



## Clinical trial results:

### A Phase Ib/II, open label, multicenter study of MCS110 in combination with PDR001 in patients with advanced malignancies

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2016-000210-29    |
| Trial protocol           | FI DE ES FR BE IT |
| Global end of trial date | 04 June 2020      |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1           |
| This version publication date  | 12 June 2021 |
| First version publication date | 12 June 2021 |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | CMCS110Z2102 |
|-----------------------|--------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02807844 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Novartis Pharma AG  |
| Sponsor organisation address | Novartis Campus, Basel, Switzerland,  |
| Public contact               | Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com |
| Scientific contact           | Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.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**

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|  |              |
|--|--------------|
| Analysis stage                                       | Final        |
| Date of interim/final analysis                       | 04 June 2020 |
| Is this the analysis of the primary completion data? | No           |

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|                                  |              |
|----------------------------------|--------------|
| Global end of trial reached?     | Yes          |
| Global end of trial date         | 04 June 2020 |
| Was the trial ended prematurely? | No           |

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Notes:

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**General information about the trial**

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Main objective of the trial:

Phase Ib part: To characterize the safety and tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

Phase II part: To estimate the anti-tumor activity of the combination of MCS110 with PDR001

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Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

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Background therapy: -

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Evidence for comparator: -

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|   |              |
|---|--------------|
| Actual start date of recruitment                          | 29 June 2016 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | No           |

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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Belgium: 2             |
| Country: Number of subjects enrolled | Finland: 12            |
| Country: Number of subjects enrolled | France: 5              |
| Country: Number of subjects enrolled | Germany: 12            |
| Country: Number of subjects enrolled | Hong Kong: 3           |
| Country: Number of subjects enrolled | Italy: 15              |
| Country: Number of subjects enrolled | Japan: 5               |
| Country: Number of subjects enrolled | Korea, Republic of: 17 |
| Country: Number of subjects enrolled | Spain: 40              |
| Country: Number of subjects enrolled | Switzerland: 17        |
| Country: Number of subjects enrolled | United States: 13      |
| Worldwide total number of subjects   | 141                    |
| EEA total number of subjects         | 86                     |

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Notes:

| <b>Subjects enrolled per age group</b>    |    |
|---|----|
| 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)                      | 95 |
| From 65 to 84 years                       | 46 |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

In Phase Ib: planned minimum 15 patients; analyzed 60 patients.

In Phase II: planned approximatively 20 patients in each group (80); analyzed 81 patients.

### Period 1

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

### Arms

|                              |   |
|------------------------------|---|
| Are arms mutually exclusive? | Yes   |
| <b>Arm title</b>             | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W |

Arm description:

Phase Ib: MCS110 1 mg/kg every 3 weeks (Q3W) + PDR001 100 mg Q3W

|  |                                  |
|--|----------------------------------|
| Arm type                               | Experimental                     |
| Investigational medicinal product name | PDR001                           |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Powder for solution for infusion |
| Routes of administration               | Intravenous use                  |

Dosage and administration details:

100 mg Every 3 weeks

|  |                                       |
|--|---------------------------------------|
| Investigational medicinal product name | MCS110                                |
| Investigational medicinal product code |                                       |
| Other name                             |                                       |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

1 mg/kg Every 3 weeks

|                  |   |
|------------------|---|
| <b>Arm title</b> | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W |
|------------------|---|

Arm description:

Phase Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W

|  |                                  |
|--|----------------------------------|
| Arm type                               | Experimental                     |
| Investigational medicinal product name | PDR001                           |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Powder for solution for infusion |
| Routes of administration               | Intravenous use                  |

Dosage and administration details:

100 mg Every 3 weeks

|  |                                       |
|--|---------------------------------------|
| Investigational medicinal product name | MCS110                                |
| Investigational medicinal product code |                                       |
| Other name                             |                                       |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

3 mg/kg Every 3 weeks

|                  |   |
|------------------|---|
| <b>Arm title</b> | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W |
|------------------|---|

Arm description:

Phase Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W

|  |                                  |
|--|----------------------------------|
| Arm type                               | Experimental                     |
| Investigational medicinal product name | PDR001                           |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Powder for solution for infusion |
| Routes of administration               | Intravenous use                  |

Dosage and administration details:

300 mg Every 3 weeks

|  |                                       |
|--|---------------------------------------|
| Investigational medicinal product name | MCS110                                |
| Investigational medicinal product code |                                       |
| Other name                             |                                       |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

3 mg/kg Every 3 weeks

|                  |   |
|------------------|---|
| <b>Arm title</b> | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
|------------------|---|

Arm description:

Phase Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W

|  |                                  |
|--|----------------------------------|
| Arm type                               | Experimental                     |
| Investigational medicinal product name | PDR001                           |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Powder for solution for infusion |
| Routes of administration               | Intravenous use                  |

Dosage and administration details:

300 mg Every 3 weeks

|  |                                       |
|--|---------------------------------------|
| Investigational medicinal product name | MCS110                                |
| Investigational medicinal product code |                                       |
| Other name                             |                                       |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

5 mg/kg Every 3 weeks

|                  |   |
|------------------|---|
| <b>Arm title</b> | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W |
|------------------|---|

Arm description:

Phase Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W

|  |                                  |
|--|----------------------------------|
| Arm type                               | Experimental                     |
| Investigational medicinal product name | PDR001                           |
| Investigational medicinal product code |                                  |
| Other name                             |                                  |
| Pharmaceutical forms                   | Powder for solution for infusion |
| Routes of administration               | Intravenous use                  |

|   |  |
|---|--|
| Dosage and administration details:  |  |
| 300 mg Every 3 weeks  |  |
| Investigational medicinal product name  | MCS110   |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Concentrate for solution for infusion                  |
| Routes of administration  | Intravenous use  |
| Dosage and administration details:  |  |
| 7.5 mg/kg Every 3 weeks   |  |
| <b>Arm title</b>  | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W         |
| Arm description:  |  |
| Phase Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W   |  |
| Arm type  | Experimental   |
| Investigational medicinal product name  | PDR001   |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Powder for solution for infusion                       |
| Routes of administration  | Intravenous use  |
| Dosage and administration details:  |  |
| 300 mg Every 3 weeks  |  |
| Investigational medicinal product name  | MCS110   |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Concentrate for solution for infusion                  |
| Routes of administration  | Intravenous use  |
| Dosage and administration details:  |  |
| 10 mg/kg Every 3 weeks  |  |
| <b>Arm title</b>  | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC |
| Arm description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Triple negative breast cancer (TNBC) |  |
| Arm type  | Experimental   |
| Investigational medicinal product name  | PDR001   |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Powder for solution for infusion                       |
| Routes of administration  | Intravenous use  |
| Dosage and administration details:  |  |
| 300 mg Every 3 weeks  |  |
| Investigational medicinal product name  | MCS110   |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Concentrate for solution for infusion                  |
| Routes of administration  | Intravenous use  |
| Dosage and administration details:  |  |
| 7.5 mg/kg Every 3 weeks   |  |
| <b>Arm title</b>  | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC   |
| Arm description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Pancreatic cancer (PC)               |  |
| Arm type  | Experimental   |

|  |  |
|--|--|
| Investigational medicinal product name                                       | PDR001   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Powder for solution for infusion                     |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 300 mg Every 3 weeks   |  |
| Investigational medicinal product name                                       | MCS110   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Concentrate for solution for infusion                |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 7.5 mg/kg Every 3 weeks  |  |
| <b>Arm title</b>   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC |
| Arm description:   |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Endometrial cancer (EC) |  |
| Arm type   | Experimental   |
| Investigational medicinal product name                                       | PDR001   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Powder for solution for infusion                     |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 300 mg Every 3 weeks   |  |
| Investigational medicinal product name                                       | MCS110   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Concentrate for solution for infusion                |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 7.5 mg/kg Every 3 weeks  |  |
| <b>Arm title</b>   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |
| Arm description:   |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Melanoma (ME)           |  |
| Arm type   | Experimental   |
| Investigational medicinal product name                                       | MCS110   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Concentrate for solution for infusion                |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 7.5 mg/kg Every 3 weeks  |  |
| Investigational medicinal product name                                       | PDR001   |
| Investigational medicinal product code                                       |  |
| Other name   |  |
| Pharmaceutical forms   | Powder for solution for infusion                     |
| Routes of administration   | Intravenous use                                      |
| Dosage and administration details:   |  |
| 300 mg Every 3 weeks   |  |

| <b>Number of subjects in period 1</b> | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W |
|---------------------------------------|---|---|---|
| Started                               | 6   | 12  | 12  |
| Completed                             | 0   | 0   | 0   |
| Not completed                         | 6   | 12  | 12  |
| Adverse event, serious fatal          | -   | -   | 2   |
| Consent withdrawn by subject          | -   | -   | 2   |
| Physician decision                    | -   | -   | -   |
| Adverse event, non-fatal              | 1   | -   | -   |
| Progressive disease                   | 5   | 12  | 8   |

| <b>Number of subjects in period 1</b> | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W |
|---------------------------------------|---|---|--|
| Started                               | 13  | 6   | 11   |
| Completed                             | 0   | 0   | 0  |
| Not completed                         | 13  | 6   | 11   |
| Adverse event, serious fatal          | 4   | 1   | 2  |
| Consent withdrawn by subject          | 1   | 1   | -  |
| Physician decision                    | -   | -   | -  |
| Adverse event, non-fatal              | -   | 1   | 1  |
| Progressive disease                   | 8   | 3   | 8  |

| <b>Number of subjects in period 1</b> | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC |
|---------------------------------------|--|--|--|
| Started                               | 20   | 20   | 21   |
| Completed                             | 0  | 0  | 0  |
| Not completed                         | 20   | 20   | 21   |
| Adverse event, serious fatal          | 1  | 2  | -  |
| Consent withdrawn by subject          | 1  | -  | -  |
| Physician decision                    | 3  | -  | 1  |
| Adverse event, non-fatal              | 1  | 1  | 1  |
| Progressive disease                   | 14   | 17   | 19   |

| <b>Number of subjects in period 1</b> | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |
|---------------------------------------|--|
| Started                               | 20   |
| Completed                             | 0  |
| Not completed                         | 20   |



|                              |    |
|------------------------------|----|
| Adverse event, serious fatal | 1  |
| Consent withdrawn by subject | -  |
| Physician decision           | 2  |
| Adverse event, non-fatal     | 2  |
| Progressive disease          | 15 |

## Baseline characteristics

### Reporting groups

|   |  |
|---|--|
| Reporting group title   | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 1 mg/kg every 3 weeks (Q3W) + PDR001 100 mg Q3W                          |  |
| Reporting group title   | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W        |
| Reporting group description:  |  |
| Phase Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W         |
| Reporting group description:  |  |
| Phase Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W   |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Triple negative breast cancer (TNBC) |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Pancreatic cancer (PC)               |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Endometrial cancer (EC)              |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Melanoma (ME)                        |  |

| Reporting group values                 | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W |
|--|---|---|---|
| Number of subjects                     | 6   | 12  | 12  |
| Age Categorical<br>Units: Participants |   |   |   |
| <=18 years                             | 0   | 0   | 0   |
| Between 18 and 65 years                | 3   | 9   | 8   |
| >=65 years                             | 3   | 3   | 4   |
| Age Continuous<br>Units: years         |   |   |   |
| arithmetic mean                        | 64.3  | 56.9  | 59.3  |
| standard deviation                     | ± 14.72                                       | ± 11.13                                       | ± 9.94  |

|   |   |    |    |
|---|---|----|----|
| Sex: Female, Male<br>Units: Participants  |   |    |    |
| Female                                    | 4 | 10 | 6  |
| Male                                      | 2 | 2  | 6  |
| Race (NIH/OMB)<br>Units: Subjects         |   |    |    |
| American Indian or Alaska Native          | 0 | 0  | 0  |
| Asian                                     | 0 | 0  | 1  |
| Native Hawaiian or Other Pacific Islander | 0 | 0  | 0  |
| Black or African American                 | 0 | 0  | 0  |
| White                                     | 5 | 12 | 10 |
| More than one race                        | 0 | 0  | 0  |
| Unknown or Not Reported                   | 1 | 0  | 1  |

| Reporting group values                    | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W |
|---|---|---|--|
| Number of subjects                        | 13  | 6   | 11   |
| Age Categorical<br>Units: Participants    |   |   |  |
| <=18 years                                | 0   | 0   | 0  |
| Between 18 and 65 years                   | 10  | 5   | 8  |
| >=65 years                                | 3   | 1   | 3  |
| Age Continuous<br>Units: years            |   |   |  |
| arithmetic mean                           | 55.4  | 57.3  | 58.6   |
| standard deviation                        | ± 10.03                                       | ± 14.02   | ± 11.13  |
| Sex: Female, Male<br>Units: Participants  |   |   |  |
| Female                                    | 8   | 4   | 6  |
| Male                                      | 5   | 2   | 5  |
| Race (NIH/OMB)<br>Units: Subjects         |   |   |  |
| American Indian or Alaska Native          | 0   | 0   | 0  |
| Asian                                     | 2   | 1   | 2  |
| Native Hawaiian or Other Pacific Islander | 0   | 0   | 0  |
| Black or African American                 | 0   | 0   | 0  |
| White                                     | 11  | 5   | 9  |
| More than one race                        | 0   | 0   | 0  |
| Unknown or Not Reported                   | 0   | 0   | 0  |

| Reporting group values                 | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC |
|--|--|--|--|
| Number of subjects                     | 20   | 20   | 21   |
| Age Categorical<br>Units: Participants |  |  |  |
| <=18 years                             | 0  | 0  | 0  |
| Between 18 and 65 years                | 20   | 11   | 9  |
| >=65 years                             | 0  | 9  | 12   |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| Age Continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 50.0<br>± 8.29 | 61.5<br>± 11.33 | 62.8<br>± 10.13 |
| Sex: Female, Male<br>Units: Participants                                |                |                 |                 |
| Female  | 20             | 8               | 21              |
| Male  | 0              | 12              | 0               |
| Race (NIH/OMB)<br>Units: Subjects                                       |                |                 |                 |
| American Indian or Alaska Native  | 0              | 0               | 0               |
| Asian   | 5              | 4               | 4               |
| Native Hawaiian or Other Pacific Islander                               | 0              | 0               | 0               |
| Black or African American   | 0              | 1               | 0               |
| White   | 14             | 14              | 14              |
| More than one race  | 0              | 0               | 1               |
| Unknown or Not Reported   | 1              | 1               | 2               |

|   |  |       |  |
|---|--|-------|--|
| <b>Reporting group values</b>   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME | Total |  |
| Number of subjects  | 20   | 141   |  |
| Age Categorical<br>Units: Participants                                  |  |       |  |
| <=18 years  | 0  | 0     |  |
| Between 18 and 65 years   | 12   | 95    |  |
| >=65 years  | 8  | 46    |  |
| Age Continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 60.7<br>± 13.15                                      | -     |  |
| Sex: Female, Male<br>Units: Participants                                |  |       |  |
| Female  | 9  | 96    |  |
| Male  | 11   | 45    |  |
| Race (NIH/OMB)<br>Units: Subjects                                       |  |       |  |
| American Indian or Alaska Native  | 0  | 0     |  |
| Asian   | 7  | 26    |  |
| Native Hawaiian or Other Pacific Islander                               | 0  | 0     |  |
| Black or African American   | 0  | 1     |  |
| White   | 12   | 106   |  |
| More than one race  | 0  | 1     |  |
| Unknown or Not Reported   | 1  | 7     |  |

## End points

### End points reporting groups

|   |  |
|---|--|
| Reporting group title   | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 1 mg/kg every 3 weeks (Q3W) + PDR001 100 mg Q3W                          |  |
| Reporting group title   | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W          |
| Reporting group description:  |  |
| Phase Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W        |
| Reporting group description:  |  |
| Phase Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W  |  |
| Reporting group title   | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W         |
| Reporting group description:  |  |
| Phase Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W   |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Triple negative breast cancer (TNBC) |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Pancreatic cancer (PC)               |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Endometrial cancer (EC)              |  |
| Reporting group title   | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME   |
| Reporting group description:  |  |
| Phase II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - Melanoma (ME)                        |  |

### Primary: Phase Ib: Percentage of participants with adverse events, as a measure of safety

|  |  |
|--|--|
| End point title  | Phase Ib: Percentage of participants with adverse events, as a measure of safety <sup>[1][2]</sup> |
| End point description:   |  |
| Phase Ib: To characterize the safety and tolerability of MCS110 in combination with PDR001 in patients with advanced solid malignancies and to identify a recommended dose combination for Phase II. |  |
| End point type   | Primary  |
| End point timeframe:   |  |
| From start of treatment to a maximum timeframe of 116.4 weeks for phase Ib   |  |

#### 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the

baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| <b>End point values</b>                              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--|--|--|--|--|
| Subject group type                                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                          | 6  | 12   | 12   | 13   |
| Units: Participants                                  |  |  |  |  |
| Adverse events (AEs) - all grades                    | 6  | 12   | 12   | 13   |
| AEs - Treatment-related - all grades                 | 6  | 12   | 11   | 8  |
| SAEs - all grades                                    | 3  | 4  | 4  | 7  |
| SAEs - Treatment-related - all grades                | 0  | 1  | 0  | 0  |
| Fatal SAEs - all grades                              | 0  | 0  | 0  | 2  |
| Fatal SAEs - Treatt-related - all grades             | 0  | 0  | 0  | 0  |
| AEs leading to disc.- all grades                     | 0  | 0  | 0  | 0  |
| AEs leading to disc.- Treat-related - all<br>grades  | 0  | 0  | 0  | 0  |
| AEs leading to dose adjust / interrupt-all<br>grades | 4  | 4  | 4  | 2  |
| AEs requiring addit. therapy - all grades            | 6  | 12   | 10   | 12   |

| <b>End point values</b>                              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|--|---|---|--|--|
| Subject group type                                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                          | 6   | 11  |  |  |
| Units: Participants                                  |   |   |  |  |
| Adverse events (AEs) - all grades                    | 6   | 11  |  |  |
| AEs - Treatment-related - all grades                 | 6   | 8   |  |  |
| SAEs - all grades                                    | 2   | 5   |  |  |
| SAEs - Treatment-related - all grades                | 2   | 1   |  |  |
| Fatal SAEs - all grades                              | 0   | 0   |  |  |
| Fatal SAEs - Treatt-related - all grades             | 0   | 0   |  |  |
| AEs leading to disc.- all grades                     | 2   | 1   |  |  |
| AEs leading to disc.- Treat-related - all<br>grades  | 2   | 1   |  |  |
| AEs leading to dose adjust / interrupt-all<br>grades | 2   | 6   |  |  |
| AEs requiring addit. therapy - all grades            | 4   | 10  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase II : Overall Response rate (ORR) - per RECIST v1.1

|   |  |
|---|--|
| End point title   | Phase II : Overall Response rate (ORR) - per RECIST v1.1 <sup>[3][4]</sup> |
| End point description:<br>Phase II: Overall Response Rate (Complete response (CR) or Partial response (PR)) (with confirmation) as per investigator based on Response evaluation criteria in solid tumors (RECIST) v1.1 - (FAS) |  |
| End point type  | Primary  |
| End point timeframe:<br>4 years   |  |

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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed       | 20  | 20   | 21   | 20   |
| Units: Percentage of participants |   |  |  |  |
| number (confidence interval 90%)  | 5 (0.3 to 21.6)   | 0 (0.0 to 13.9)  | 9.5 (1.7 to 27.1)  | 0 (0.0 to 13.9)  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase II : Bayesian inference of Overall Response rate (ORR) - per RECIST v1.1 - mean

|  |   |
|--|---|
| End point title  | Phase II : Bayesian inference of Overall Response rate (ORR) - per RECIST v1.1 - mean <sup>[5][6]</sup> |
| End point description:<br>Phase II: Overall Response Rate (Complete response (CR) or Partial response (PR)) (with confirmation) as per investigator based on Response evaluation criteria in solid tumors (RECIST) v1.1 - mean (FAS) |   |
| End point type   | Primary   |
| End point timeframe:<br>4 years  |   |

Notes:

[5] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                          | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|---|---|--|--|--|
| Subject group type                        | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed               | 20  | 20   | 21   | 20   |
| Units: Percentage of participants         |   |  |  |  |
| arithmetic mean (confidence interval 90%) | 6.7 (0.8 to 17.1)   | 999 (999 to 999)   | 10.8 (2.6 to 23.1)   | 0.8 (0 to 4.5)   |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) - per RECIST v1.1

|                        |  |
|------------------------|--|
| End point title        | Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) - per RECIST v1.1 <sup>[7][8]</sup>  |
| End point description: | Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) per investigator based on Response evaluation criteria in solid tumors (RECIST) v1.1 |
| End point type         | Primary  |
| End point timeframe:   | 4 years  |

Notes:

[7] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed       | 20  | 20   | 21   | 20   |
| Units: Percentage of participants |   |  |  |  |
| number (confidence interval 90%)  | 20 (7.1 to 40.1)  | 0 (0.0 to 13.9)  | 9.5 (1.7 to 27.1)  | 10.0 (1.8 to 28.3)   |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase II: Bayesian inference of Clinical Benefit Rate - per RECIST v1.1-



