footnote was added to clarify when tumor assessment is not required at SFU Visit.</li> <li>- Footnote was added to specify predose eligibility assessment at Cycle 1 Day 1.</li> <li>- Footnote was added to clarify liver laboratory assessments in the case of bone metastases.</li> <li>- Footnote was added to specify completion of survival census.</li> <li>- Footnote was added to clarify timing of complete and symptom-directed physical examinations.</li> <li>- Row for Part B: colorectal carcinoma changed to colorectal adenocarcinoma.</li> <li>- Sentence "Higher or lower doses may be considered based on emerging data." was deleted.</li> <li>- Pancreatic carcinoma changed to pancreatic adenocarcinoma.</li> <li>- Specified 16-day observation for participants who enroll after sentinel participant experiences a dose limiting toxicity (DLT).</li> <li>- Clarification of design choices with expanded explanatory text.</li> <li>- Clarified Safety Monitoring Committee (SMC) role in dose decisions and role in adding additional dose levels. Clarified that doses above 2000mg require an amendment.</li> <li>- 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.</li> </ul> |
| 11 June 2020 | <p>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.</p> <ul style="list-style-type: none"> <li>- Inclusion criterion was renumbered and was changed from "or" to "and".</li> <li>- Exclusion criterion was deleted.</li> </ul> <p>Exclusion criterion was renumbered; and was modified to add history of biliary stent.</p> <ul style="list-style-type: none"> <li>- Exclusion criterion was renumbered and was modified to remove "or any other type of medical research".</li> <li>- New criterion: Exclusion criterion was added to specify criterion for renal function.</li> <li>- New criterion: Exclusion criterion was added to exclude major surgery prior to study drug initiation.</li> <li>- New criterion: Exclusion criterion was added to specify criteria for coagulation parameters.</li> <li>- Drug accountability procedure changed to use of drug accountability logs instead of electronic case report form (eCRF).</li> <li>- Term "concomitant" was deleted from (redundant with sentence preceding bulleted list)</li> <li>- Footnote was changed to spell out pharmacokinetics (PK) terms.</li> <li>- List of abbreviations for table was updated.</li> <li>- Footnote was deleted as any doses higher than 2000mg would be subject to a substantial protocol amendment.</li> <li>- Text was added to specify the maximum amount of blood collected from participants during each part of the study.</li> <li>- Coagulation added to sample types; number and volumes of samples updated, total blood volumes updated.</li> <li>- Clarified timing of complete and symptomdirected physical examinations. Clarified that height were only be recorded at Screening.</li> <li>- Coagulation added to types of laboratory assessments.</li> <li>- Text was updated to reflect use of serum or urine pregnancy tests.</li> <li>- AUCtau changed to AUC0-336h.</li> <li>- Footnote was updated to reflect reporting.</li> <li>- Deleted PK sample collection from Final Visit.</li> </ul>  |



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| 11 June 2020    | <p>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.</p> <ul style="list-style-type: none"> <li>- Cycle 2, Day 1 (samples 13, 14, and 15) sampling times and predose/postdose timepoints updated.</li> <li>- First note in footnotes updated to reflect number of samples and blood volumes.</li> <li>- New note added to footnotes to specify predose sample summarization in statistical analysis.</li> <li>- Footnote added to specify collection of Cycle 3 Day 1 PK sample in subjects who were not continuing treatment.</li> <li>- Specified exception for prior CT or MRI scan. Moved tumor assessments from Final Visit to SFU visit.</li> <li>- 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).</li> <li>- 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.</li> <li>- Added coagulation to abnormal laboratory test results bullet for events meeting the AE definition.</li> </ul> |
| 11 June 2020    | <p>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.</p>   |
| 12 October 2020 | <p>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.</p>   |
| 12 October 2020 | <p>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.</p>   |

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| 07 January 2021 | <p>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, benefit-risk assessment, dose selection, selection and withdrawal criteria, treatments administered, concomitant medications, dose modifications, and statistical analyses. - Clarification 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.</p>   |
| 17 June 2021    | <p>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 have 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.</p>   |
| 17 June 2021    | <p>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.</p> |

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| 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).  |

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| 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. |
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Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date        | Interruption   | Restart date |
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| 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).<br>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