**mean**

|                 |  |
|-----------------|--|
| End point title | Phase II: Bayesian inference of Clinical Benefit Rate - per RECIST v1.1- mean <sup>[9][10]</sup> |
|-----------------|--|

End point description:

Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) per investigator based on Response evaluation criteria in solid tumors (RECIST) v1.1

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

4 years

Notes:

[9] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                          | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |
|---|--|--|--|--|
| Subject group type                        | Reporting group  | Reporting group                                      | Reporting group                                      | Reporting group                                      |
| Number of subjects analysed               | 20   | 20   | 21   | 20   |
| Units: Percentage of participants         |  |  |  |  |
| arithmetic mean (confidence interval 90%) | 999 (999 to 999)                                       | 0.8 (0 to 4.5)                                       | 999 (999 to 999)                                     | 999 (999 to 999)                                     |

**Statistical analyses**

No statistical analyses for this end point

**Primary: Phase Ib: Planned Dose intensity - MCS110**

|                 |   |
|-----------------|---|
| End point title | Phase Ib: Planned Dose intensity - MCS110 <sup>[11][12]</sup> |
|-----------------|---|

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Measured up to a max of 112.4 weeks

Notes:

[11] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 12   | 12   | 13   |
| Units: mg/kg                         |  |  |  |  |
| arithmetic mean (standard deviation) | 0.86 (± 0.191)   | 2.74 (± 0.386)   | 2.66 (± 0.435)   | 4.85 (± 0.286)   |

|                                      |   |   |  |  |
|--------------------------------------|---|---|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 6   | 11  |  |  |
| Units: mg/kg                         |   |   |  |  |
| arithmetic mean (standard deviation) | 7.05 (± 0.594)  | 9.47 (± 1.093)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase Ib: Relative Dose intensity - MCS110

|                 |  |
|-----------------|--|
| End point title | Phase Ib: Relative Dose intensity - MCS110 <sup>[13]</sup> <sup>[14]</sup> |
|-----------------|--|

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Measured up to a max of 112.4 weeks

Notes:

[13] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 12   | 12   | 13   |
| Units: Percentage                    |  |  |  |  |
| arithmetic mean (standard deviation) | 100 (± 100)  | 100 (± 100)  | 100 (± 100)  | 99.23 (± 2.774)  |

|                                      |   |   |  |  |
|--------------------------------------|---|---|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 6   | 11  |  |  |
| Units: Percentage                    |   |   |  |  |
| arithmetic mean (standard deviation) | 100 (± 100)   | 100 (± 100)   |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Phase Ib: Planned Dose intensity - PDR001

|  |  |
|--|--|
| End point title  | Phase Ib: Planned Dose intensity - PDR001 <sup>[15]</sup> [16] |
| End point description:   |  |
| To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II. |  |
| End point type   | Primary  |
| End point timeframe:   |  |
| Measured up to a max of 112.4 weeks  |  |

Notes:

[15] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 12   | 12   | 13   |
| Units: mg                            |  |  |  |  |
| arithmetic mean (standard deviation) | 86.09 (±<br>19.058)                                    | 91.18 (±<br>12.873)                                    | 265.83 (±<br>43.528)                                   | 293.59 (±<br>16.013)                                   |

|                             |   |   |  |  |
|-----------------------------|---|---|--|--|
| <b>End point values</b>     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
| Subject group type          | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed | 6   | 11  |  |  |

|                                      |                        |                        |  |  |
|--------------------------------------|------------------------|------------------------|--|--|
| Units: mg                            |                        |                        |  |  |
| arithmetic mean (standard deviation) | 282.12 ( $\pm$ 23.773) | 289.04 ( $\pm$ 20.329) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Phase Ib: Relative Dose intensity - PDR001

|                 |  |
|-----------------|--|
| End point title | Phase Ib: Relative Dose intensity - PDR001 <sup>[17]</sup> <sup>[18]</sup> |
|-----------------|--|

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Measured up to a max of 112.4 weeks

Notes:

[17] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                     | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
|--------------------------------------|---|---|---|---|
| Subject group type                   | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed          | 6   | 12  | 12  | 13  |
| Units: Percentage                    |   |   |   |   |
| arithmetic mean (standard deviation) | 100.00 ( $\pm$ 100.00)                        | 100.00 ( $\pm$ 100.00)                        | 100.00 ( $\pm$ 100.00)                        | 100.00 ( $\pm$ 100.00)                        |

| End point values                     | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W |  |  |
|--------------------------------------|---|--|--|--|
| Subject group type                   | Reporting group                                 | Reporting group                                |  |  |
| Number of subjects analysed          | 6   | 11   |  |  |
| Units: Percentage                    |   |  |  |  |
| arithmetic mean (standard deviation) | 100.00 ( $\pm$ 100.00)                          | 100.00 ( $\pm$ 100.00)                         |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Phase Ib: Dose reductions

|  |   |
|--|---|
| End point title  | Phase Ib: Dose reductions <sup>[19][20]</sup> |
| End point description:<br>To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II. |   |
| End point type   | Primary                                       |
| End point timeframe:<br>Measured up to a max of 112.4 weeks  |   |

Notes:

[19] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[20] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                                    | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|---|--|--|--|--|
| Subject group type                                  | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                         | 6  | 12   | 12   | 13   |
| Units: Participants                                 |  |  |  |  |
| n of participants with no dose reduction-<br>MCS110 | 6  | 12   | 12   | 13   |
| n of participants with no dose reduction-<br>PDR001 | 6  | 12   | 12   | 13   |

| End point values                                    | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|---|---|---|--|--|
| Subject group type                                  | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                         | 6   | 11  |  |  |
| Units: Participants                                 |   |   |  |  |
| n of participants with no dose reduction-<br>MCS110 | 6   | 9   |  |  |
| n of participants with no dose reduction-<br>PDR001 | 6   | 11  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase Ib: Number of dose interruptions per participant

|                 |  |
|-----------------|--|
| End point title | Phase Ib: Number of dose interruptions per participant <sup>[21][22]</sup> |
|-----------------|--|

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

End point type Primary

End point timeframe:

Measured up to a max of 112.4 weeks

Notes:

[21] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[22] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                                     | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--|--|--|--|--|
| Subject group type                                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                          | 6  | 12   | 12   | 13   |
| Units: Dose interruptions per participant            |  |  |  |  |
| arithmetic mean (standard deviation)                 |  |  |  |  |
| Number of dose interruptions per<br>subject - MCS110 | 1.3 (± 1.97)   | 0.3 (± 0.45)   | 0.3 (± 0.45)   | 0.0 (± 0.0)  |
| Number of dose interruptions per<br>subject - PDR001 | 1.3 (± 1.97)   | 0.3 (± 0.45)   | 0.3 (± 0.45)   | 0.0 (± 0.0)  |

| End point values                                     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|--|---|---|--|--|
| Subject group type                                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                          | 6   | 11  |  |  |
| Units: Dose interruptions per participant            |   |   |  |  |
| arithmetic mean (standard deviation)                 |   |   |  |  |
| Number of dose interruptions per<br>subject - MCS110 | 0.3 (± 0.52)  | 0.1 (± 0.30)  |  |  |
| Number of dose interruptions per<br>subject - PDR001 | 0.3 (± 0.52)  | 0.1 (± 0.30)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase Ib: Number of subjects with at least one dose interruption

End point title Phase Ib: Number of subjects with at least one dose interruption<sup>[23]</sup><sup>[24]</sup>

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Measured up to a max of 112.4 weeks

Notes:

[23] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[24] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|---|--|--|--|--|
| Subject group type                            | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                   | 6  | 12   | 12   | 13   |
| Units: Participants                           |  |  |  |  |
| N w/ at least 1 dose interruption -<br>MCS110 | 3  | 3  | 3  | 0  |
| N w/ at least 1 dose interruption -<br>PDR001 | 3  | 3  | 3  | 0  |

| End point values                              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|---|---|---|--|--|
| Subject group type                            | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                   | 6   | 11  |  |  |
| Units: Participants                           |   |   |  |  |
| N w/ at least 1 dose interruption -<br>MCS110 | 2   | 1   |  |  |
| N w/ at least 1 dose interruption -<br>PDR001 | 2   | 1   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase Ib: Incidence rate of dose limiting toxicities (DLTs) during the first 2 cycles of study treatment.

|                 |   |
|-----------------|---|
| End point title | Phase Ib: Incidence rate of dose limiting toxicities (DLTs) during the first 2 cycles of study treatment. <sup>[25][26]</sup> |
|-----------------|---|

End point description:

Phase Ib: Dose limiting toxicities occurring during the first 2 cycles by system organ class, preferred term and maximum grade for Phase Ib. The National Cancer Institute Common Terminology Criteria for Adverse events (NCI CTCAE) version 4.03 was used for all grading.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

the first 2 cycles of study treatment; cycle = 21 days (i.e., at day 42)

Notes:

[25] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

[26] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                                      | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|---|--|--|--|--|
| Subject group type                                    | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                           | 5  | 11   | 9  | 7  |
| Units: Participants                                   |  |  |  |  |
| n of subjects with at least one event -<br>all grades | 0  | 0  | 1  | 0  |
| n Investigations - all grades                         | 0  | 0  | 1  | 0  |
| n Blood creatine phosphokinase<br>increased           | 0  | 0  | 1  | 0  |

| End point values                                      | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|---|---|---|--|--|
| Subject group type                                    | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                           | 4   | 4   |  |  |
| Units: Participants                                   |   |   |  |  |
| n of subjects with at least one event -<br>all grades | 0   | 1   |  |  |
| n Investigations - all grades                         | 0   | 1   |  |  |
| n Blood creatine phosphokinase<br>increased           | 0   | 1   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase II : Overall Response rate (ORR) - per irRC

|                        |  |
|------------------------|--|
| End point title        | Phase II : Overall Response rate (ORR) - per irRC <sup>[27]</sup>  |
| End point description: | Phase II: Overall Response Rate (Complete response (CR) or Partial response (PR)) (with confirmation) as per investigator based on immune related Response criteria (irRC) (FAS) |
| End point type         | Secondary  |
| End point timeframe:   | 4 years  |



Notes:

[27] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed       | 20  | 20   | 21   | 20   |
| Units: Percentage of participants |   |  |  |  |
| number (confidence interval 90%)  | 5 (0.3 to 21.6)   | 0 (0.0 to 13.9)  | 9.5 (1.7 to 27.1)  | 0 (0.0 to 13.9)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib: Overall Response Rate (ORR)

|                        |  |
|------------------------|--|
| End point title        | Phase Ib: Overall Response Rate (ORR) <sup>[28]</sup>  |
| End point description: | Phase Ib: Overall Response Rate (Complete response (CR) or Partial response (PR)), per RECIST v1.1 and per immune related Response criteria (irRC) |
| End point type         | Secondary  |
| End point timeframe:   | 4 years  |

Notes:

[28] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                    | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|-------------------------------------|--|--|--|--|
| Subject group type                  | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed         | 6  | 12   | 12   | 13   |
| Units: Percentage of participants   |  |  |  |  |
| number (confidence interval 90%)    |  |  |  |  |
| Overall Response Rate - RECIST v1.1 | 16.7 (0.9 to 58.2)                                     | 0 (0.0 to 22.1)  | 0 (0.0 to 22.1)  | 0 (0.0 to 20.6)  |
| Overall Response Rate - irRC        | 16.7 (0.9 to 58.2)                                     | 0 (0.0 to 22.1)  | 0 (0.0 to 22.1)  | 0 (0.0 to 20.6)  |

|                  |                            |                               |  |  |
|------------------|----------------------------|-------------------------------|--|--|
| End point values | Ph Ib: MCS110<br>7.5 mg/kg | Ph Ib: MCS110<br>10 mg/kg Q3W |  |  |
|------------------|----------------------------|-------------------------------|--|--|

|                                     | Q3W +<br>PDR001 300<br>mg Q3W | + PDR001 300<br>mg Q3W |  |  |
|-------------------------------------|-------------------------------|------------------------|--|--|
| Subject group type                  | Reporting group               | Reporting group        |  |  |
| Number of subjects analysed         | 6                             | 11                     |  |  |
| Units: Percentage of participants   |                               |                        |  |  |
| number (confidence interval 90%)    |                               |                        |  |  |
| Overall Response Rate - RECIST v1.1 | 0 (0.0 to 39.3)               | 9.1 (0.5 to 36.4)      |  |  |
| Overall Response Rate - irRC        | 0 (0.0 to 39.3)               | 9.1 (0.5 to 36.4)      |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase II : Bayesian inference of Overall Response rate (ORR) - per irRC - mean

|                 |  |
|-----------------|--|
| End point title | Phase II : Bayesian inference of Overall Response rate (ORR) - per irRC - mean <sup>[29]</sup> |
|-----------------|--|

End point description:

Full Analysis Set. Since objective responses are rare in advanced pancreatic cancer and that long lasting stable disease is considered beneficial to patients, clinical benefit rate (confirmed objective response or SD>4 months) was used as the primary endpoint for antitumor activity in this study changed from objective response to for this patient population.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

4 years

Notes:

[29] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                          | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|---|---|--|--|--|
| Subject group type                        | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed               | 20  | 0 <sup>[30]</sup>  | 21   | 20   |
| Units: Percentage of participants         |   |  |  |  |
| arithmetic mean (confidence interval 90%) | 6.7 (0.8 to 17.1)   | ( to )   | 10.8 (2.6 to 23.1)   | 0.8 (0 to 4.5)   |

Notes:

[30] - See Bayesian inference of Clinical Benefit Rate - per irRC - mean results

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 1b: Clinical Benefit Rate (CBR)

|                 |   |
|-----------------|---|
| End point title | Phase 1b: Clinical Benefit Rate (CBR) <sup>[31]</sup> |
|-----------------|---|

End point description:

Phase 1b: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) per RECIST v1.1 and per immune related Response criteria (irRC)

End point type Secondary

End point timeframe:

4 years

Notes:

[31] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                    | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|-------------------------------------|--|--|--|--|
| Subject group type                  | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed         | 6  | 12   | 12   | 13   |
| Units: Percentage of participants   |  |  |  |  |
| number (confidence interval 90%)    |  |  |  |  |
| Clinical Benefit Rate - RECIST v1.1 | 33.3 (6.3 to 72.9)                                     | 8.3 (0.4 to 33.9)                                      | 0 (0.0 to 22.1)  | 0 (0.0 to 20.6)  |
| Clinical Benefit Rate - irRC        | 50.0 (15.3 to 84.7)                                    | 8.3 (0.4 to 33.9)                                      | 0 (0.0 to 22.1)  | 7.7 (0.4 to 31.6)                                      |

| End point values                    | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |  |  |
|-------------------------------------|---|---|--|--|
| Subject group type                  | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed         | 6   | 11  |  |  |
| Units: Percentage of participants   |   |   |  |  |
| number (confidence interval 90%)    |   |   |  |  |
| Clinical Benefit Rate - RECIST v1.1 | 0 (0.0 to 39.3)   | 18.2 (3.3 to 47.0)                                      |  |  |
| Clinical Benefit Rate - irRC        | 33.3 (6.3 to 72.9)  | 18.2 (3.3 to 47.0)                                      |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) - per irRC

|                 |  |
|-----------------|--|
| End point title | Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) - per irRC <sup>[32]</sup> |
|-----------------|--|

End point description:

Phase II: Clinical Benefit Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) per immune related Response criteria (irRC)

End point type Secondary

End point timeframe:

4 years

Notes:

[32] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed       | 20  | 20   | 21   | 20   |
| Units: Percentage of participants |   |  |  |  |
| number (confidence interval 90%)  | 20.0 (7.1 to<br>40.1)   | 5.0 (0.3 to<br>21.6)   | 19.0 (6.8 to<br>38.4)  | 30.0 (14.0 to<br>50.8)   |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase II: Bayesian inference of Clinical Benefit Rate - per irRC - mean

|                 |   |
|-----------------|---|
| End point title | Phase II: Bayesian inference of Clinical Benefit Rate - per irRC - mean <sup>[33]</sup> |
|-----------------|---|

End point description:

Full Analysis Set. Since objective responses are rare in advanced pancreatic cancer and that long lasting stable disease is considered beneficial to patients, clinical benefit rate (confirmed objective response or SD>4 months) was used as the primary endpoint for antitumor activity in this study changed from objective response to for this patient population.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

4 years

Notes:

[33] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                          | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|---|---|--|--|--|
| Subject group type                        | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed               | 0 <sup>[34]</sup>   | 20   | 0 <sup>[35]</sup>  | 0 <sup>[36]</sup>  |
| Units: Percentage of participants         |   |  |  |  |
| arithmetic mean (confidence interval 90%) | ( to )  | 5.6 (0.4 to<br>15.3)   | ( to )   | ( to )   |

Notes:

[34] - See the Bayesian inference of Overall Response rate - per irRC - mean results

[35] - See the Bayesian inference of Overall Response rate - per irRC - mean results

[36] - See the Bayesian inference of Overall Response rate - per irRC - mean results

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 1b and Phase II: Progression Free Survival based on investigator assessment as per RECIST v1.1 and per immune related Response criteria (irRC) - using Kaplan-Meier method - Median

|                 |   |
|-----------------|---|
| End point title | Phase 1b and Phase II: Progression Free Survival based on investigator assessment as per RECIST v1.1 and per immune related Response criteria (irRC) - using Kaplan-Meier method - Median |
|-----------------|---|

End point description:

Phase 1b and Phase II: Progression Free Survival based on investigator assessment as per RECIST v1.1 and per immune related Response criteria (irRC) - using Kaplan-Meier method - Median

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to year 4

| End point values                 | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
|----------------------------------|---|---|---|---|
| Subject group type               | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed      | 6   | 12  | 12  | 13  |
| Units: months                    |   |   |   |   |
| median (confidence interval 90%) |   |   |   |   |
| Median PFS - per RECIST v1.1     | 1.5 (1.1 to 14.8)                             | 1.3 (1.3 to 2.7)                              | 1.3 (0.8 to 1.3)                              | 1.1 (0.6 to 1.3)                              |
| Median PFS - per irRC            | 8.2 (1.2 to 25.8)                             | 2.2 (1.3 to 2.7)                              | 1.3 (0.9 to 1.3)                              | 1.0 (0.5 to 1.3)                              |

| End point values                 | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC |
|----------------------------------|---|--|--|--|
| Subject group type               | Reporting group                                 | Reporting group                                | Reporting group  | Reporting group                                      |
| Number of subjects analysed      | 6   | 11   | 20   | 20   |
| Units: months                    |   |  |  |  |
| median (confidence interval 90%) |   |  |  |  |
| Median PFS - per RECIST v1.1     | 1.3 (0.5 to 4.0)                                | 1.2 (0.6 to 2.4)                               | 1.6 (1.4 to 2.8)                                       | 1.3 (1.2 to 1.4)                                     |
| Median PFS - per irRC            | 1.3 (0.5 to 16.8)                               | 1.2 (0.7 to 2.4)                               | 1.6 (1.4 to 2.8)                                       | 1.3 (1.2 to 1.5)                                     |

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| <b>End point values</b>          | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type               | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed      | 21   | 20   |  |  |
| Units: months                    |  |  |  |  |
| median (confidence interval 90%) |  |  |  |  |
| Median PFS - per RECIST v1.1     | 1.3 (1.2 to 1.4)   | 2.4 (1.4 to 3.7)   |  |  |
| Median PFS - per iIRC            | 1.3 (1.2 to 1.4)   | 3.7 (1.4 to 4.2)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1b and Phase II: Overall Survival - using Kaplan-Meier method - Median

|                        |  |
|------------------------|--|
| End point title        | Phase 1b and Phase II: Overall Survival - using Kaplan-Meier method - Median |
| End point description: | Phase 1b and Phase II: Overall Survival - using Kaplan-Meier method - Median |
| End point type         | Secondary  |
| End point timeframe:   | Up to year 4   |

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| <b>End point values</b>          | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type               | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed      | 6  | 12   | 12   | 13   |
| Units: months                    |  |  |  |  |
| median (confidence interval 90%) | 12.3 (3.1 to 26.6)                                     | 9.6 (3.8 to 12.2)                                      | 4.2 (1.5 to 7.9)                                       | 2.8 (1.2 to 3.8)                                       |

|                             |   |   |   |  |
|-----------------------------|---|---|---|--|
| <b>End point values</b>     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type          | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed | 6   | 11  | 20  | 20   |

|                                  |                    |                  |                   |                  |
|----------------------------------|--------------------|------------------|-------------------|------------------|
| Units: months                    |                    |                  |                   |                  |
| median (confidence interval 90%) | 22.8 (1.1 to 26.8) | 5.7 (1.2 to 8.2) | 8.9 (5.6 to 16.6) | 2.6 (1.8 to 5.0) |

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| <b>End point values</b>          | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type               | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed      | 21   | 20   |  |  |
| Units: months                    |  |  |  |  |
| median (confidence interval 90%) | 11.7 (9.2 to 14.6)   | 19.7 (9.2 to 20.3)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1b and Phase II: Duration of Response (DOR)

|                        |   |
|------------------------|---|
| End point title        | Phase 1b and Phase II: Duration of Response (DOR)   |
| End point description: | Phase 1b and Phase II: Duration of Response (DOR) per RECIST v1.1 and per immune related Response criteria (irRC) |
| End point type         | Secondary   |
| End point timeframe:   | 4 years   |

|   |  |  |  |  |
|---|--|--|--|--|
| <b>End point values</b>                           | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                                | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                       | 6  | 12   | 12   | 13   |
| Units: days                                       |  |  |  |  |
| median (full range (min-max))                     |  |  |  |  |
| Duration of response(days) - based on RECIST v1.1 | 372.0 (372 to 372)                                     | 999 (999 to 999)                                       | 999 (999 to 999)                                       | 999 (999 to 999)                                       |
| Duration of response(days) - based on irRC        | 372.0 (372.0 to 372.0)                                 | 999 (999 to 999)                                       | 999 (999 to 999)                                       | 999 (999 to 999)                                       |

|                         |   |   |   |  |
|-------------------------|---|---|---|--|
| <b>End point values</b> | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|-------------------------|---|---|---|--|

|   |                  |                        | TNBC             |                  |
|---|------------------|------------------------|------------------|------------------|
| Subject group type                                | Reporting group  | Reporting group        | Reporting group  | Reporting group  |
| Number of subjects analysed                       | 6                | 11                     | 20               | 20               |
| Units: days                                       |                  |                        |                  |                  |
| median (full range (min-max))                     |                  |                        |                  |                  |
| Duration of response(days) - based on RECIST v1.1 | 999 (999 to 999) | 155.0 (155.0 to 155.0) | 169 (169 to 169) | 999 (999 to 999) |
| Duration of response(days) - based on irRC        | 999 (999 to 999) | 155.0 (155.0 to 155.0) | 169 (169 to 169) | 999 (999 to 999) |

|   |  |  |  |  |
|---|--|--|--|--|
| <b>End point values</b>                           | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |  |  |
| Subject group type                                | Reporting group                                      | Reporting group                                      |  |  |
| Number of subjects analysed                       | 21   | 20   |  |  |
| Units: days                                       |  |  |  |  |
| median (full range (min-max))                     |  |  |  |  |
| Duration of response(days) - based on RECIST v1.1 | 328.5 (194 to 463)                                   | 999 (999 to 999)                                     |  |  |
| Duration of response(days) - based on irRC        | 328.5 (194 to 463)                                   | 999 (999 to 999)                                     |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase 1b and Phase II: Disease Control Rate (DCR)

|   |   |
|---|---|
| End point title   | Phase 1b and Phase II: Disease Control Rate (DCR) |
| End point description:  |   |
| Phase 1b and Phase II: Disease Control Rate (Complete response (CR) or Partial response (PR) or Stable disease (SD) > 4 month)) per RECIST v1.1 and per immune related Response criteria (irRC) |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| 4 years   |   |

|                                    |   |   |   |   |
|------------------------------------|---|---|---|---|
| <b>End point values</b>            | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
| Subject group type                 | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed        | 6   | 12  | 12  | 13  |
| Units: Percentage                  |   |   |   |   |
| number (confidence interval 90%)   |   |   |   |   |
| Disease Control Rate - RECIST v1.1 | 33.3 (6.3 to 72.9)                            | 8.3 (0.4 to 33.9)                             | 0 (0.0 to 22.1)                               | 15.4 (2.8 to 41.0)                            |



|                            |                     |                   |                 |                    |
|----------------------------|---------------------|-------------------|-----------------|--------------------|
| Disease Control Rate -irRC | 50.0 (15.3 to 84.7) | 8.3 (0.4 to 33.9) | 0 (0.0 to 22.1) | 15.4 (2.8 to 41.0) |
|----------------------------|---------------------|-------------------|-----------------|--------------------|

|                                    |   |  |  |  |
|------------------------------------|---|--|--|--|
| <b>End point values</b>            | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC |
| Subject group type                 | Reporting group                                 | Reporting group                                | Reporting group  | Reporting group                                      |
| Number of subjects analysed        | 6   | 11   | 20   | 20   |
| Units: Percentage                  |   |  |  |  |
| number (confidence interval 90%)   |   |  |  |  |
| Disease Control Rate - RECIST v1.1 | 16.7 (0.9 to 58.2)                              | 18.2 (3.3 to 47.0)                             | 20.0 (7.1 to 40.1)                                     | 0 (0.0 to 13.9)                                      |
| Disease Control Rate -irRC         | 33.3 (6.3 to 72.9)                              | 18.2 (3.3 to 47.0)                             | 20.0 (7.1 to 40.1)                                     | 5.0 (0.3 to 21.6)                                    |

|                                    |  |  |  |  |
|------------------------------------|--|--|--|--|
| <b>End point values</b>            | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |  |  |
| Subject group type                 | Reporting group                                      | Reporting group                                      |  |  |
| Number of subjects analysed        | 21   | 20   |  |  |
| Units: Percentage                  |  |  |  |  |
| number (confidence interval 90%)   |  |  |  |  |
| Disease Control Rate - RECIST v1.1 | 19.0 (6.8 to 38.4)                                   | 35.0 (17.7 to 55.8)                                  |  |  |
| Disease Control Rate -irRC         | 19.0 (6.8 to 38.4)                                   | 45.0 (25.9 to 65.3)                                  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase II: Percentage of participants with adverse events, as a measure of safety

|  |  |
|--|--|
| End point title  | Phase II: Percentage of participants with adverse events, as a measure of safety <sup>[37]</sup> |
| End point description:   |  |
| Phase II: To further characterize the safety and tolerability of MCS110 given in combination with PDR001 |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| From start of treatment to a maximum timeframe of 92.4 weeks for phase II.                               |  |

Notes:

[37] - 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: Summary statistics was provided, but statistical analysis is not applicable for this endpoint.

| End point values                                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |
|---|---|--|--|--|
| Subject group type                                | Reporting group   | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                       | 20  | 20   | 21   | 20   |
| Units: Participants                               |   |  |  |  |
| Adverse events - all grades                       | 20  | 20   | 21   | 20   |
| AEs - Treatment-related - all grades              | 16  | 15   | 17   | 19   |
| SAEs - all grades                                 | 8   | 14   | 8  | 7  |
| SAEs - Treatment-related - all grades             | 1   | 4  | 4  | 1  |
| Fatal SAEs - all grades                           | 1   | 1  | 0  | 1  |
| Fatal SAEs - Treatment-related - all grades       | 0   | 1  | 0  | 0  |
| AEs leading to disc.- all grades                  | 1   | 1  | 1  | 2  |
| AEs leading to disc.- Treat-related - all grades  | 1   | 0  | 1  | 1  |
| AEs leading to dose adjust / interrupt-all grades | 11  | 4  | 8  | 11   |
| AEs requiring addit.l therapy - all grades        | 19  | 18   | 19   | 17   |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Immunogenicity MCS110

|                        |   |
|------------------------|---|
| End point title        | Phase Ib and Phase II: Immunogenicity MCS110              |
| End point description: | Phase Ib and Phase II: Presence of anti-MCS110 antibodies |
| End point type         | Secondary   |
| End point timeframe:   | 4 years   |

| End point values            | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed | 6  | 12   | 12   | 13   |
| Units: Participants         |  |  |  |  |
| Baseline (B/I) positive     | 0  | 1  | 1  | 1  |
| Baseline negative           | 6  | 11   | 11   | 12   |

|  |   |    |   |   |
|--|---|----|---|---|
| Baseline missing                               | 0 | 0  | 0 | 0 |
| B/I positive, on treatment persistent positive | 0 | 0  | 0 | 0 |
| B/I positive, on treatment only last positive  | 0 | 0  | 0 | 1 |
| Baseline positive, on treatment any positive   | 0 | 0  | 0 | 0 |
| Baseline positive, on treatment all negative   | 0 | 1  | 1 | 0 |
| B/I negative, on treatment persistent positive | 0 | 0  | 0 | 0 |
| B/I negative, on treatment only last positive  | 0 | 0  | 0 | 0 |
| B/I negative, on treatment any positive        | 1 | 0  | 0 | 0 |
| Baseline negative, on treatment all negative   | 5 | 10 | 8 | 6 |
| B/I missing, on treatment persistent positive  | 0 | 0  | 0 | 0 |
| B/I missing, on treatment only last positive   | 0 | 0  | 0 | 0 |
| B/I missing, on treatment any positive         | 0 | 0  | 0 | 0 |
| B/I missing, on treatment all negative         | 0 | 0  | 0 | 0 |

| <b>End point values</b>                        | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC |
|--|---|--|--|--|
| Subject group type                             | Reporting group                                 | Reporting group                                | Reporting group  | Reporting group                                      |
| Number of subjects analysed                    | 6   | 11   | 20   | 20   |
| Units: Participants                            |   |  |  |  |
| Baseline (B/I) positive                        | 0   | 0  | 0  | 0  |
| Baseline negative                              | 6   | 11   | 19   | 19   |
| Baseline missing                               | 0   | 0  | 1  | 1  |
| B/I positive, on treatment persistent positive | 0   | 0  | 0  | 0  |
| B/I positive, on treatment only last positive  | 0   | 0  | 0  | 0  |
| Baseline positive, on treatment any positive   | 0   | 0  | 0  | 0  |
| Baseline positive, on treatment all negative   | 0   | 0  | 0  | 0  |
| B/I negative, on treatment persistent positive | 0   | 0  | 0  | 0  |
| B/I negative, on treatment only last positive  | 0   | 0  | 0  | 0  |
| B/I negative, on treatment any positive        | 0   | 0  | 0  | 0  |
| Baseline negative, on treatment all negative   | 5   | 6  | 12   | 16   |
| B/I missing, on treatment persistent positive  | 0   | 0  | 0  | 0  |
| B/I missing, on treatment only last positive   | 0   | 0  | 0  | 0  |
| B/I missing, on treatment any positive         | 0   | 0  | 0  | 0  |
| B/I missing, on treatment all negative         | 0   | 0  | 0  | 0  |

| <b>End point values</b>                        | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--|--|--|--|--|
| Subject group type                             | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed                    | 21   | 20   |  |  |
| Units: Participants                            |  |  |  |  |
| Baseline (B/I) positive                        | 0  | 0  |  |  |
| Baseline negative                              | 17   | 18   |  |  |
| Baseline missing                               | 4  | 2  |  |  |
| B/I positive, on treatment persistent positive | 0  | 0  |  |  |
| B/I positive, on treatment only last positive  | 0  | 0  |  |  |
| Baseline positive, on treatment any positive   | 0  | 0  |  |  |
| Baseline positive, on treatment all negative   | 0  | 0  |  |  |
| B/I negative, on treatment persistent positive | 0  | 0  |  |  |
| B/I negative, on treatment only last positive  | 0  | 0  |  |  |
| B/I negative, on treatment any positive        | 0  | 0  |  |  |
| Baseline negative, on treatment all negative   | 14   | 17   |  |  |
| B/I missing, on treatment persistent positive  | 0  | 0  |  |  |
| B/I missing, on treatment only last positive   | 0  | 0  |  |  |
| B/I missing, on treatment any positive         | 0  | 0  |  |  |
| B/I missing, on treatment all negative         | 0  | 0  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Immunogenicity PDR001

|                        |   |
|------------------------|---|
| End point title        | Phase Ib and Phase II: Immunogenicity PDR001              |
| End point description: | Phase Ib and Phase II: Presence of Anti-PDR001 antibodies |
| End point type         | Secondary   |
| End point timeframe:   | 4 years   |

| <b>End point values</b>                        | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--|--|--|--|--|
| Subject group type                             | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed                    | 6  | 12   | 12   | 13   |
| Units: Participants                            |  |  |  |  |
| Baseline (B/I) positive                        | 0  | 2  | 1  | 2  |
| Baseline negative                              | 6  | 10   | 11   | 10   |
| Baseline missing                               | 0  | 0  | 0  | 1  |
| B/I positive, on treatment persistent positive | 0  | 1  | 0  | 1  |
| B/I positive, on treatment only last positive  | 0  | 1  | 0  | 0  |
| B/I positive, on treatment any positive        | 0  | 0  | 0  | 0  |
| BI/ positive, on treatment all negative        | 0  | 0  | 0  | 0  |
| B/I negative, on treatment persistent positive | 0  | 1  | 0  | 0  |
| B/I negative, on treatment only last positive  | 1  | 1  | 0  | 0  |
| B/I negative, on treatment any positive        | 1  | 3  | 1  | 0  |
| B/I negative, on treatment all negative        | 4  | 4  | 8  | 6  |
| B/I missing, on treatment persistent positive  | 0  | 0  | 0  | 0  |
| B/I missing, on treatment only last positive   | 0  | 0  | 0  | 0  |
| B/I missing, on treatment any positive         | 0  | 0  | 0  | 0  |
| B/I missing, on treatment all negative         | 0  | 0  | 0  | 1  |

| <b>End point values</b>                        | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--|---|---|---|--|
| Subject group type                             | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed                    | 6   | 11  | 20  | 20   |
| Units: Participants                            |   |   |   |  |
| Baseline (B/I) positive                        | 1   | 2   | 1   | 1  |
| Baseline negative                              | 5   | 8   | 18  | 17   |
| Baseline missing                               | 0   | 1   | 1   | 2  |
| B/I positive, on treatment persistent positive | 0   | 0   | 0   | 0  |
| B/I positive, on treatment only last positive  | 0   | 0   | 0   | 1  |
| B/I positive, on treatment any positive        | 1   | 1   | 1   | 0  |
| BI/ positive, on treatment all negative        | 0   | 0   | 0   | 0  |
| B/I negative, on treatment persistent positive | 0   | 1   | 0   | 0  |
| B/I negative, on treatment only last positive  | 0   | 1   | 0   | 4  |
| B/I negative, on treatment any positive        | 0   | 0   | 0   | 1  |
| B/I negative, on treatment all negative        | 4   | 2   | 11  | 10   |
| B/I missing, on treatment persistent positive  | 0   | 0   | 0   | 0  |

|  |   |   |   |   |
|--|---|---|---|---|
| B/I missing, on treatment only last positive | 0 | 0 | 0 | 0 |
| B/I missing, on treatment any positive       | 0 | 0 | 0 | 0 |
| B/I missing, on treatment all negative       | 0 | 1 | 1 | 0 |

| End point values                               | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--|--|--|--|--|
| Subject group type                             | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed                    | 21   | 20   |  |  |
| Units: Participants                            |  |  |  |  |
| Baseline (B/I) positive                        | 0  | 1  |  |  |
| Baseline negative                              | 19   | 19   |  |  |
| Baseline missing                               | 2  | 0  |  |  |
| B/I positive, on treatment persistent positive | 0  | 0  |  |  |
| B/I positive, on treatment only last positive  | 0  | 0  |  |  |
| B/I positive, on treatment any positive        | 0  | 1  |  |  |
| Bl/ positive, on treatment all negative        | 0  | 0  |  |  |
| B/I negative, on treatment persistent positive | 0  | 1  |  |  |
| B/I negative, on treatment only last positive  | 1  | 0  |  |  |
| B/I negative, on treatment any positive        | 0  | 2  |  |  |
| B/I negative, on treatment all negative        | 16   | 13   |  |  |
| B/I missing, on treatment persistent positive  | 0  | 0  |  |  |
| B/I missing, on treatment only last positive   | 0  | 0  |  |  |
| B/I missing, on treatment any positive         | 0  | 0  |  |  |
| B/I missing, on treatment all negative         | 0  | 1  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - AUClast and AUCinf

|                 |  |
|-----------------|--|
| End point title | Phase Ib and Phase II: Pharmacokinetics of MCS110 - AUClast and AUCinf |
|-----------------|--|

End point description:

Phase Ib and Phase II: PK Parameters - AUClast, which is the AUC from time zero to the last measurable concentration sampling time (tlast) (mass × time × volume-1); and AUCinf, which is the AUC from time zero to infinity (mass × time × volume-1) - MCS110

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

cycle 1 (day 21) and cycle 4 (day 84)

| <b>End point values</b>                | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--|--|--|--|--|
| Subject group type                     | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed            | 6  | 11   | 12   | 13   |
| Units: day*ng/mL                       |  |  |  |  |
| arithmetic mean (standard deviation)   |  |  |  |  |
| AUClast (day*ng/mL) - cycle 1 - day 21 | 46900 (±<br>9080)                                      | 343000 (±<br>142000)                                   | 249000 (±<br>93400)                                    | 490000 (±<br>149000)                                   |
| AUCinf (day*ng/mL) - cycle 1 - day 21  | 50100 (±<br>11600)                                     | 383000 (±<br>178000)                                   | 330000 (±<br>73400)                                    | 560000 (±<br>177000)                                   |
| AUClast (day*ng/mL) - cycle 4 - day 84 | 41000 (±<br>22800)                                     | 213000 (±<br>92200)                                    | 232000 (±<br>99300)                                    | 710000 (±<br>171000)                                   |
| AUCinf (day*ng/mL) - cycle 4 - day 84  | 42300 (±<br>21900)                                     | 260000 (±<br>73500)                                    | 253000 (±<br>114000)                                   | 619000 (±<br>999)                                      |

| <b>End point values</b>                | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--|---|---|---|--|
| Subject group type                     | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed            | 6   | 11  | 20  | 19   |
| Units: day*ng/mL                       |   |   |   |  |
| arithmetic mean (standard deviation)   |   |   |   |  |
| AUClast (day*ng/mL) - cycle 1 - day 21 | 909000 (±<br>233000)  | 1090000 (±<br>231000)                                   | 1200000 (±<br>507000)   | 1090000 (±<br>352000)  |
| AUCinf (day*ng/mL) - cycle 1 - day 21  | 1020000 (±<br>336000)                                       | 988000 (±<br>116000)                                    | 999 (± 999)   | 999 (± 999)  |
| AUClast (day*ng/mL) - cycle 4 - day 84 | 1520000 (±<br>353000)                                       | 1200000 (±<br>1030000)                                  | 1200000 (±<br>389000)   | 918000 (±<br>102000)   |
| AUCinf (day*ng/mL) - cycle 4 - day 84  | 999 (± 999)   | 769000 (±<br>999)                                       | 999 (± 999)   | 999 (± 999)  |

| <b>End point values</b>                | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--|--|--|--|--|
| Subject group type                     | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed            | 20   | 20   |  |  |
| Units: day*ng/mL                       |  |  |  |  |
| arithmetic mean (standard deviation)   |  |  |  |  |
| AUClast (day*ng/mL) - cycle 1 - day 21 | 1120000 (±<br>440000)  | 1270000 (±<br>335000)  |  |  |
| AUCinf (day*ng/mL) - cycle 1 - day 21  | 999 (± 999)  | 999 (± 999)  |  |  |

|  |                         |                         |  |  |
|--|-------------------------|-------------------------|--|--|
| AUClast (day*ng/mL) - cycle 4 - day 84 | 1010000 ( $\pm$ 337000) | 1240000 ( $\pm$ 499000) |  |  |
| AUCinf (day*ng/mL) - cycle 4 - day 84  | 999 ( $\pm$ 999)        | 999 ( $\pm$ 999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - AUClast and AUCinf

|  |  |
|--|--|
| End point title  | Phase Ib and Phase II: Pharmacokinetics of PDR001 - AUClast and AUCinf |
| End point description:<br>Phase Ib and Phase II: Pharmacokinetics (PK) Parameters - AUClast, which is the AUC from time zero to the last measurable concentration sampling time (tlast) (mass $\times$ time $\times$ volume <sup>-1</sup> ); and AUCinf, which is the AUC from time zero to infinity (mass $\times$ time $\times$ volume <sup>-1</sup> ) and AUCinf - PDR001 |  |
| End point type   | Secondary  |
| End point timeframe:<br>cycle 1 (day 21) and cycle 4 (day 84)  |  |

| End point values                       | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
|--|---|---|---|---|
| Subject group type                     | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed            | 6   | 11  | 12  | 13  |
| Units: day*ug/mL                       |   |   |   |   |
| arithmetic mean (standard deviation)   |   |   |   |   |
| AUClast (day*ug/mL) - cycle 1 - day 21 | 229 ( $\pm$ 68.3)                             | 271 ( $\pm$ 53.8)                             | 651 ( $\pm$ 322)                              | 604 ( $\pm$ 309)                              |
| AUCinf (day*ug/mL) - cycle 1 - day 21  | 999 ( $\pm$ 999)                              | 274 ( $\pm$ 999)                              | 610 ( $\pm$ 999)                              | 999 ( $\pm$ 999)                              |
| AUClast (day*ug/mL) - cycle 4 - day 84 | 369 ( $\pm$ 26.4)                             | 330 ( $\pm$ 182)                              | 1020 ( $\pm$ 526)                             | 2020 ( $\pm$ 1170)                            |
| AUCinf (day*ug/mL) - cycle 4 - day 84  | 999 ( $\pm$ 999)                              | 196 ( $\pm$ 999)                              | 999 ( $\pm$ 999)                              | 999 ( $\pm$ 999)                              |

| End point values                       | Ph Ib: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 10 mg/kg Q3W + PDR001 300 mg Q3W | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - TNBC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC |
|--|---|--|--|--|
| Subject group type                     | Reporting group                                 | Reporting group                                | Reporting group  | Reporting group                                      |
| Number of subjects analysed            | 6   | 11   | 20   | 19   |
| Units: day*ug/mL                       |   |  |  |  |
| arithmetic mean (standard deviation)   |   |  |  |  |
| AUClast (day*ug/mL) - cycle 1 - day 21 | 581 ( $\pm$ 147)                                | 450 ( $\pm$ 135)                               | 825 ( $\pm$ 402)                                       | 782 ( $\pm$ 264)                                     |
| AUCinf (day*ug/mL) - cycle 1 - day 21  | 747 ( $\pm$ 999)                                | 710 ( $\pm$ 999)                               | 999 ( $\pm$ 999)                                       | 999 ( $\pm$ 999)                                     |
| AUClast (day*ug/mL) - cycle 4 - day 84 | 954 ( $\pm$ 179)                                | 718 ( $\pm$ 288)                               | 1170 ( $\pm$ 388)                                      | 1330 ( $\pm$ 555)                                    |



|                                       |             |             |             |             |
|---------------------------------------|-------------|-------------|-------------|-------------|
| AUCinf (day*ug/mL) - cycle 4 - day 84 | 999 (± 999) | 999 (± 999) | 999 (± 999) | 999 (± 999) |
|---------------------------------------|-------------|-------------|-------------|-------------|

|  |  |  |  |  |
|--|--|--|--|--|
| <b>End point values</b>                | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type                     | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed            | 20   | 20   |  |  |
| Units: day*ug/mL                       |  |  |  |  |
| arithmetic mean (standard deviation)   |  |  |  |  |
| AUClast (day*ug/mL) - cycle 1 - day 21 | 764 (± 311)  | 782 (± 307)  |  |  |
| AUCinf (day*ug/mL) - cycle 1 - day 21  | 999 (± 999)  | 999 (± 999)  |  |  |
| AUClast (day*ug/mL) - cycle 4 - day 84 | 1660 (± 283)   | 1260 (± 533)   |  |  |
| AUCinf (day*ug/mL) - cycle 4 - day 84  | 999 (± 999)  | 999 (± 999)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - Cmax and Clast

|                 |  |
|-----------------|--|
| End point title | Phase Ib and Phase II: Pharmacokinetics of MCS110 - Cmax and Clast |
|-----------------|--|

End point description:

Phase Ib and Phase II: PK Parameters - Cmax, which is the maximum (peak) observed plasma, blood, serum, or other body fluid drug concentration after single dose administration (mass × volume<sup>-1</sup>); and Clast - MCS110

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

cycle 1 (day 21) and cycle 4 (day 84)

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 11   | 12   | 13   |
| Units: ng/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Cmax (ng/mL) - cycle 1 - day 21      | 17400 (± 1870)   | 58800 (± 16900)  | 56700 (± 17800)  | 96900 (± 28600)  |
| Clast (ng/mL) - cycle 1 - day 21     | 1120 (± 795)   | 1290 (± 2760)  | 6600 (± 6370)  | 9130 (± 11500)   |
| Cmax (ng/mL) -- cycle 4 - day 84     | 13500 (± 5580)   | 53000 (± 9790)   | 48900 (± 14100)  | 76400 (± 24000)  |
| Clast (ng/mL) - cycle 4 - day 84     | 510 (± 457)  | 5700 (± 10300)   | 3490 (± 2410)  | 7350 (± 5870)  |

| <b>End point values</b>              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|---|---|---|--|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed          | 6   | 11  | 20  | 19   |
| Units: ng/mL                         |   |   |   |  |
| arithmetic mean (standard deviation) |   |   |   |  |
| Cmax (ng/mL) - cycle 1 - day 21      | 122000 (±<br>17100)   | 186000 (±<br>54000)                                     | 158000 (±<br>44800)   | 130000 (±<br>38400)  |
| Clast (ng/mL) - cycle 1 - day 21     | 15100 (±<br>9070)   | 28700 (±<br>27800)                                      | 33000 (±<br>21300)  | 12900 (±<br>10700)   |
| Cmax (ng/mL) -- cycle 4 - day 84     | 176000 (±<br>19800)   | 189000 (±<br>29400)                                     | 159000 (±<br>39800)   | 152000 (±<br>58000)  |
| Clast (ng/mL) - cycle 4 - day 84     | 45100 (±<br>12400)  | 34100 (±<br>29800)                                      | 57600 (±<br>45000)  | 33300 (±<br>42600)   |

| <b>End point values</b>              | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 20   | 20   |  |  |
| Units: ng/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Cmax (ng/mL) - cycle 1 - day 21      | 134000 (±<br>64900)  | 151000 (±<br>42500)  |  |  |
| Clast (ng/mL) - cycle 1 - day 21     | 24500 (±<br>20100)   | 17500 (±<br>11400)   |  |  |
| Cmax (ng/mL) -- cycle 4 - day 84     | 128000 (±<br>42600)  | 147000 (±<br>38300)  |  |  |
| Clast (ng/mL) - cycle 4 - day 84     | 18600 (±<br>21700)   | 29400 (±<br>20700)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - Cmax and Clast

|                 |  |
|-----------------|--|
| End point title | Phase Ib and Phase II: Pharmacokinetics of PDR001 - Cmax and Clast |
|-----------------|--|

End point description:

Phase Ib and Phase II: PK Parameters - Cmax, which is the maximum (peak) observed plasma, blood, serum, or other body fluid drug concentration after single dose administration (mass × volume-1); and Clast - PDR001

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

cycle 1 (day 21) and cycle 4 (day 84)

| End point values                     | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 11   | 12   | 13   |
| Units: ug/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Cmax (ug/mL) - cycle 1 - day 21      | 24 (± 9.52)  | 29.5 (± 6.56)  | 73.4 (± 22.3)  | 77 (± 24.3)  |
| Clast (ug/mL) - cycle 1 - day 21     | 7.73 (± 2.97)  | 7.24 (± 2.95)  | 19.4 (± 11.7)  | 26.4 (± 11.8)  |
| Cmax (ug/mL) -- cycle 4 - day 84     | 29.5 (± 9.3)   | 36.8 (± 10.5)  | 126 (± 54.6)   | 153 (± 22.6)   |
| Clast (ug/mL) - cycle 4 - day 84     | 10.7 (± 2.25)  | 14.5 (± 8.47)  | 65.1 (± 37.6)  | 71 (± 6.65)  |

| End point values                     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|---|---|---|--|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed          | 6   | 11  | 20  | 19   |
| Units: ug/mL                         |   |   |   |  |
| arithmetic mean (standard deviation) |   |   |   |  |
| Cmax (ug/mL) - cycle 1 - day 21      | 76.6 (± 36.8)   | 64.2 (± 20.4)   | 94.5 (± 27.4)   | 75.3 (± 23.9)  |
| Clast (ug/mL) - cycle 1 - day 21     | 22.7 (± 12.8)   | 17.2 (± 8.67)   | 34.5 (± 13.3)   | 24 (± 12)  |
| Cmax (ug/mL) -- cycle 4 - day 84     | 92 (± 22.1)   | 85.9 (± 16.8)   | 123 (± 56.8)  | 127 (± 7)  |
| Clast (ug/mL) - cycle 4 - day 84     | 47.5 (± 25.7)   | 35.6 (± 14.7)   | 81.4 (± 43.6)   | 62.1 (± 9.93)  |

| End point values                     | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 20   | 20   |  |  |
| Units: ug/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Cmax (ug/mL) - cycle 1 - day 21      | 80.2 (± 24)  | 70.3 (± 21.6)  |  |  |
| Clast (ug/mL) - cycle 1 - day 21     | 22.8 (± 9.44)  | 24.4 (± 14.6)  |  |  |
| Cmax (ug/mL) -- cycle 4 - day 84     | 122 (± 23.6)   | 108 (± 23.4)   |  |  |
| Clast (ug/mL) - cycle 4 - day 84     | 48.8 (± 20.6)  | 51.3 (± 23.7)  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - Tmax

|  |  |
|--|--|
| End point title  | Phase Ib and Phase II: Pharmacokinetics of MCS110 - Tmax |
| End point description:<br>Phase Ib and Phase II: PK Parameters - Tmax, which is the time to reach maximum (peak) plasma, blood, serum, or other body fluid drug concentration after single dose administration (time) - MCS110 |  |
| End point type   | Secondary  |
| End point timeframe:<br>cycle 1 (day 21) and cycle 4 (day 84)  |  |

| End point values              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed   | 6  | 11   | 12   | 13   |
| Units: hour                   |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| Tmax (h) - cycle 1 - day 21   | 2.02 (1.5 to 2.08)                                     | 1.92 (0.5 to 23.7)                                     | 2.08 (1.5 to 22.2)                                     | 2.13 (1.92 to 24)                                      |
| Tmax (h) - cycle 4 - day 84   | 2 (2 to 2)   | 2.05 (0.5 to 2.08)                                     | 2.03 (2 to 23.7)                                       | 13 (2.02 to 24)  |

| End point values              | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|-------------------------------|---|---|---|--|
| Subject group type            | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed   | 6   | 11  | 20  | 19   |
| Units: hour                   |   |   |   |  |
| median (full range (min-max)) |   |   |   |  |
| Tmax (h) - cycle 1 - day 21   | 2.06 (2 to 24.4)  | 2.04 (1.92 to 26.2)                                     | 2.01 (0.5 to 162)   | 2.08 (1.92 to 2.28)  |
| Tmax (h) - cycle 4 - day 84   | 2 (2 to 20.8)   | 2.03 (1.98 to 21.3)                                     | 2 (1.92 to 2.12)  | 2.02 (1.98 to 2.08)  |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type            | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed   | 20   | 20   |  |  |
| Units: hour                   |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| Tmax (h) - cycle 1 - day 21   | 2.09 (2 to 163)  | 2.08 (1.5 to 188)  |  |  |
| Tmax (h) - cycle 4 - day 84   | 2.04 (2 to 2.12)   | 2.05 (2 to 2.13)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - Tmax

|                        |  |
|------------------------|--|
| End point title        | Phase Ib and Phase II: Pharmacokinetics of PDR001 - Tmax   |
| End point description: | Phase Ib and Phase II: PK Parameters - Tmax, which is the time to reach maximum (peak) plasma, blood, serum, or other body fluid drug concentration after single dose administration (time) - PDR001 |
| End point type         | Secondary  |
| End point timeframe:   | cycle 1 (day 21) and cycle 4 (day 84)  |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type            | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed   | 6  | 11   | 12   | 13   |
| Units: hour                   |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| Tmax (h) - cycle 1 - day 21   | 11.5 (1.48 to 26)                                      | 2.08 (1.5 to 25.5)                                     | 1.53 (1 to 26.5)                                       | 1.57 (1.5 to 22.3)                                     |
| Tmax (h) - cycle 4 - day 84   | 1.52 (1.5 to 22.4)                                     | 1.53 (0 to 23.7)                                       | 1.2 (0 to 1.5)   | 1.57 (1.55 to 1.58)                                    |

|                             |   |   |   |  |
|-----------------------------|---|---|---|--|
| <b>End point values</b>     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type          | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed | 6   | 11  | 20  | 19   |
| Units: hour                 |   |   |   |  |

|                               |                      |                     |                   |                     |
|-------------------------------|----------------------|---------------------|-------------------|---------------------|
| median (full range (min-max)) |                      |                     |                   |                     |
| Tmax (h) - cycle 1 - day 21   | 1.53 (0.983 to 25.8) | 1.52 (1.5 to 22.8)  | 1.5 (1 to 168)    | 1.5 (0.5 to 3.22)   |
| Tmax (h) - cycle 4 - day 84   | 1.5 (1.5 to 3.42)    | 1.45 (1.43 to 2.92) | 1.53 (1.5 to 165) | 1.47 (1.42 to 1.48) |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |  |  |
| Subject group type            | Reporting group                                      | Reporting group                                      |  |  |
| Number of subjects analysed   | 20   | 20   |  |  |
| Units: hour                   |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| Tmax (h) - cycle 1 - day 21   | 1.5 (1.42 to 166)                                    | 1.5 (1.45 to 624)                                    |  |  |
| Tmax (h) - cycle 4 - day 84   | 1.54 (1.48 to 1.62)                                  | 1.5 (1.43 to 1.67)                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - T1/2

|                        |  |
|------------------------|--|
| End point title        | Phase Ib and Phase II: Pharmacokinetics of MCS110 - T1/2   |
| End point description: | Phase Ib and Phase II: PK Parameters - T1/2, which is the terminal half-life associated with the terminal slope of a semi logarithmic concentration time curve (time) - MCS110 |
| End point type         | Secondary  |
| End point timeframe:   | cycle 1 (day 21) and cycle 4 (day 84)  |

|                               |   |   |   |   |
|-------------------------------|---|---|---|---|
| <b>End point values</b>       | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
| Subject group type            | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed   | 6   | 11  | 12  | 13  |
| Units: day                    |   |   |   |   |
| median (full range (min-max)) |   |   |   |   |
| T1/2 (day) - cycle 1 - day 21 | 1.5 (1.25 to 2.38)                            | 2.16 (1.68 to 6.71)                           | 3.3 (1.85 to 5.32)                            | 3.48 (1.73 to 7.82)                           |
| T1/2 (day) - cycle 4 - day 84 | 1.77 (1.23 to 1.81)                           | 1.53 (1.03 to 2.49)                           | 4.08 (1.41 to 4.26)                           | 6.32 (6.32 to 6.32)                           |

|                               |   |   |   |  |
|-------------------------------|---|---|---|--|
| <b>End point values</b>       | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type            | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed   | 6   | 11  | 20  | 19   |
| Units: day                    |   |   |   |  |
| median (full range (min-max)) |   |   |   |  |
| T1/2 (day) - cycle 1 - day 21 | 6.35 (2.17 to<br>8.05)                                      | 4.36 (2.25 to<br>6.62)                                  | 999 (999 to<br>999)   | 999 (999 to<br>999)  |
| T1/2 (day) - cycle 4 - day 84 | 999 (999 to<br>999)   | 4.82 (4.82 to<br>4.82)                                  | 999 (999 to<br>999)   | 999 (999 to<br>999)  |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type            | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed   | 20   | 20   |  |  |
| Units: day                    |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| T1/2 (day) - cycle 1 - day 21 | 999 (999 to<br>999)  | 999 (999 to<br>999)  |  |  |
| T1/2 (day) - cycle 4 - day 84 | 999 (999 to<br>999)  | 999 (999 to<br>999)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - T1/2

|  |  |
|--|--|
| End point title  | Phase Ib and Phase II: Pharmacokinetics of PDR001 - T1/2 |
| End point description:<br>Phase Ib and Phase II: PK Parameters - T1/2, which is the terminal half-life associated with the terminal slope of a semi logarithmic concentration time curve (time) - PDR001 |  |
| End point type   | Secondary  |
| End point timeframe:<br>cycle 1 (day 21) and cycle 4 (day 84)  |  |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type            | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed   | 6  | 11   | 12   | 13   |
| Units: day                    |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| T1/2 (day) - cycle 1 - day 21 | 999 (999 to<br>999)                                    | 8.14 (8.14 to<br>8.14)                                 | 7.71 (7.71 to<br>7.71)                                 | 999 (999 to<br>999)                                    |
| T1/2 (day) - cycle 4 - day 84 | 999 (999 to<br>999)                                    | 7.81 (7.81 to<br>7.81)                                 | 999 (999 to<br>999)                                    | 999 (999 to<br>999)                                    |

|                               |   |   |   |  |
|-------------------------------|---|---|---|--|
| <b>End point values</b>       | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type            | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed   | 6   | 11  | 20  | 19   |
| Units: day                    |   |   |   |  |
| median (full range (min-max)) |   |   |   |  |
| T1/2 (day) - cycle 1 - day 21 | 7.13 (7.13 to<br>7.13)                                      | 7.33 (7.33 to<br>7.33)                                  | 999 (999 to<br>999)   | 999 (999 to<br>999)  |
| T1/2 (day) - cycle 4 - day 84 | 999 (999 to<br>999)   | 999 (999 to<br>999)                                     | 999 (999 to<br>999)   | 999 (999 to<br>999)  |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type            | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed   | 20   | 20   |  |  |
| Units: day                    |  |  |  |  |
| median (full range (min-max)) |  |  |  |  |
| T1/2 (day) - cycle 1 - day 21 | 999 (999 to<br>999)  | 999 (999 to<br>999)  |  |  |
| T1/2 (day) - cycle 4 - day 84 | 999 (999 to<br>999)  | 999 (999 to<br>999)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - CL

|                 |  |
|-----------------|--|
| End point title | Phase Ib and Phase II: Pharmacokinetics of MCS110 - CL |
|-----------------|--|



End point description:

Phase Ib and Phase II: PK Parameters - CL, which is the total body clearance of drug from the plasma (volume × time-1) - MCS110

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

cycle 1 (day 21) and cycle 4 (day 84)

| End point values                     | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 11   | 12   | 13   |
| Units: L/h/kg                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| CL (L/h/kg) - cycle 1 - day 21       | 0.000863 (±<br>0.000158)                               | 0.000388 (±<br>0.000181)                               | 0.000394 (±<br>0.0000833)                              | 0.000407 (±<br>0.000131)                               |
| CL (L/h/kg) - cycle 4 - day 84       | 0.00117 (±<br>0.000549)                                | 0.000523 (±<br>0.000199)                               | 0.000315 (±<br>0.000218)                               | 0.000337 (±<br>999)                                    |

| End point values                     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|---|---|---|--|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed          | 6   | 11  | 20  | 19   |
| Units: L/h/kg                        |   |   |   |  |
| arithmetic mean (standard deviation) |   |   |   |  |
| CL (L/h/kg) - cycle 1 - day 21       | 0.000338 (±<br>0.000117)                                    | 0.000427 (±<br>0.0000558)                               | 999 (± 999)   | 999 (± 999)  |
| CL (L/h/kg) - cycle 4 - day 84       | 999 (± 999)   | 0.000541 (±<br>999)                                     | 999 (± 999)   | 999 (± 999)  |

| End point values                     | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 20   | 20   |  |  |
| Units: L/h/kg                        |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| CL (L/h/kg) - cycle 1 - day 21       | 999 (± 999)  | 999 (± 999)  |  |  |
| CL (L/h/kg) - cycle 4 - day 84       | 999 (± 999)  | 999 (± 999)  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - CL

|   |  |
|---|--|
| End point title   | Phase Ib and Phase II: Pharmacokinetics of PDR001 - CL |
| End point description:  |  |
| Phase Ib and Phase II: PK Parameters - CL, which is the total body clearance of drug from the plasma (volume × time-1) - PDR001 |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| cycle 1 (day 21) and cycle 4 (day 84)   |  |

| End point values                     | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 11   | 12   | 13   |
| Units: L/h                           |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| CL (L/h) - cycle 1 - day 21          | 999 (± 999)  | 0.0152 (± 999)   | 0.0205 (± 999)   | 999 (± 999)  |
| CL (L/h) - cycle 4 - day 84          | 999 (± 999)  | 0.0213 (± 999)   | 999 (± 999)  | 999 (± 999)  |

| End point values                     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|---|---|---|--|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed          | 6   | 11  | 20  | 19   |
| Units: L/h                           |   |   |   |  |
| arithmetic mean (standard deviation) |   |   |   |  |
| CL (L/h) - cycle 1 - day 21          | 0.0167 (± 999)  | 0.0176 (± 999)  | 999 (± 999)   | 999 (± 999)  |
| CL (L/h) - cycle 4 - day 84          | 999 (± 999)   | 999 (± 999)   | 999 (± 999)   | 999 (± 999)  |

| End point values | Ph II: MCS110<br>7.5 mg/kg<br>Q3W + | Ph II: MCS110<br>7.5 mg/kg<br>Q3W + |  |  |
|------------------|-------------------------------------|-------------------------------------|--|--|
|------------------|-------------------------------------|-------------------------------------|--|--|

|                                      | PDR001 300<br>mg Q3W - EC | PDR001 300<br>mg Q3W - ME |  |  |
|--------------------------------------|---------------------------|---------------------------|--|--|
| Subject group type                   | Reporting group           | Reporting group           |  |  |
| Number of subjects analysed          | 20                        | 20                        |  |  |
| Units: L/h                           |                           |                           |  |  |
| arithmetic mean (standard deviation) |                           |                           |  |  |
| CL (L/h) - cycle 1 - day 21          | 999 (± 999)               | 999 (± 999)               |  |  |
| CL (L/h) - cycle 4 - day 84          | 999 (± 999)               | 999 (± 999)               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - Vz

|   |  |
|---|--|
| End point title   | Phase Ib and Phase II: Pharmacokinetics of MCS110 - Vz |
| End point description:<br>Phase Ib and Phase II: PK Parameters - Vz, which is the apparent volume of distribution during terminal phase (volume) - MCS110 |  |
| End point type  | Secondary  |
| End point timeframe:<br>cycle 1 (day 21) and cycle 4 (day 84)   |  |

| End point values                     | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 6  | 11   | 12   | 13   |
| Units: L/kg                          |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Vz (L/kg) - cycle 1 - day 21         | 0.0486 (±<br>0.00989)                                  | 0.0334 (±<br>0.00783)                                  | 0.0423 (±<br>0.00875)                                  | 0.051 (±<br>0.0206)                                    |
| Vz (L/kg) - cycle 4 - day 84         | 0.0684 (±<br>0.0407)                                   | 0.0294 (±<br>0.0128)                                   | 0.045 (±<br>0.0308)                                    | 0.0736 (± 999)   |

| End point values                     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|---|---|---|--|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed          | 6   | 11  | 20  | 19   |
| Units: L/kg                          |   |   |   |  |
| arithmetic mean (standard deviation) |   |   |   |  |
| Vz (L/kg) - cycle 1 - day 21         | 0.0651 (±<br>0.0201)  | 0.065 (±<br>0.0267)                                     | 999 (± 999)   | 999 (± 999)  |
| Vz (L/kg) - cycle 4 - day 84         | 999 (± 999)   | 0.0904 (± 999)  | 999 (± 999)   | 999 (± 999)  |

|  |  |  |  |  |
|--|--|--|--|--|
| <b>End point values</b>                  | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type                       | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed              | 20   | 20   |  |  |
| Units: L/kg                              |  |  |  |  |
| arithmetic mean (standard deviation)     |  |  |  |  |
| V <sub>z</sub> (L/kg) - cycle 1 - day 21 | 999 (± 999)  | 999 (± 999)  |  |  |
| V <sub>z</sub> (L/kg) - cycle 4 - day 84 | 999 (± 999)  | 999 (± 999)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - V<sub>z</sub>

|                        |  |
|------------------------|--|
| End point title        | Phase Ib and Phase II: Pharmacokinetics of PDR001 - V <sub>z</sub>   |
| End point description: | Phase Ib and Phase II: PK Parameters - V <sub>z</sub> , which is the apparent volume of distribution during terminal phase (volume) - PDR001 |
| End point type         | Secondary  |
| End point timeframe:   | cycle 1 (day 21) and cycle 4 (day 84)  |

|                                       |  |  |  |  |
|---------------------------------------|--|--|--|--|
| <b>End point values</b>               | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                    | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed           | 6  | 11   | 12   | 13   |
| Units: Liters (L)                     |  |  |  |  |
| arithmetic mean (standard deviation)  |  |  |  |  |
| V <sub>z</sub> (L) - cycle 1 - day 21 | 999 (± 999)  | 4.28 (± 999)   | 5.47 (± 999)   | 999 (± 999)  |
| V <sub>z</sub> (L) - cycle 4 - day 84 | 999 (± 999)  | 5.76 (± 999)   | 999 (± 999)  | 999 (± 999)  |

|                             |   |   |   |  |
|-----------------------------|---|---|---|--|
| <b>End point values</b>     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type          | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed | 6   | 11  | 20  | 19   |

|                                      |              |              |             |             |
|--------------------------------------|--------------|--------------|-------------|-------------|
| Units: Liters (L)                    |              |              |             |             |
| arithmetic mean (standard deviation) |              |              |             |             |
| Vz (L) - cycle 1 - day 21            | 4.13 (± 999) | 4.47 (± 999) | 999 (± 999) | 999 (± 999) |
| Vz (L) - cycle 4 - day 84            | 999 (± 999)  | 999 (± 999)  | 999 (± 999) | 999 (± 999) |

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 20   | 20   |  |  |
| Units: Liters (L)                    |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Vz (L) - cycle 1 - day 21            | 999 (± 999)  | 999 (± 999)  |  |  |
| Vz (L) - cycle 4 - day 84            | 999 (± 999)  | 999 (± 999)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Phase Ib and Phase II: Pharmacokinetics of MCS110 - Accumulation ratio (AR)

|  |   |
|--|---|
| End point title  | Phase Ib and Phase II: Pharmacokinetics of MCS110 - Accumulation ratio (AR) |
| End point description:<br>Phase Ib and Phase II: PK Parameters - Accumulation ratio (AR), which is the AUClast (multiple Dose)/AUClast (single dose) (for cycle 4 only) - MCS110 |   |
| End point type   | Secondary   |
| End point timeframe:<br>cycle 4 (day 84)   |   |

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 3  | 6  | 4  | 2  |
| Units: Ratio of AUC                  |  |  |  |  |
| arithmetic mean (standard deviation) | 0.789 (±<br>0.232)                                     | 0.744 (±<br>0.307)                                     | 0.833 (±<br>0.0739)                                    | 1.14 (±<br>0.0991)                                     |

|                         |                                     |   |                                     |                                     |
|-------------------------|-------------------------------------|---|-------------------------------------|-------------------------------------|
| <b>End point values</b> | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W + | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300 | Ph II: MCS110<br>7.5 mg/kg<br>Q3W + | Ph II: MCS110<br>7.5 mg/kg<br>Q3W + |
|-------------------------|-------------------------------------|---|-------------------------------------|-------------------------------------|

|                                      | PDR001 300 mg Q3W | mg Q3W          | PDR001 300 mg Q3W - TNBC | PDR001 300 mg Q3W - PC |
|--------------------------------------|-------------------|-----------------|--------------------------|------------------------|
| Subject group type                   | Reporting group   | Reporting group | Reporting group          | Reporting group        |
| Number of subjects analysed          | 3                 | 3               | 4                        | 3                      |
| Units: Ratio of AUC                  |                   |                 |                          |                        |
| arithmetic mean (standard deviation) | 1.37 (± 0.278)    | 1.04 (± 0.731)  | 0.712 (± 0.205)          | 0.829 (± 0.177)        |

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - EC | Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME |  |  |
| Subject group type                   | Reporting group                                      | Reporting group                                      |  |  |
| Number of subjects analysed          | 4  | 12   |  |  |
| Units: Ratio of AUC                  |  |  |  |  |
| arithmetic mean (standard deviation) | 0.723 (± 0.315)                                      | 0.987 (± 0.35)                                       |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - Accumulation ratio (AR)

|                 |   |
|-----------------|---|
| End point title | Phase Ib and Phase II: Pharmacokinetics of PDR001 - Accumulation ratio (AR) |
|-----------------|---|

End point description:

Phase Ib and Phase II: PK Parameters - Accumulation ratio (AR), which is the AUClast (multiple Dose)/AUClast (single dose) (for cycle 4 only) - PDR001

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

cycle 4 (day 84)

|                                      |   |   |   |   |
|--------------------------------------|---|---|---|---|
| <b>End point values</b>              | Ph Ib: MCS110 1 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 100 mg Q3W | Ph Ib: MCS110 3 mg/kg Q3W + PDR001 300 mg Q3W | Ph Ib: MCS110 5 mg/kg Q3W + PDR001 300 mg Q3W |
| Subject group type                   | Reporting group                               | Reporting group                               | Reporting group                               | Reporting group                               |
| Number of subjects analysed          | 3   | 6   | 4   | 2   |
| Units: Ratio of AUC                  |   |   |   |   |
| arithmetic mean (standard deviation) | 1.48 (± 0.17)                                 | 1.15 (± 0.522)                                | 1.14 (± 0.176)                                | 1.89 (± 0.84)                                 |

|                         |               |               |               |               |
|-------------------------|---------------|---------------|---------------|---------------|
| <b>End point values</b> | Ph Ib: MCS110 | Ph Ib: MCS110 | Ph II: MCS110 | Ph II: MCS110 |
|-------------------------|---------------|---------------|---------------|---------------|

|                                      | 7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | 10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | 7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | 7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
|--------------------------------------|--|--|--|---|
| Subject group type                   | Reporting group                            | Reporting group                        | Reporting group                                      | Reporting group                                 |
| Number of subjects analysed          | 3  | 3                                      | 5  | 3   |
| Units: Ratio of AUC                  |  |  |  |   |
| arithmetic mean (standard deviation) | 1.85 (± 0.348)                             | 1.5 (± 0.848)                          | 1.08 (± 0.235)                                       | 1.56 (± 0.593)                                  |

| End point values                     | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed          | 4  | 13   |  |  |
| Units: Ratio of AUC                  |  |  |  |  |
| arithmetic mean (standard deviation) | 2.05 (± 0.156)   | 1.54 (± 0.664)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Post-hoc: Phase Ib and Phase II: All Collected Deaths

|  |   |
|--|---|
| End point title  | Phase Ib and Phase II: All Collected Deaths |
| End point description:   |   |
| On treatment deaths are reported from the start of treatment until end of study treatment plus 30 days, up to maximum duration of 116.4 weeks for phase Ib and 92.4 weeks for phase II. Deaths post treatment survival follow up are reported after the on-treatment period, up to a maximum timeframe of 46 months (3.8 years). |   |
| End point type   | Post-hoc                                    |
| End point timeframe:   |   |
| For on-treatment deaths: up to maximum timeframe of 116.4 weeks for phase Ib and 92.4 weeks for phase II. For total deaths: up to 3.8 years  |   |

| End point values            | Ph Ib: MCS110<br>1 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 100<br>mg Q3W | Ph Ib: MCS110<br>3 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>5 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed | 6  | 12   | 12   | 13   |
| Units: Participants         |  |  |  |  |
| Total Deaths                | 6  | 12   | 10   | 12   |
| On-treatment Deaths         | 0  | 1  | 4  | 4  |

|                             |   |   |   |  |
|-----------------------------|---|---|---|--|
| <b>End point values</b>     | Ph Ib: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W | Ph Ib: MCS110<br>10 mg/kg Q3W<br>+ PDR001 300<br>mg Q3W | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W -<br>TNBC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - PC |
| Subject group type          | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed | 6   | 11  | 20  | 20   |
| Units: Participants         |   |   |   |  |
| Total Deaths                | 4   | 10  | 11  | 19   |
| On-treatment Deaths         | 1   | 4   | 1   | 3  |

|                             |  |  |  |  |
|-----------------------------|--|--|--|--|
| <b>End point values</b>     | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - EC | Ph II: MCS110<br>7.5 mg/kg<br>Q3W +<br>PDR001 300<br>mg Q3W - ME |  |  |
| Subject group type          | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed | 21   | 20   |  |  |
| Units: Participants         |  |  |  |  |
| Total Deaths                | 14   | 11   |  |  |
| On-treatment Deaths         | 0  | 2  |  |  |

### Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

On-treatment adverse events are reported, from first dose of study treatment until end of study treatment plus 30 days, up to maximum timeframe of 116.4 weeks for phase Ib and 92.4 weeks for phase II.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

### Reporting groups

|                       |   |
|-----------------------|---|
| Reporting group title | Ph Ib: MCS110@1 mg/kg Q3W@+ PDR001 100@mg Q3W |
|-----------------------|---|

Reporting group description:

Ph Ib: MCS110@1 mg/kg Q3W@+ PDR001 100@mg Q3W

|                       |   |
|-----------------------|---|
| Reporting group title | Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 100@mg Q3W |
|-----------------------|---|

Reporting group description:

Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 100@mg Q3W

|                       |   |
|-----------------------|---|
| Reporting group title | Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 300@mg Q3W |
|-----------------------|---|

Reporting group description:

Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 300@mg Q3W

|                       |   |
|-----------------------|---|
| Reporting group title | Ph Ib: MCS110@5 mg/kg Q3W@+ PDR001 300@mg Q3W |
|-----------------------|---|

Reporting group description:

Ph Ib: MCS110@5 mg/kg Q3W@+ PDR001 300@mg Q3W

|                       |   |
|-----------------------|---|
| Reporting group title | Ph Ib: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W |
|-----------------------|---|

Reporting group description:

Ph Ib: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W

|                       |  |
|-----------------------|--|
| Reporting group title | Ph Ib: MCS110@10 mg/kg Q3W@+ PDR001 300@mg Q3W |
|-----------------------|--|

Reporting group description:

Ph Ib: MCS110@10 mg/kg Q3W@+ PDR001 300@mg Q3W

|                       |  |
|-----------------------|--|
| Reporting group title | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - TNBC |
|-----------------------|--|

Reporting group description:

Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - TNBC

|                       |  |
|-----------------------|--|
| Reporting group title | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - PC |
|-----------------------|--|

Reporting group description:

Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - PC

|                       |  |
|-----------------------|--|
| Reporting group title | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - EC |
|-----------------------|--|

Reporting group description:

Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - EC

|                       |  |
|-----------------------|--|
| Reporting group title | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - ME |
|-----------------------|--|

Reporting group description:

Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - ME

| <b>Serious adverse events</b>                                       | Ph Ib: MCS110@1<br>mg/kg Q3W@+<br>PDR001 100@mg<br>Q3W | Ph Ib: MCS110@3<br>mg/kg Q3W@+<br>PDR001 100@mg<br>Q3W | Ph Ib: MCS110@3<br>mg/kg Q3W@+<br>PDR001 300@mg<br>Q3W |
|---|--|--|--|
| Total subjects affected by serious adverse events                   |  |  |  |
| subjects affected / exposed   | 3 / 6 (50.00%)   | 4 / 12 (33.33%)  | 4 / 12 (33.33%)  |
| number of deaths (all causes)                                       | 0  | 1  | 4  |
| number of deaths resulting from adverse events                      | 0  | 0  | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |  |
| Infected neoplasm   |  |  |  |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 12 (0.00%)   | 0 / 12 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0  |
| Lymphangiosis carcinomatosa   |  |  |  |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 12 (0.00%)   | 0 / 12 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0  |
| Metastases to central nervous system                                |  |  |  |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 12 (0.00%)   | 1 / 12 (8.33%)   |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 1  |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0  |
| Tumour pain   |  |  |  |
| subjects affected / exposed   | 1 / 6 (16.67%)   | 0 / 12 (0.00%)   | 0 / 12 (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  |
| Vascular disorders  |  |  |  |
| Deep vein thrombosis  |  |  |  |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 12 (0.00%)   | 0 / 12 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0  |
| Hypertensive crisis   |  |  |  |
| subjects affected / exposed   | 0 / 6 (0.00%)  | 0 / 12 (0.00%)   | 0 / 12 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0  |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Thrombosis   |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 |                |                |                |
| Asthenia   |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Chills   |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Fatigue  |                |                |                |
| subjects affected / exposed                          | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| General physical health deterioration                |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Generalised oedema                                   |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Pyrexia  |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Ulcer  |                |                |                |
| subjects affected / exposed                          | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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%)  | 1 / 12 (8.33%) | 0 / 12 (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 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia aspiration                            |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Pneumonitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 failure                             |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Product issues                                  |                |                |                |
| Device breakage                                 |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Investigations                                  |                |                |                |
| Alanine aminotransferase increased              |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 creatinine increased                      |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Injury, poisoning and procedural complications  |                |                |                |
| Gastrointestinal procedural complication        |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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                        |                |                |                |
| Cerebral infarction                             |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Guillain-Barre syndrome                         |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Seizure   |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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>               |                |                |                |
| Abdominal pain                                  |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ascites   |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Constipation                                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Dyspepsia                                       |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Gastric haemorrhage                             |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 haemorrhage                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Haemoperitoneum                                 |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 perforation                          |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Large intestinal obstruction                    |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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 gastrointestinal haemorrhage              |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nausea  |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Rectal haemorrhage                              |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Hepatobiliary disorders                         |                |                |                |
| Bile duct obstruction                           |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Cholecystitis                                   |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Jaundice cholestatic                            |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Rash papular                                    |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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                     |                |                |                |
| Anuria  |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (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 failure                                   |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 impairment                                |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                |                |                |
| Arthritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |



|   |                |                |                |
|---|----------------|----------------|----------------|
| Bone pain                                       |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Fistula   |                |                |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (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          |
| Flank pain                                      |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pain in extremity                               |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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                     |                |                |                |
| Cystitis  |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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 infection                               |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infection                                       |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Peritonitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumocystis jirovecii pneumonia                |                |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin infection                                  |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper respiratory tract infection               |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (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 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |               |                |                |
| Dehydration                                     |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperkalaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyponatraemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypophosphataemia                               |               |                |                |
| subjects affected / exposed                     | 0 / 6 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| 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>                                       | Ph Ib: MCS110@5 mg/kg Q3W@+ PDR001 300@mg Q3W | Ph Ib: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W | Ph Ib: MCS110@10 mg/kg Q3W@+ PDR001 300@mg Q3W |
|---|---|---|--|
| Total subjects affected by serious adverse events                   |   |   |  |
| subjects affected / exposed   | 7 / 13 (53.85%)                               | 2 / 6 (33.33%)                                  | 5 / 11 (45.45%)                                |
| number of deaths (all causes)                                       | 4   | 1   | 4  |
| number of deaths resulting from adverse events                      | 0   | 0   | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |  |
| Infected neoplasm   |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0  |
| Lymphangiosis carcinomatosa   |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0  |
| Metastases to central nervous system                                |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0  |
| Tumour pain   |   |   |  |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Vascular disorders                                   |                |                |                |
| Deep vein thrombosis                                 |                |                |                |
| subjects affected / exposed                          | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (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          |
| Hypertensive crisis                                  |                |                |                |
| subjects affected / exposed                          | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Thrombosis   |                |                |                |
| subjects affected / exposed                          | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Asthenia   |                |                |                |
| subjects affected / exposed                          | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (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          |
| Chills   |                |                |                |
| subjects affected / exposed                          | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Fatigue  |                |                |                |
| subjects affected / exposed                          | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| General physical health deterioration                |                |                |                |
| subjects affected / exposed                          | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 0 / 11 (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          |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| Generalised oedema                              |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pyrexia   |                 |                |                |
| subjects affected / exposed                     | 2 / 13 (15.38%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2           | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Ulcer   |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                 |                |                |
| Dyspnoea  |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 aspiration                            |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pneumonitis                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |                 |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 failure                             |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Product issues                                  |                |                |                |
| Device breakage                                 |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Investigations                                  |                |                |                |
| Alanine aminotransferase increased              |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Aspartate aminotransferase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 creatinine increased                      |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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  |                |                |                |
| Gastrointestinal procedural complication        |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Nervous system disorders                        |                |                |                |
| Cerebral infarction                             |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Guillain-Barre syndrome                         |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Seizure   |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |                |                |                |
| Abdominal pain                                  |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Ascites   |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Constipation                                    |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Dyspepsia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastric haemorrhage                             |                |                |                |

|   |                |               |                |
|---|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 haemorrhage                    |                |               |                |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 0 / 6 (0.00%) | 0 / 11 (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          |
| Haemoperitoneum                                 |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 1 / 11 (9.09%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 perforation                          |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 gastrointestinal haemorrhage              |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Nausea  |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Rectal haemorrhage                              |                |               |                |



|   |                |               |                |
|---|----------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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                         |                |               |                |
| Bile duct obstruction                           |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Cholecystitis                                   |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Jaundice cholestatic                            |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |               |                |
| Rash papular                                    |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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                     |                |               |                |
| Anuria  |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 failure                                   |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 impairment                                |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 |                |               |                |
| Arthritis                                       |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Bone pain                                       |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Fistula   |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Flank pain                                      |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |
| Pain in extremity                               |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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                     |                |               |                |
| Cystitis  |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| 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 infection                               |                |               |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Infection                                       |                |                |                |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0          |
| Peritonitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumocystis jirovecii pneumonia                |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin infection                                  |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Upper respiratory tract infection               |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| 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 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Dehydration                                     |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Hyperkalaemia                                   |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Hypoglycaemia                                   |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hyponatraemia                                   |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (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          |
| Hypophosphataemia                               |                |                |                |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 2 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                       | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - TNBC | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - PC | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - EC |
|---|--|--|--|
| Total subjects affected by serious adverse events                   |  |  |  |
| subjects affected / exposed   | 8 / 20 (40.00%)  | 14 / 20 (70.00%)                                     | 8 / 21 (38.10%)                                      |
| number of deaths (all causes)                                       | 1  | 3  | 0  |
| number of deaths resulting from adverse events                      | 0  | 1  | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |  |
| Infected neoplasm   |  |  |  |
| subjects affected / exposed   | 1 / 20 (5.00%)   | 0 / 20 (0.00%)                                       | 0 / 21 (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  |
| Lymphangiosis carcinomatosa   |  |  |  |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Metastases to central nervous system                 |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Tumour pain  |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Vascular disorders                                   |                |                |                |
| Deep vein thrombosis                                 |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Hypertensive crisis                                  |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Thrombosis   |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 |                |                |                |
| Asthenia   |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Chills   |                |                |                |
| subjects affected / exposed                          | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |

|   |                 |                 |                |
|---|-----------------|-----------------|----------------|
| Fatigue   |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| General physical health deterioration           |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Generalised oedema                              |                 |                 |                |
| subjects affected / exposed                     | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Pyrexia   |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 2 / 20 (10.00%) | 0 / 21 (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          |
| Ulcer   |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| 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                     | 2 / 20 (10.00%) | 1 / 20 (5.00%)  | 0 / 21 (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          |
| Pleural effusion                                |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| 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 aspiration                            |                 |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Pneumonitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |                |                |                |
| subjects affected / exposed                     | 1 / 20 (5.00%) | 0 / 20 (0.00%) | 0 / 21 (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          |
| Respiratory failure                             |                |                |                |
| subjects affected / exposed                     | 1 / 20 (5.00%) | 0 / 20 (0.00%) | 0 / 21 (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          |
| Product issues                                  |                |                |                |
| Device breakage                                 |                |                |                |
| subjects affected / exposed                     | 1 / 20 (5.00%) | 0 / 20 (0.00%) | 0 / 21 (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          |
| Investigations                                  |                |                |                |
| Alanine aminotransferase increased              |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Aspartate aminotransferase increased            |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Blood creatinine increased                      |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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  |                |                |                |
| Gastrointestinal procedural complication        |                |                |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| 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 / 20 (0.00%) | 1 / 20 (5.00%)  | 0 / 21 (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          |
| Nervous system disorders                        |                |                 |                |
| Cerebral infarction                             |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Guillain-Barre syndrome                         |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Seizure   |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Blood and lymphatic system disorders            |                |                 |                |
| Anaemia   |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| 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                      |                |                 |                |
| Abdominal pain                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 2 / 20 (10.00%) | 0 / 21 (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          |
| Ascites   |                |                 |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |



|   |                |                |                |
|---|----------------|----------------|----------------|
| Constipation                                    |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Dyspepsia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastric haemorrhage                             |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Gastrointestinal haemorrhage                    |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Haemoperitoneum                                 |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Intestinal perforation                          |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 gastrointestinal haemorrhage              |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Nausea  |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Rectal haemorrhage                              |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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                         |                |                |                |
| Bile duct obstruction                           |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cholecystitis                                   |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Jaundice cholestatic                            |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Rash papular                                    |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (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          |
| Renal and urinary disorders                     |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Anuria  |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 failure                                   |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 1 / 1          | 0 / 0          |
| Renal impairment                                |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 |                |                |                |
| Arthritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Bone pain                                       |                |                |                |
| subjects affected / exposed                     | 1 / 20 (5.00%) | 0 / 20 (0.00%) | 0 / 21 (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          |
| Fistula   |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Flank pain                                      |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pain in extremity                               |                |                |                |
| subjects affected / exposed                     | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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>Cystitis<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 1 / 20 (5.00%)<br>1 / 1<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Febrile infection<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                       | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Infection<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                               | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Peritonitis<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                             | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Pneumocystis jirovecii pneumonia<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all        | 1 / 20 (5.00%)<br>0 / 1<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (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 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (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 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Skin infection<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                          | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 20 (0.00%)<br>0 / 0<br>0 / 0 | 0 / 21 (0.00%)<br>0 / 0<br>0 / 0 |
| Upper respiratory tract infection   |                                  |                                  |                                  |

|   |  |                |                |
|---|--|----------------|----------------|
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all   | 0 / 0  | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all        | 0 / 0  | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders                |  |                |                |
| Dehydration                                       |  |                |                |
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0  | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0  | 0 / 0          | 0 / 0          |
| Hyperkalaemia                                     |  |                |                |
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences causally related to treatment / all   | 0 / 0  | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all        | 0 / 0  | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                     |  |                |                |
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 1 / 20 (5.00%) | 0 / 21 (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          |
| Hyponatraemia                                     |  |                |                |
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0  | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0  | 0 / 0          | 0 / 0          |
| Hypophosphataemia                                 |  |                |                |
| subjects affected / exposed                       | 0 / 20 (0.00%)                                       | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| 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>                     | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - ME |                |                |
| Total subjects affected by serious adverse events |  |                |                |
| subjects affected / exposed                       | 7 / 20 (35.00%)                                      |                |                |
| number of deaths (all causes)                     | 2  |                |                |

|   |                |  |  |
|---|----------------|--|--|
| number of deaths resulting from adverse events                      | 0              |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |  |  |
| Infected neoplasm   |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Lymphangiosis carcinomatosa   |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Metastases to central nervous system                                |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Tumour pain   |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Vascular disorders  |                |  |  |
| Deep vein thrombosis  |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Hypertensive crisis   |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| Thrombosis  |                |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all                     | 0 / 0          |  |  |
| deaths causally related to treatment / all                          | 0 / 0          |  |  |
| General disorders and administration site conditions                |                |  |  |
| Asthenia  |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Chills  |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Fatigue   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| General physical health deterioration           |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Generalised oedema                              |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pyrexia   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Ulcer   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Respiratory, thoracic and mediastinal disorders |                |  |  |
| Dyspnoea  |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pleural effusion                                |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumonia aspiration                            |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumonitis                                     |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumothorax                                    |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Respiratory failure                             |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Product issues                                  |                |  |  |
| Device breakage                                 |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Investigations                                  |                |  |  |
| Alanine aminotransferase increased              |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Aspartate aminotransferase increased            |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |



|   |                |  |  |
|---|----------------|--|--|
| Blood creatinine increased<br>subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Injury, poisoning and procedural<br>complications         |                |  |  |
| Gastrointestinal procedural<br>complication               |                |  |  |
| subjects affected / exposed                               | 1 / 20 (5.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 1          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 1          |  |  |
| Infusion related reaction                                 |                |  |  |
| subjects affected / exposed                               | 1 / 20 (5.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 1 / 1          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Nervous system disorders                                  |                |  |  |
| Cerebral infarction                                       |                |  |  |
| subjects affected / exposed                               | 0 / 20 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Guillain-Barre syndrome                                   |                |  |  |
| subjects affected / exposed                               | 0 / 20 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Seizure   |                |  |  |
| subjects affected / exposed                               | 0 / 20 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Blood and lymphatic system disorders                      |                |  |  |
| Anaemia   |                |  |  |
| subjects affected / exposed                               | 0 / 20 (0.00%) |  |  |
| occurrences causally related to<br>treatment / all        | 0 / 0          |  |  |
| deaths causally related to<br>treatment / all             | 0 / 0          |  |  |
| Gastrointestinal disorders                                |                |  |  |
| Abdominal pain  |                |  |  |

|   |                |  |  |  |
|---|----------------|--|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Ascites   |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Constipation                                    |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Dyspepsia                                       |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Gastric haemorrhage                             |                |  |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Gastrointestinal haemorrhage                    |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Haemoperitoneum                                 |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Intestinal obstruction                          |                |  |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Intestinal perforation                          |                |  |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Large intestinal obstruction                    |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Lower gastrointestinal haemorrhage              |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Nausea  |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Rectal haemorrhage                              |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Vomiting  |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hepatobiliary disorders                         |                |  |  |
| Bile duct obstruction                           |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Cholecystitis                                   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Jaundice cholestatic                            |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Skin and subcutaneous tissue disorders          |                |  |  |
| Rash papular                                    |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Renal and urinary disorders                     |                |  |  |
| Anuria  |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Renal failure                                   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Renal impairment                                |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Musculoskeletal and connective tissue disorders |                |  |  |
| Arthritis                                       |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Bone pain                                       |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Fistula   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

|   |                |  |  |
|---|----------------|--|--|
| Flank pain                                      |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pain in extremity                               |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Infections and infestations                     |                |  |  |
| Cystitis  |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Febrile infection                               |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Infection                                       |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Peritonitis                                     |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumocystis jirovecii pneumonia                |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumonia                                       |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Sepsis  |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Skin infection                                  |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Upper respiratory tract infection               |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Urinary tract infection                         |                |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Metabolism and nutrition disorders              |                |  |  |
| Dehydration                                     |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hyperkalaemia                                   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hypoglycaemia                                   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hyponatraemia                                   |                |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hypophosphataemia                               |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

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

| <b>Non-serious adverse events</b>                                   | Ph Ib: MCS110@1 mg/kg Q3W@+ PDR001 100@mg Q3W | Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 100@mg Q3W | Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 300@mg Q3W |
|---|---|---|---|
| Total subjects affected by non-serious adverse events               |   |   |   |
| subjects affected / exposed   | 6 / 6 (100.00%)                               | 12 / 12 (100.00%)                             | 12 / 12 (100.00%)                             |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Cancer pain   |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 0 / 12 (0.00%)                                | 1 / 12 (8.33%)                                |
| occurrences (all)   | 0   | 0   | 1   |
| Metastases to central nervous system                                |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 0 / 12 (0.00%)                                | 1 / 12 (8.33%)                                |
| occurrences (all)   | 0   | 0   | 1   |
| Tumour pain   |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 0 / 12 (0.00%)                                | 1 / 12 (8.33%)                                |
| occurrences (all)   | 0   | 0   | 1   |
| Vascular disorders  |   |   |   |
| Deep vein thrombosis  |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 0 / 12 (0.00%)                                | 0 / 12 (0.00%)                                |
| occurrences (all)   | 0   | 0   | 0   |
| Hypertension  |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 1 / 12 (8.33%)                                | 1 / 12 (8.33%)                                |
| occurrences (all)   | 0   | 1   | 1   |
| General disorders and administration site conditions                |   |   |   |
| Adverse reaction  |   |   |   |
| subjects affected / exposed   | 0 / 6 (0.00%)                                 | 0 / 12 (0.00%)                                | 1 / 12 (8.33%)                                |
| occurrences (all)   | 0   | 0   | 1   |
| Asthenia  |   |   |   |
| subjects affected / exposed   | 3 / 6 (50.00%)                                | 5 / 12 (41.67%)                               | 3 / 12 (25.00%)                               |
| occurrences (all)   | 3   | 5   | 3   |
| Chest discomfort  |   |   |   |

|                                       |                |                 |                 |
|---------------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed           | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                     | 0              | 0               | 1               |
| Chills                                |                |                 |                 |
| subjects affected / exposed           | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 2 / 12 (16.67%) |
| occurrences (all)                     | 1              | 1               | 3               |
| Face oedema                           |                |                 |                 |
| subjects affected / exposed           | 0 / 6 (0.00%)  | 2 / 12 (16.67%) | 2 / 12 (16.67%) |
| occurrences (all)                     | 0              | 2               | 2               |
| Fatigue                               |                |                 |                 |
| subjects affected / exposed           | 2 / 6 (33.33%) | 3 / 12 (25.00%) | 5 / 12 (41.67%) |
| occurrences (all)                     | 2              | 3               | 5               |
| Gait disturbance                      |                |                 |                 |
| subjects affected / exposed           | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                     | 1              | 0               | 0               |
| General physical health deterioration |                |                 |                 |
| subjects affected / exposed           | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 1 / 12 (8.33%)  |
| occurrences (all)                     | 0              | 1               | 1               |
| Generalised oedema                    |                |                 |                 |
| subjects affected / exposed           | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                     | 0              | 1               | 0               |
| Influenza like illness                |                |                 |                 |
| subjects affected / exposed           | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                     | 0              | 0               | 1               |
| Non-cardiac chest pain                |                |                 |                 |
| subjects affected / exposed           | 1 / 6 (16.67%) | 3 / 12 (25.00%) | 2 / 12 (16.67%) |
| occurrences (all)                     | 1              | 3               | 2               |
| Oedema peripheral                     |                |                 |                 |
| subjects affected / exposed           | 2 / 6 (33.33%) | 1 / 12 (8.33%)  | 2 / 12 (16.67%) |
| occurrences (all)                     | 3              | 1               | 2               |
| Pyrexia                               |                |                 |                 |
| subjects affected / exposed           | 1 / 6 (16.67%) | 4 / 12 (33.33%) | 3 / 12 (25.00%) |
| occurrences (all)                     | 1              | 6               | 3               |
| Suprapubic pain                       |                |                 |                 |
| subjects affected / exposed           | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                     | 0              | 1               | 0               |
| Immune system disorders               |                |                 |                 |



|   |                     |                      |                      |
|---|---------------------|----------------------|----------------------|
| Cytokine release syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Reproductive system and breast disorders                                      |                     |                      |                      |
| Breast pain<br>subjects affected / exposed<br>occurrences (all)               | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Metrorrhagia<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Varicocele<br>subjects affected / exposed<br>occurrences (all)                | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                               |                     |                      |                      |
| Aphonia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Cough<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 6 (0.00%)<br>0  | 3 / 12 (25.00%)<br>4 | 0 / 12 (0.00%)<br>0  |
| Dysphonia<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Dyspnoea<br>subjects affected / exposed<br>occurrences (all)                  | 2 / 6 (33.33%)<br>2 | 2 / 12 (16.67%)<br>3 | 2 / 12 (16.67%)<br>2 |
| Epistaxis<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Haemoptysis<br>subjects affected / exposed<br>occurrences (all)               | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>2  | 0 / 12 (0.00%)<br>0  |
| Lung opacity<br>subjects affected / exposed<br>occurrences (all)              | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Nasal congestion  |                     |                      |                      |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Nasal mucosal ulcer         |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Oropharyngeal pain          |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Pleural effusion            |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |
| Pneumonitis                 |                |                |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Productive cough            |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 2              | 0              |
| Pulmonary embolism          |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Respiratory failure         |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Rhinalgia                   |                |                |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Rhinorrhoea                 |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Psychiatric disorders       |                |                |                |
| Anxiety                     |                |                |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Confusional state           |                |                |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0              | 1              |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| Depression                                      |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0              | 1               | 0               |
| Disorientation                                  |                |                 |                 |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                               | 1              | 0               | 0               |
| Eating disorder                                 |                |                 |                 |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                               | 1              | 0               | 0               |
| Insomnia  |                |                 |                 |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 2 / 12 (16.67%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 2              | 2               | 0               |
| Investigations                                  |                |                 |                 |
| Activated partial thromboplastin time prolonged |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Alanine aminotransferase increased              |                |                 |                 |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 2 / 12 (16.67%) |
| occurrences (all)                               | 1              | 1               | 2               |
| Amylase increased                               |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Aspartate aminotransferase increased            |                |                 |                 |
| subjects affected / exposed                     | 4 / 6 (66.67%) | 3 / 12 (25.00%) | 3 / 12 (25.00%) |
| occurrences (all)                               | 5              | 3               | 3               |
| Blood alkaline phosphatase increased            |                |                 |                 |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 3 / 12 (25.00%) |
| occurrences (all)                               | 0              | 0               | 3               |
| Blood bilirubin increased                       |                |                 |                 |
| subjects affected / exposed                     | 3 / 6 (50.00%) | 0 / 12 (0.00%)  | 2 / 12 (16.67%) |
| occurrences (all)                               | 5              | 0               | 2               |
| Blood creatine phosphokinase increased          |                |                 |                 |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 3 / 12 (25.00%) | 3 / 12 (25.00%) |
| occurrences (all)                               | 1              | 4               | 3               |
| Blood creatinine increased                      |                |                 |                 |

|  |                |                 |                |
|--|----------------|-----------------|----------------|
| subjects affected / exposed                    | 1 / 6 (16.67%) | 2 / 12 (16.67%) | 1 / 12 (8.33%) |
| occurrences (all)                              | 3              | 2               | 1              |
| Blood lactate dehydrogenase increased          |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 0               | 0              |
| Blood pressure increased                       |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 0               | 0              |
| Blood thyroid stimulating hormone increased    |                |                 |                |
| subjects affected / exposed                    | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 1              | 0               | 0              |
| C-reactive protein increased                   |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 1               | 0              |
| Lipase increased                               |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 0               | 0              |
| Lymphocyte count decreased                     |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 2               | 0              |
| Neutrophil count increased                     |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 0               | 0              |
| Platelet count decreased                       |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 0               | 0              |
| Transaminases increased                        |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)                              | 0              | 1               | 0              |
| Weight decreased                               |                |                 |                |
| subjects affected / exposed                    | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)                              | 0              | 0               | 1              |
| Injury, poisoning and procedural complications |                |                 |                |

|  |                     |                      |                     |
|--|---------------------|----------------------|---------------------|
| Abdominal injury<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0 |
| Fall<br>subjects affected / exposed<br>occurrences (all)   | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Foot fracture<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Infusion related reaction<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 6 (16.67%)<br>1 | 3 / 12 (25.00%)<br>3 | 1 / 12 (8.33%)<br>1 |
| Post procedural haemorrhage<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0 |
| Post procedural inflammation<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Procedural pain<br>subjects affected / exposed<br>occurrences (all)                              | 1 / 6 (16.67%)<br>1 | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0 |
| Rib fracture<br>subjects affected / exposed<br>occurrences (all)                                 | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Cardiac disorders<br>Tachycardia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Nervous system disorders<br>Balance disorder<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0 |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 6 (0.00%)<br>0  | 1 / 12 (8.33%)<br>2  | 1 / 12 (8.33%)<br>1 |
| Dysgeusia  |                     |                      |                     |

|                                      |                |                 |                 |
|--------------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed          | 0 / 6 (0.00%)  | 2 / 12 (16.67%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 2               | 0               |
| Headache                             |                |                 |                 |
| subjects affected / exposed          | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 1 / 12 (8.33%)  |
| occurrences (all)                    | 1              | 2               | 1               |
| Hypoaesthesia                        |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1               | 0               |
| Neuropathy peripheral                |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0               |
| Paraesthesia                         |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1               | 0               |
| Somnolence                           |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 3 / 12 (25.00%) |
| occurrences (all)                    | 0              | 0               | 3               |
| Blood and lymphatic system disorders |                |                 |                 |
| Anaemia                              |                |                 |                 |
| subjects affected / exposed          | 4 / 6 (66.67%) | 2 / 12 (16.67%) | 3 / 12 (25.00%) |
| occurrences (all)                    | 8              | 2               | 4               |
| Leukocytosis                         |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0               |
| Ear and labyrinth disorders          |                |                 |                 |
| Vertigo                              |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                    | 0              | 0               | 1               |
| Eye disorders                        |                |                 |                 |
| Dry eye                              |                |                 |                 |
| subjects affected / exposed          | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                    | 0              | 1               | 0               |
| Eye pruritus                         |                |                 |                 |
| subjects affected / exposed          | 1 / 6 (16.67%) | 2 / 12 (16.67%) | 0 / 12 (0.00%)  |
| occurrences (all)                    | 1              | 2               | 0               |
| Eyelid oedema                        |                |                 |                 |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 3 / 12 (25.00%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 3               | 1               |
| Lacrimation increased       |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 4 / 12 (33.33%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 1              | 4               | 0               |
| Panophthalmitis             |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Periorbital oedema          |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 3 / 12 (25.00%) | 2 / 12 (16.67%) |
| occurrences (all)           | 0              | 3               | 2               |
| Uveitis                     |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Visual impairment           |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Xerophthalmia               |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0               |
| Gastrointestinal disorders  |                |                 |                 |
| Abdominal discomfort        |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Abdominal distension        |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 1              | 0               | 1               |
| Abdominal pain              |                |                 |                 |
| subjects affected / exposed | 2 / 6 (33.33%) | 3 / 12 (25.00%) | 3 / 12 (25.00%) |
| occurrences (all)           | 2              | 3               | 4               |
| Abdominal pain lower        |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 1              | 0               | 0               |
| Abdominal pain upper        |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 1               | 1               |

|                                  |                |                 |                 |
|----------------------------------|----------------|-----------------|-----------------|
| Aphthous ulcer                   |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 0              | 1               | 0               |
| Ascites                          |                |                 |                 |
| subjects affected / exposed      | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 1              | 1               | 0               |
| Colitis                          |                |                 |                 |
| subjects affected / exposed      | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 1              | 0               | 0               |
| Constipation                     |                |                 |                 |
| subjects affected / exposed      | 3 / 6 (50.00%) | 2 / 12 (16.67%) | 2 / 12 (16.67%) |
| occurrences (all)                | 3              | 2               | 2               |
| Diarrhoea                        |                |                 |                 |
| subjects affected / exposed      | 3 / 6 (50.00%) | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 6              | 3               | 0               |
| Dry mouth                        |                |                 |                 |
| subjects affected / exposed      | 2 / 6 (33.33%) | 2 / 12 (16.67%) | 2 / 12 (16.67%) |
| occurrences (all)                | 2              | 2               | 2               |
| Dyspepsia                        |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 1 / 12 (8.33%)  |
| occurrences (all)                | 0              | 1               | 1               |
| Epigastric discomfort            |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 0              | 1               | 0               |
| Flatulence                       |                |                 |                 |
| subjects affected / exposed      | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 1              | 1               | 0               |
| Gastritis                        |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 0              | 0               | 0               |
| Gastrooesophageal reflux disease |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 0              | 0               | 0               |
| Gingival bleeding                |                |                 |                 |
| subjects affected / exposed      | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)                | 0              | 1               | 0               |



|  |                |                 |                 |
|--|----------------|-----------------|-----------------|
| Haematochezia                          |                |                 |                 |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)                      | 0              | 0               | 1               |
| Melaena                                |                |                 |                 |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0               |
| Nausea                                 |                |                 |                 |
| subjects affected / exposed            | 2 / 6 (33.33%) | 5 / 12 (41.67%) | 3 / 12 (25.00%) |
| occurrences (all)                      | 2              | 6               | 3               |
| Odynophagia                            |                |                 |                 |
| subjects affected / exposed            | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 1              | 0               | 0               |
| Stomatitis                             |                |                 |                 |
| subjects affected / exposed            | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 1 / 12 (8.33%)  |
| occurrences (all)                      | 2              | 1               | 1               |
| Vomiting                               |                |                 |                 |
| subjects affected / exposed            | 1 / 6 (16.67%) | 5 / 12 (41.67%) | 3 / 12 (25.00%) |
| occurrences (all)                      | 2              | 5               | 4               |
| Hepatobiliary disorders                |                |                 |                 |
| Cholestasis                            |                |                 |                 |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0               |
| Hyperbilirubinaemia                    |                |                 |                 |
| subjects affected / exposed            | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 1              | 0               | 0               |
| Portal vein thrombosis                 |                |                 |                 |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0               |
| Skin and subcutaneous tissue disorders |                |                 |                 |
| Alopecia                               |                |                 |                 |
| subjects affected / exposed            | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)                      | 0              | 0               | 0               |
| Dry skin                               |                |                 |                 |
| subjects affected / exposed            | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 2 / 12 (16.67%) |
| occurrences (all)                      | 1              | 0               | 2               |
| Hair colour changes                    |                |                 |                 |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Hyperhidrosis               |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 2              | 0               | 0               |
| Intertrigo                  |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Nail dystrophy              |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Petechiae                   |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Pruritus                    |                |                 |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 2 / 12 (16.67%) |
| occurrences (all)           | 1              | 1               | 2               |
| Rash                        |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 2 / 12 (16.67%) | 2 / 12 (16.67%) |
| occurrences (all)           | 0              | 4               | 2               |
| Rash maculo-papular         |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Rash pruritic               |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 2               | 0               |
| Renal and urinary disorders |                |                 |                 |
| Choluria                    |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0               | 1               |
| Dysuria                     |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Haematuria                  |                |                 |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| Pollakiuria                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 1               | 0              |
| Proteinuria                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Renal colic                                     |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 0               | 0              |
| Renal failure                                   |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 0               | 0              |
| Ureterolithiasis                                |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 0               | 0              |
| Endocrine disorders                             |                |                 |                |
| Hypopituitarism                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Hypothyroidism                                  |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 1               | 0              |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Arthralgia                                      |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 3 / 12 (25.00%) | 1 / 12 (8.33%) |
| occurrences (all)                               | 1              | 6               | 2              |
| Arthritis                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 0               | 0              |
| Back pain                                       |                |                 |                |
| subjects affected / exposed                     | 1 / 6 (16.67%) | 2 / 12 (16.67%) | 0 / 12 (0.00%) |
| occurrences (all)                               | 1              | 2               | 0              |
| Flank pain                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 6 (0.00%)  | 4 / 12 (33.33%) | 0 / 12 (0.00%) |
| occurrences (all)                               | 0              | 4               | 0              |
| Groin pain                                      |                |                 |                |

|                             |                |                |                 |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 1              | 0              | 0               |
| Joint stiffness             |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0               |
| Joint warmth                |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0               |
| Muscle spasms               |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Muscle twitching            |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0              | 1               |
| Muscular weakness           |                |                |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 12 (8.33%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 1              | 1              | 0               |
| Musculoskeletal chest pain  |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Myalgia                     |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 1              | 1               |
| Neck pain                   |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0               |
| Pain in extremity           |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%) | 2 / 12 (16.67%) |
| occurrences (all)           | 0              | 1              | 2               |
| Infections and infestations |                |                |                 |
| Abscess                     |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0              | 1               |
| Cellulitis                  |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 0              | 0              | 1               |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| Conjunctivitis              |                |                 |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)           | 1              | 0               | 1              |
| Diarrhoea infectious        |                |                 |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0               | 0              |
| Helicobacter infection      |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0               | 0              |
| Infection                   |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0               | 1              |
| Influenza                   |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1               | 0              |
| Nasopharyngitis             |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)           | 0              | 0               | 1              |
| Otitis media                |                |                 |                |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 1              | 0               | 0              |
| Peritonitis                 |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 1 / 12 (8.33%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 1               | 0              |
| Pneumonia                   |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 2 / 12 (16.67%) | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 2               | 0              |
| Pyuria                      |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0               | 0              |
| Respiratory tract infection |                |                 |                |
| subjects affected / exposed | 2 / 6 (33.33%) | 2 / 12 (16.67%) | 0 / 12 (0.00%) |
| occurrences (all)           | 6              | 2               | 0              |
| Skin infection              |                |                 |                |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)           | 0              | 0               | 0              |

|   |                     |                      |                      |
|---|---------------------|----------------------|----------------------|
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>2 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)           | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Viral skin infection<br>subjects affected / exposed<br>occurrences (all)              | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Metabolism and nutrition disorders  |                     |                      |                      |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)                | 3 / 6 (50.00%)<br>3 | 7 / 12 (58.33%)<br>7 | 4 / 12 (33.33%)<br>5 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)                       | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Hyperkalaemia<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 2 / 12 (16.67%)<br>3 |
| Hypermagnesaemia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 6 (16.67%)<br>1 | 1 / 12 (8.33%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Hypoalbuminaemia<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 6 (16.67%)<br>1 | 0 / 12 (0.00%)<br>0  | 2 / 12 (16.67%)<br>2 |
| Hypocalcaemia<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 6 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  | 2 / 12 (16.67%)<br>2 |
| Hypokalaemia  |                     |                      |                      |

|                             |                |                |                 |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Hypomagnesaemia             |                |                |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 2              | 0              | 0               |
| Hyponatraemia               |                |                |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 12 (8.33%) | 2 / 12 (16.67%) |
| occurrences (all)           | 3              | 1              | 2               |
| Hypophagia                  |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Hypophosphataemia           |                |                |                 |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 12 (8.33%) | 1 / 12 (8.33%)  |
| occurrences (all)           | 1              | 1              | 1               |
| Vitamin D deficiency        |                |                |                 |
| subjects affected / exposed | 0 / 6 (0.00%)  | 0 / 12 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |

| <b>Non-serious adverse events</b>                                   | Ph Ib: MCS110@5 mg/kg Q3W@+ PDR001 300@mg Q3W | Ph Ib: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W | Ph Ib: MCS110@10 mg/kg Q3W@+ PDR001 300@mg Q3W |
|---|---|---|--|
| Total subjects affected by non-serious adverse events               |   |   |  |
| subjects affected / exposed   | 13 / 13 (100.00%)                             | 6 / 6 (100.00%)                                 | 11 / 11 (100.00%)                              |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |  |
| Cancer pain   |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences (all)   | 0   | 0   | 0  |
| Metastases to central nervous system                                |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences (all)   | 0   | 0   | 0  |
| Tumour pain   |   |   |  |
| subjects affected / exposed   | 0 / 13 (0.00%)                                | 0 / 6 (0.00%)                                   | 0 / 11 (0.00%)                                 |
| occurrences (all)   | 0   | 0   | 0  |
| Vascular disorders  |   |   |  |
| Deep vein thrombosis  |   |   |  |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed                          | 1 / 13 (7.69%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 1               | 1              | 0               |
| Hypertension   |                 |                |                 |
| subjects affected / exposed                          | 1 / 13 (7.69%)  | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                                    | 1               | 1              | 1               |
| General disorders and administration site conditions |                 |                |                 |
| Adverse reaction                                     |                 |                |                 |
| subjects affected / exposed                          | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 0               | 0              | 0               |
| Asthenia   |                 |                |                 |
| subjects affected / exposed                          | 3 / 13 (23.08%) | 3 / 6 (50.00%) | 5 / 11 (45.45%) |
| occurrences (all)                                    | 3               | 3              | 5               |
| Chest discomfort                                     |                 |                |                 |
| subjects affected / exposed                          | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 0               | 0              | 0               |
| Chills   |                 |                |                 |
| subjects affected / exposed                          | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 2               | 0              | 0               |
| Face oedema  |                 |                |                 |
| subjects affected / exposed                          | 3 / 13 (23.08%) | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                                    | 3               | 1              | 1               |
| Fatigue  |                 |                |                 |
| subjects affected / exposed                          | 2 / 13 (15.38%) | 2 / 6 (33.33%) | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 2               | 3              | 0               |
| Gait disturbance                                     |                 |                |                 |
| subjects affected / exposed                          | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 1               | 0              | 0               |
| General physical health deterioration                |                 |                |                 |
| subjects affected / exposed                          | 1 / 13 (7.69%)  | 2 / 6 (33.33%) | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 1               | 2              | 0               |
| Generalised oedema                                   |                 |                |                 |
| subjects affected / exposed                          | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                                    | 0               | 0              | 0               |
| Influenza like illness                               |                 |                |                 |



|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Non-cardiac chest pain                          |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Oedema peripheral                               |                 |                |                 |
| subjects affected / exposed                     | 2 / 13 (15.38%) | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                               | 3               | 1              | 1               |
| Pyrexia   |                 |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 5 / 11 (45.45%) |
| occurrences (all)                               | 1               | 0              | 7               |
| Suprapubic pain                                 |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Immune system disorders                         |                 |                |                 |
| Cytokine release syndrome                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Reproductive system and breast disorders        |                 |                |                 |
| Breast pain                                     |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Metrorrhagia                                    |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Varicocele                                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 1              | 0               |
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Aphonia   |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Cough   |                 |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0               | 0              | 1               |
| Dysphonia                                       |                 |                |                 |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Dyspnoea                    |                |                |                |
| subjects affected / exposed | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 1              | 1              | 0              |
| Epistaxis                   |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0              | 0              | 1              |
| Haemoptysis                 |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Lung opacity                |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Nasal congestion            |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0              | 0              | 1              |
| Nasal mucosal ulcer         |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Oropharyngeal pain          |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pleural effusion            |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pneumonitis                 |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Productive cough            |                |                |                |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 2              | 0              | 0              |
| Pulmonary embolism          |                |                |                |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 1              | 0              | 1              |
| Respiratory failure         |                |                |                |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Rhinalgia                                       |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Rhinorrhoea                                     |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Psychiatric disorders                           |                |                |                 |
| Anxiety   |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 1              | 0               |
| Confusional state                               |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Depression                                      |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0               |
| Disorientation                                  |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0               |
| Eating disorder                                 |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Insomnia  |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Investigations                                  |                |                |                 |
| Activated partial thromboplastin time prolonged |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Alanine aminotransferase increased              |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 2 / 11 (18.18%) |
| occurrences (all)                               | 1              | 3              | 2               |
| Amylase increased                               |                |                |                 |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed                 | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0              | 0               |
| Aspartate aminotransferase increased        |                 |                |                 |
| subjects affected / exposed                 | 5 / 13 (38.46%) | 3 / 6 (50.00%) | 4 / 11 (36.36%) |
| occurrences (all)                           | 6               | 3              | 4               |
| Blood alkaline phosphatase increased        |                 |                |                 |
| subjects affected / exposed                 | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 2               | 0              | 0               |
| Blood bilirubin increased                   |                 |                |                 |
| subjects affected / exposed                 | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 2               | 0              | 0               |
| Blood creatine phosphokinase increased      |                 |                |                 |
| subjects affected / exposed                 | 3 / 13 (23.08%) | 4 / 6 (66.67%) | 3 / 11 (27.27%) |
| occurrences (all)                           | 3               | 4              | 3               |
| Blood creatinine increased                  |                 |                |                 |
| subjects affected / exposed                 | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0              | 0               |
| Blood lactate dehydrogenase increased       |                 |                |                 |
| subjects affected / exposed                 | 0 / 13 (0.00%)  | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                           | 0               | 1              | 1               |
| Blood pressure increased                    |                 |                |                 |
| subjects affected / exposed                 | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 1               | 0              | 0               |
| Blood thyroid stimulating hormone increased |                 |                |                 |
| subjects affected / exposed                 | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 1               | 0              | 0               |
| C-reactive protein increased                |                 |                |                 |
| subjects affected / exposed                 | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                           | 1               | 0              | 1               |
| Lipase increased                            |                 |                |                 |
| subjects affected / exposed                 | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                           | 0               | 0              | 0               |
| Lymphocyte count decreased                  |                 |                |                 |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Neutrophil count increased                     |                |                |                |
| subjects affected / exposed                    | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 1              | 0              | 0              |
| Platelet count decreased                       |                |                |                |
| subjects affected / exposed                    | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 1              | 0              | 0              |
| Transaminases increased                        |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Weight decreased                               |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Injury, poisoning and procedural complications |                |                |                |
| Abdominal injury                               |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Fall   |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)                              | 0              | 0              | 1              |
| Foot fracture                                  |                |                |                |
| subjects affected / exposed                    | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 1              | 0              | 0              |
| Infusion related reaction                      |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 1 / 11 (9.09%) |
| occurrences (all)                              | 0              | 1              | 1              |
| Post procedural haemorrhage                    |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Post procedural inflammation                   |                |                |                |
| subjects affected / exposed                    | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Procedural pain                                |                |                |                |

|  |                      |                    |                     |
|--|----------------------|--------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Rib fracture<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Cardiac disorders<br>Tachycardia<br>subjects affected / exposed<br>occurrences (all)             | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 |
| Nervous system disorders<br>Balance disorder<br>subjects affected / exposed<br>occurrences (all) | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                    | 2 / 13 (15.38%)<br>2 | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 |
| Headache<br>subjects affected / exposed<br>occurrences (all)                                     | 1 / 13 (7.69%)<br>1  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Neuropathy peripheral<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)                                 | 1 / 13 (7.69%)<br>1  | 0 / 6 (0.00%)<br>0 | 1 / 11 (9.09%)<br>1 |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)                                   | 0 / 13 (0.00%)<br>0  | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Blood and lymphatic system disorders   |                      |                    |                     |

|                             |                 |                |                 |
|-----------------------------|-----------------|----------------|-----------------|
| Anaemia                     |                 |                |                 |
| subjects affected / exposed | 3 / 13 (23.08%) | 3 / 6 (50.00%) | 3 / 11 (27.27%) |
| occurrences (all)           | 4               | 3              | 4               |
| Leukocytosis                |                 |                |                 |
| subjects affected / exposed | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 2               | 0              | 0               |
| Ear and labyrinth disorders |                 |                |                 |
| Vertigo                     |                 |                |                 |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0              | 0               |
| Eye disorders               |                 |                |                 |
| Dry eye                     |                 |                |                 |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0              | 0               |
| Eye pruritus                |                 |                |                 |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0              | 0               |
| Eyelid oedema               |                 |                |                 |
| subjects affected / exposed | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 2 / 11 (18.18%) |
| occurrences (all)           | 1               | 0              | 2               |
| Lacrimation increased       |                 |                |                 |
| subjects affected / exposed | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 1               | 0              | 0               |
| Panophthalmitis             |                 |                |                 |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0              | 0               |
| Periorbital oedema          |                 |                |                 |
| subjects affected / exposed | 1 / 13 (7.69%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)           | 1               | 1              | 0               |
| Uveitis                     |                 |                |                 |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 0               | 0              | 0               |
| Visual impairment           |                 |                |                 |
| subjects affected / exposed | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)           | 1               | 0              | 0               |
| Xerophthalmia               |                 |                |                 |

|  |                     |                    |                     |
|--|---------------------|--------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0 |
| Gastrointestinal disorders                       |                     |                    |                     |
| Abdominal discomfort                             |                     |                    |                     |
| subjects affected / exposed                      | 1 / 13 (7.69%)      | 0 / 6 (0.00%)      | 0 / 11 (0.00%)      |
| occurrences (all)                                | 1                   | 0                  | 0                   |
| Abdominal distension                             |                     |                    |                     |
| subjects affected / exposed                      | 0 / 13 (0.00%)      | 0 / 6 (0.00%)      | 0 / 11 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Abdominal pain                                   |                     |                    |                     |
| subjects affected / exposed                      | 3 / 13 (23.08%)     | 1 / 6 (16.67%)     | 1 / 11 (9.09%)      |
| occurrences (all)                                | 3                   | 1                  | 1                   |
| Abdominal pain lower                             |                     |                    |                     |
| subjects affected / exposed                      | 0 / 13 (0.00%)      | 0 / 6 (0.00%)      | 0 / 11 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Abdominal pain upper                             |                     |                    |                     |
| subjects affected / exposed                      | 0 / 13 (0.00%)      | 0 / 6 (0.00%)      | 1 / 11 (9.09%)      |
| occurrences (all)                                | 0                   | 0                  | 1                   |
| Aphthous ulcer                                   |                     |                    |                     |
| subjects affected / exposed                      | 0 / 13 (0.00%)      | 0 / 6 (0.00%)      | 0 / 11 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Ascites  |                     |                    |                     |
| subjects affected / exposed                      | 1 / 13 (7.69%)      | 1 / 6 (16.67%)     | 0 / 11 (0.00%)      |
| occurrences (all)                                | 1                   | 2                  | 0                   |
| Colitis  |                     |                    |                     |
| subjects affected / exposed                      | 0 / 13 (0.00%)      | 0 / 6 (0.00%)      | 0 / 11 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                   |
| Constipation                                     |                     |                    |                     |
| subjects affected / exposed                      | 2 / 13 (15.38%)     | 2 / 6 (33.33%)     | 1 / 11 (9.09%)      |
| occurrences (all)                                | 2                   | 2                  | 1                   |
| Diarrhoea  |                     |                    |                     |
| subjects affected / exposed                      | 1 / 13 (7.69%)      | 2 / 6 (33.33%)     | 3 / 11 (27.27%)     |
| occurrences (all)                                | 1                   | 2                  | 4                   |
| Dry mouth  |                     |                    |                     |
| subjects affected / exposed                      | 1 / 13 (7.69%)      | 0 / 6 (0.00%)      | 1 / 11 (9.09%)      |
| occurrences (all)                                | 1                   | 0                  | 1                   |



|                                  |                 |                |                 |
|----------------------------------|-----------------|----------------|-----------------|
| Dyspepsia                        |                 |                |                 |
| subjects affected / exposed      | 2 / 13 (15.38%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                | 2               | 1              | 0               |
| Epigastric discomfort            |                 |                |                 |
| subjects affected / exposed      | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0               | 0              | 0               |
| Flatulence                       |                 |                |                 |
| subjects affected / exposed      | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 1               | 0              | 0               |
| Gastritis                        |                 |                |                 |
| subjects affected / exposed      | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 1               | 0              | 0               |
| Gastrooesophageal reflux disease |                 |                |                 |
| subjects affected / exposed      | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 1               | 0              | 0               |
| Gingival bleeding                |                 |                |                 |
| subjects affected / exposed      | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0               | 0              | 0               |
| Haematochezia                    |                 |                |                 |
| subjects affected / exposed      | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0               | 0              | 0               |
| Melaena                          |                 |                |                 |
| subjects affected / exposed      | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                | 0               | 0              | 1               |
| Nausea                           |                 |                |                 |
| subjects affected / exposed      | 5 / 13 (38.46%) | 1 / 6 (16.67%) | 6 / 11 (54.55%) |
| occurrences (all)                | 6               | 1              | 6               |
| Odynophagia                      |                 |                |                 |
| subjects affected / exposed      | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                | 0               | 0              | 0               |
| Stomatitis                       |                 |                |                 |
| subjects affected / exposed      | 3 / 13 (23.08%) | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                | 3               | 1              | 1               |
| Vomiting                         |                 |                |                 |
| subjects affected / exposed      | 5 / 13 (38.46%) | 1 / 6 (16.67%) | 1 / 11 (9.09%)  |
| occurrences (all)                | 5               | 1              | 1               |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Hepatobiliary disorders                |                |                |                |
| Cholestasis                            |                |                |                |
| subjects affected / exposed            | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Hyperbilirubinaemia                    |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 1              | 0              |
| Portal vein thrombosis                 |                |                |                |
| subjects affected / exposed            | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Skin and subcutaneous tissue disorders |                |                |                |
| Alopecia                               |                |                |                |
| subjects affected / exposed            | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Dry skin                               |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Hair colour changes                    |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Hyperhidrosis                          |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Intertrigo                             |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 1              | 0              |
| Nail dystrophy                         |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Petechiae                              |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Pruritus                               |                |                |                |
| subjects affected / exposed            | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)                      | 0              | 1              | 0              |
| Rash                                   |                |                |                |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                        | 0 / 13 (0.00%)<br>0 | 1 / 6 (16.67%)<br>1 | 1 / 11 (9.09%)<br>1 |
| Rash maculo-papular<br>subjects affected / exposed<br>occurrences (all) | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all)       | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Renal and urinary disorders   |                     |                     |                     |
| Choluria<br>subjects affected / exposed<br>occurrences (all)            | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Dysuria<br>subjects affected / exposed<br>occurrences (all)             | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Haematuria<br>subjects affected / exposed<br>occurrences (all)          | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1 |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)         | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)         | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Renal colic<br>subjects affected / exposed<br>occurrences (all)         | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Renal failure<br>subjects affected / exposed<br>occurrences (all)       | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Ureterolithiasis<br>subjects affected / exposed<br>occurrences (all)    | 0 / 13 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0 |
| Endocrine disorders   |                     |                     |                     |
| Hypopituitarism   |                     |                     |                     |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Hypothyroidism                                  |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 2 / 11 (18.18%) |
| occurrences (all)                               | 0              | 1              | 2               |
| Musculoskeletal and connective tissue disorders |                |                |                 |
| Arthralgia                                      |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 3              | 0               |
| Arthritis                                       |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0               |
| Back pain                                       |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Flank pain                                      |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Groin pain                                      |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Joint stiffness                                 |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Joint warmth                                    |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Muscle spasms                                   |                |                |                 |
| subjects affected / exposed                     | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Muscle twitching                                |                |                |                 |
| subjects affected / exposed                     | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Muscular weakness                               |                |                |                 |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Musculoskeletal chest pain  |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 0              | 0              | 1              |
| Myalgia                     |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Neck pain                   |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Pain in extremity           |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Infections and infestations |                |                |                |
| Abscess                     |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Cellulitis                  |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Conjunctivitis              |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Diarrhoea infectious        |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Helicobacter infection      |                |                |                |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Infection                   |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Influenza                   |                |                |                |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |

|                                    |                 |                |                 |
|------------------------------------|-----------------|----------------|-----------------|
| Nasopharyngitis                    |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 1 / 11 (9.09%)  |
| occurrences (all)                  | 0               | 0              | 1               |
| Otitis media                       |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 0              | 0               |
| Peritonitis                        |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 0              | 0               |
| Pneumonia                          |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 1              | 0               |
| Pyuria                             |                 |                |                 |
| subjects affected / exposed        | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 2               | 0              | 0               |
| Respiratory tract infection        |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 0              | 0               |
| Skin infection                     |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 0              | 0               |
| Upper respiratory tract infection  |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 2 / 11 (18.18%) |
| occurrences (all)                  | 0               | 0              | 2               |
| Urinary tract infection            |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 2 / 6 (33.33%) | 1 / 11 (9.09%)  |
| occurrences (all)                  | 0               | 2              | 1               |
| Viral skin infection               |                 |                |                 |
| subjects affected / exposed        | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%)  |
| occurrences (all)                  | 0               | 0              | 0               |
| Metabolism and nutrition disorders |                 |                |                 |
| Decreased appetite                 |                 |                |                 |
| subjects affected / exposed        | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 4 / 11 (36.36%) |
| occurrences (all)                  | 1               | 0              | 6               |
| Dehydration                        |                 |                |                 |

|                             |                 |                |                |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Hyperglycaemia              |                 |                |                |
| subjects affected / exposed | 1 / 13 (7.69%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 1               | 0              | 0              |
| Hyperkalaemia               |                 |                |                |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Hypermagnesaemia            |                 |                |                |
| subjects affected / exposed | 0 / 13 (0.00%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 1              | 0              |
| Hyperuricaemia              |                 |                |                |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Hypoalbuminaemia            |                 |                |                |
| subjects affected / exposed | 1 / 13 (7.69%)  | 2 / 6 (33.33%) | 0 / 11 (0.00%) |
| occurrences (all)           | 1               | 2              | 0              |
| Hypocalcaemia               |                 |                |                |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Hypokalaemia                |                 |                |                |
| subjects affected / exposed | 2 / 13 (15.38%) | 0 / 6 (0.00%)  | 1 / 11 (9.09%) |
| occurrences (all)           | 2               | 0              | 1              |
| Hypomagnesaemia             |                 |                |                |
| subjects affected / exposed | 0 / 13 (0.00%)  | 0 / 6 (0.00%)  | 0 / 11 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Hyponatraemia               |                 |                |                |
| subjects affected / exposed | 1 / 13 (7.69%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 1               | 1              | 0              |
| Hypophagia                  |                 |                |                |
| subjects affected / exposed | 1 / 13 (7.69%)  | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 1               | 1              | 0              |
| Hypophosphataemia           |                 |                |                |
| subjects affected / exposed | 4 / 13 (30.77%) | 2 / 6 (33.33%) | 1 / 11 (9.09%) |
| occurrences (all)           | 4               | 2              | 1              |
| Vitamin D deficiency        |                 |                |                |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 13 (0.00%) | 1 / 6 (16.67%) | 0 / 11 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |

| <b>Non-serious adverse events</b>                                   | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - TNBC | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - PC | Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg Q3W - EC |
|---|--|--|--|
| Total subjects affected by non-serious adverse events               |  |  |  |
| subjects affected / exposed   | 20 / 20 (100.00%)                                      | 20 / 20 (100.00%)                                    | 21 / 21 (100.00%)                                    |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |  |
| Cancer pain   |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 1 / 20 (5.00%)                                       | 0 / 21 (0.00%)                                       |
| occurrences (all)   | 0  | 1  | 0  |
| Metastases to central nervous system                                |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 0 / 20 (0.00%)                                       | 0 / 21 (0.00%)                                       |
| occurrences (all)   | 0  | 0  | 0  |
| Tumour pain   |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 1 / 20 (5.00%)                                       | 3 / 21 (14.29%)                                      |
| occurrences (all)   | 0  | 1  | 3  |
| Vascular disorders  |  |  |  |
| Deep vein thrombosis  |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 0 / 20 (0.00%)                                       | 0 / 21 (0.00%)                                       |
| occurrences (all)   | 0  | 0  | 0  |
| Hypertension  |  |  |  |
| subjects affected / exposed   | 1 / 20 (5.00%)   | 1 / 20 (5.00%)                                       | 2 / 21 (9.52%)                                       |
| occurrences (all)   | 1  | 2  | 2  |
| General disorders and administration site conditions                |  |  |  |
| Adverse reaction  |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 0 / 20 (0.00%)                                       | 0 / 21 (0.00%)                                       |
| occurrences (all)   | 0  | 0  | 0  |
| Asthenia  |  |  |  |
| subjects affected / exposed   | 2 / 20 (10.00%)  | 3 / 20 (15.00%)                                      | 2 / 21 (9.52%)                                       |
| occurrences (all)   | 2  | 4  | 2  |
| Chest discomfort  |  |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)   | 0 / 20 (0.00%)                                       | 0 / 21 (0.00%)                                       |
| occurrences (all)   | 0  | 0  | 0  |
| Chills  |  |  |  |



|                                       |                 |                 |                 |
|---------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed           | 1 / 20 (5.00%)  | 4 / 20 (20.00%) | 3 / 21 (14.29%) |
| occurrences (all)                     | 1               | 4               | 3               |
| Face oedema                           |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 1 / 20 (5.00%)  | 3 / 21 (14.29%) |
| occurrences (all)                     | 0               | 1               | 3               |
| Fatigue                               |                 |                 |                 |
| subjects affected / exposed           | 5 / 20 (25.00%) | 2 / 20 (10.00%) | 4 / 21 (19.05%) |
| occurrences (all)                     | 6               | 2               | 5               |
| Gait disturbance                      |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 0               | 0               | 0               |
| General physical health deterioration |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 0               | 0               | 0               |
| Generalised oedema                    |                 |                 |                 |
| subjects affected / exposed           | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 1               | 0               | 0               |
| Influenza like illness                |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 0               | 0               | 0               |
| Non-cardiac chest pain                |                 |                 |                 |
| subjects affected / exposed           | 2 / 20 (10.00%) | 1 / 20 (5.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 2               | 1               | 0               |
| Oedema peripheral                     |                 |                 |                 |
| subjects affected / exposed           | 2 / 20 (10.00%) | 3 / 20 (15.00%) | 3 / 21 (14.29%) |
| occurrences (all)                     | 2               | 3               | 3               |
| Pyrexia                               |                 |                 |                 |
| subjects affected / exposed           | 4 / 20 (20.00%) | 4 / 20 (20.00%) | 1 / 21 (4.76%)  |
| occurrences (all)                     | 6               | 6               | 1               |
| Suprapubic pain                       |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 0               | 0               | 0               |
| Immune system disorders               |                 |                 |                 |
| Cytokine release syndrome             |                 |                 |                 |
| subjects affected / exposed           | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                     | 0               | 0               | 0               |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Reproductive system and breast disorders        |                 |                |                 |
| Breast pain                                     |                 |                |                 |
| subjects affected / exposed                     | 2 / 20 (10.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 2               | 0              | 0               |
| Metrorrhagia                                    |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Varicocele                                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Aphonia   |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Cough   |                 |                |                 |
| subjects affected / exposed                     | 1 / 20 (5.00%)  | 1 / 20 (5.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 1               | 1              | 0               |
| Dysphonia                                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Dyspnoea  |                 |                |                 |
| subjects affected / exposed                     | 2 / 20 (10.00%) | 1 / 20 (5.00%) | 3 / 21 (14.29%) |
| occurrences (all)                               | 2               | 1              | 3               |
| Epistaxis                                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Haemoptysis                                     |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 1 / 21 (4.76%)  |
| occurrences (all)                               | 0               | 0              | 1               |
| Lung opacity                                    |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Nasal congestion                                |                 |                |                 |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Nasal mucosal ulcer                             |                 |                |                 |

|                             |                |                |                 |
|-----------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Oropharyngeal pain          |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 1              | 0               |
| Pleural effusion            |                |                |                 |
| subjects affected / exposed | 1 / 20 (5.00%) | 1 / 20 (5.00%) | 1 / 21 (4.76%)  |
| occurrences (all)           | 1              | 1              | 1               |
| Pneumonitis                 |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%)  |
| occurrences (all)           | 0              | 0              | 1               |
| Productive cough            |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Pulmonary embolism          |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 1 / 21 (4.76%)  |
| occurrences (all)           | 0              | 1              | 1               |
| Respiratory failure         |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Rhinalgia                   |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Rhinorrhoea                 |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Psychiatric disorders       |                |                |                 |
| Anxiety                     |                |                |                 |
| subjects affected / exposed | 1 / 20 (5.00%) | 1 / 20 (5.00%) | 3 / 21 (14.29%) |
| occurrences (all)           | 1              | 1              | 3               |
| Confusional state           |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%)  |
| occurrences (all)           | 0              | 0              | 0               |
| Depression                  |                |                |                 |
| subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%) | 1 / 21 (4.76%)  |
| occurrences (all)           | 0              | 1              | 1               |

|   |                 |                  |                  |
|---|-----------------|------------------|------------------|
| Disorientation                                  |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)   | 0 / 21 (0.00%)   |
| occurrences (all)                               | 0               | 0                | 0                |
| Eating disorder                                 |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)   | 0 / 21 (0.00%)   |
| occurrences (all)                               | 0               | 0                | 0                |
| Insomnia  |                 |                  |                  |
| subjects affected / exposed                     | 3 / 20 (15.00%) | 1 / 20 (5.00%)   | 2 / 21 (9.52%)   |
| occurrences (all)                               | 3               | 1                | 2                |
| Investigations                                  |                 |                  |                  |
| Activated partial thromboplastin time prolonged |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 1 / 20 (5.00%)   | 0 / 21 (0.00%)   |
| occurrences (all)                               | 0               | 1                | 0                |
| Alanine aminotransferase increased              |                 |                  |                  |
| subjects affected / exposed                     | 4 / 20 (20.00%) | 5 / 20 (25.00%)  | 7 / 21 (33.33%)  |
| occurrences (all)                               | 8               | 5                | 11               |
| Amylase increased                               |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)   | 0 / 21 (0.00%)   |
| occurrences (all)                               | 0               | 0                | 0                |
| Aspartate aminotransferase increased            |                 |                  |                  |
| subjects affected / exposed                     | 9 / 20 (45.00%) | 7 / 20 (35.00%)  | 13 / 21 (61.90%) |
| occurrences (all)                               | 14              | 7                | 18               |
| Blood alkaline phosphatase increased            |                 |                  |                  |
| subjects affected / exposed                     | 2 / 20 (10.00%) | 3 / 20 (15.00%)  | 3 / 21 (14.29%)  |
| occurrences (all)                               | 2               | 3                | 3                |
| Blood bilirubin increased                       |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)   | 0 / 21 (0.00%)   |
| occurrences (all)                               | 0               | 0                | 0                |
| Blood creatine phosphokinase increased          |                 |                  |                  |
| subjects affected / exposed                     | 9 / 20 (45.00%) | 10 / 20 (50.00%) | 12 / 21 (57.14%) |
| occurrences (all)                               | 14              | 10               | 12               |
| Blood creatinine increased                      |                 |                  |                  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  | 0 / 20 (0.00%)   | 2 / 21 (9.52%)   |
| occurrences (all)                               | 0               | 0                | 2                |
| Blood lactate dehydrogenase                     |                 |                  |                  |

|  |                 |                 |                |
|--|-----------------|-----------------|----------------|
| increased                                      |                 |                 |                |
| subjects affected / exposed                    | 3 / 20 (15.00%) | 1 / 20 (5.00%)  | 2 / 21 (9.52%) |
| occurrences (all)                              | 3               | 1               | 2              |
| Blood pressure increased                       |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Blood thyroid stimulating hormone increased    |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| C-reactive protein increased                   |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Lipase increased                               |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Lymphocyte count decreased                     |                 |                 |                |
| subjects affected / exposed                    | 2 / 20 (10.00%) | 2 / 20 (10.00%) | 0 / 21 (0.00%) |
| occurrences (all)                              | 3               | 2               | 0              |
| Neutrophil count increased                     |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Platelet count decreased                       |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Transaminases increased                        |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Weight decreased                               |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 2 / 20 (10.00%) | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 2               | 0              |
| Injury, poisoning and procedural complications |                 |                 |                |
| Abdominal injury                               |                 |                 |                |
| subjects affected / exposed                    | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)                              | 0               | 0               | 0              |
| Fall   |                 |                 |                |

|                              |                 |                 |                 |
|------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Foot fracture                |                 |                 |                 |
| subjects affected / exposed  | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 1               | 0               | 0               |
| Infusion related reaction    |                 |                 |                 |
| subjects affected / exposed  | 3 / 20 (15.00%) | 2 / 20 (10.00%) | 3 / 21 (14.29%) |
| occurrences (all)            | 3               | 2               | 3               |
| Post procedural haemorrhage  |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Post procedural inflammation |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Procedural pain              |                 |                 |                 |
| subjects affected / exposed  | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 1               | 0               | 0               |
| Rib fracture                 |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Cardiac disorders            |                 |                 |                 |
| Tachycardia                  |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Nervous system disorders     |                 |                 |                 |
| Balance disorder             |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 0               | 0               |
| Dizziness                    |                 |                 |                 |
| subjects affected / exposed  | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 2 / 21 (9.52%)  |
| occurrences (all)            | 1               | 0               | 2               |
| Dysgeusia                    |                 |                 |                 |
| subjects affected / exposed  | 0 / 20 (0.00%)  | 1 / 20 (5.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)            | 0               | 1               | 0               |
| Headache                     |                 |                 |                 |

|                                      |                 |                 |                 |
|--------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed          | 5 / 20 (25.00%) | 0 / 20 (0.00%)  | 3 / 21 (14.29%) |
| occurrences (all)                    | 7               | 0               | 7               |
| Hypoaesthesia                        |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Neuropathy peripheral                |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 2 / 20 (10.00%) | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 2               | 0               |
| Paraesthesia                         |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Somnolence                           |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Blood and lymphatic system disorders |                 |                 |                 |
| Anaemia                              |                 |                 |                 |
| subjects affected / exposed          | 4 / 20 (20.00%) | 6 / 20 (30.00%) | 5 / 21 (23.81%) |
| occurrences (all)                    | 6               | 9               | 6               |
| Leukocytosis                         |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Ear and labyrinth disorders          |                 |                 |                 |
| Vertigo                              |                 |                 |                 |
| subjects affected / exposed          | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 1               | 0               | 0               |
| Eye disorders                        |                 |                 |                 |
| Dry eye                              |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%)  |
| occurrences (all)                    | 0               | 0               | 1               |
| Eye pruritus                         |                 |                 |                 |
| subjects affected / exposed          | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 0               | 0               | 0               |
| Eyelid oedema                        |                 |                 |                 |
| subjects affected / exposed          | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                    | 1               | 0               | 0               |
| Lacrimation increased                |                 |                 |                 |

|                             |                 |                 |                 |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 1               | 0               | 0               |
| Panophthalmitis             |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Periorbital oedema          |                 |                 |                 |
| subjects affected / exposed | 3 / 20 (15.00%) | 3 / 20 (15.00%) | 4 / 21 (19.05%) |
| occurrences (all)           | 3               | 3               | 4               |
| Uveitis                     |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Visual impairment           |                 |                 |                 |
| subjects affected / exposed | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 1               | 0               | 0               |
| Xerophthalmia               |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Gastrointestinal disorders  |                 |                 |                 |
| Abdominal discomfort        |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Abdominal distension        |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 1 / 20 (5.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 1               | 0               |
| Abdominal pain              |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 3 / 20 (15.00%) | 3 / 21 (14.29%) |
| occurrences (all)           | 0               | 3               | 3               |
| Abdominal pain lower        |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |
| Abdominal pain upper        |                 |                 |                 |
| subjects affected / exposed | 3 / 20 (15.00%) | 1 / 20 (5.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 3               | 1               | 0               |
| Aphthous ulcer              |                 |                 |                 |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)           | 0               | 0               | 0               |



|                                  |                 |                 |                 |
|----------------------------------|-----------------|-----------------|-----------------|
| Ascites                          |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Colitis                          |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Constipation                     |                 |                 |                 |
| subjects affected / exposed      | 6 / 20 (30.00%) | 4 / 20 (20.00%) | 4 / 21 (19.05%) |
| occurrences (all)                | 6               | 4               | 5               |
| Diarrhoea                        |                 |                 |                 |
| subjects affected / exposed      | 2 / 20 (10.00%) | 4 / 20 (20.00%) | 2 / 21 (9.52%)  |
| occurrences (all)                | 2               | 4               | 2               |
| Dry mouth                        |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%)  |
| occurrences (all)                | 0               | 0               | 1               |
| Dyspepsia                        |                 |                 |                 |
| subjects affected / exposed      | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%)  |
| occurrences (all)                | 1               | 0               | 1               |
| Epigastric discomfort            |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Flatulence                       |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%)  |
| occurrences (all)                | 0               | 0               | 1               |
| Gastritis                        |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Gastrooesophageal reflux disease |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Gingival bleeding                |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |
| Haematochezia                    |                 |                 |                 |
| subjects affected / exposed      | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                | 0               | 0               | 0               |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| Melaena                                |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Nausea                                 |                 |                 |                 |
| subjects affected / exposed            | 6 / 20 (30.00%) | 8 / 20 (40.00%) | 6 / 21 (28.57%) |
| occurrences (all)                      | 6               | 8               | 8               |
| Odynophagia                            |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Stomatitis                             |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 1 / 20 (5.00%)  | 1 / 21 (4.76%)  |
| occurrences (all)                      | 0               | 1               | 1               |
| Vomiting                               |                 |                 |                 |
| subjects affected / exposed            | 3 / 20 (15.00%) | 4 / 20 (20.00%) | 2 / 21 (9.52%)  |
| occurrences (all)                      | 5               | 6               | 2               |
| Hepatobiliary disorders                |                 |                 |                 |
| Cholestasis                            |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Hyperbilirubinaemia                    |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Portal vein thrombosis                 |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Skin and subcutaneous tissue disorders |                 |                 |                 |
| Alopecia                               |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Dry skin                               |                 |                 |                 |
| subjects affected / exposed            | 1 / 20 (5.00%)  | 1 / 20 (5.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 1               | 1               | 0               |
| Hair colour changes                    |                 |                 |                 |
| subjects affected / exposed            | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%)  |
| occurrences (all)                      | 0               | 0               | 0               |
| Hyperhidrosis                          |                 |                 |                 |

|                             |                 |                 |                |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Intertrigo                  |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Nail dystrophy              |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Petechiae                   |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Pruritus                    |                 |                 |                |
| subjects affected / exposed | 2 / 20 (10.00%) | 2 / 20 (10.00%) | 2 / 21 (9.52%) |
| occurrences (all)           | 2               | 2               | 2              |
| Rash                        |                 |                 |                |
| subjects affected / exposed | 3 / 20 (15.00%) | 2 / 20 (10.00%) | 2 / 21 (9.52%) |
| occurrences (all)           | 3               | 3               | 4              |
| Rash maculo-papular         |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 1 / 20 (5.00%)  | 2 / 21 (9.52%) |
| occurrences (all)           | 0               | 1               | 2              |
| Rash pruritic               |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Renal and urinary disorders |                 |                 |                |
| Choluria                    |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Dysuria                     |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences (all)           | 0               | 0               | 1              |
| Haematuria                  |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences (all)           | 0               | 0               | 1              |
| Pollakiuria                 |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |

|   |                      |                      |                     |
|---|----------------------|----------------------|---------------------|
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 2 / 21 (9.52%)<br>2 |
| Renal colic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Renal failure<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Ureterolithiasis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Endocrine disorders<br>Hypopituitarism<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Hypothyroidism<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  | 0 / 21 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 3 / 20 (15.00%)<br>3 | 0 / 20 (0.00%)<br>0  | 1 / 21 (4.76%)<br>1 |
| Arthritis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)   | 2 / 20 (10.00%)<br>2 | 2 / 20 (10.00%)<br>2 | 1 / 21 (4.76%)<br>1 |
| Flank pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Groin pain<br>subjects affected / exposed<br>occurrences (all)  | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Joint stiffness   |                      |                      |                     |

|                             |                 |                 |                |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Joint warmth                |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Muscle spasms               |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Muscle twitching            |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Muscular weakness           |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Musculoskeletal chest pain  |                 |                 |                |
| subjects affected / exposed | 1 / 20 (5.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Myalgia                     |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 4 / 20 (20.00%) | 2 / 21 (9.52%) |
| occurrences (all)           | 0               | 4               | 2              |
| Neck pain                   |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Pain in extremity           |                 |                 |                |
| subjects affected / exposed | 2 / 20 (10.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 2               | 0               | 0              |
| Infections and infestations |                 |                 |                |
| Abscess                     |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Cellulitis                  |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Conjunctivitis              |                 |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%)  | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences (all)           | 0               | 0               | 1              |

|                                   |                |                |                |
|-----------------------------------|----------------|----------------|----------------|
| Diarrhoea infectious              |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Helicobacter infection            |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Infection                         |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Influenza                         |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Nasopharyngitis                   |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 1 / 21 (4.76%) |
| occurrences (all)                 | 0              | 0              | 1              |
| Otitis media                      |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Peritonitis                       |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Pneumonia                         |                |                |                |
| subjects affected / exposed       | 1 / 20 (5.00%) | 1 / 20 (5.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 1              | 1              | 0              |
| Pyuria                            |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Respiratory tract infection       |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Skin infection                    |                |                |                |
| subjects affected / exposed       | 1 / 20 (5.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 1              | 0              | 0              |
| Upper respiratory tract infection |                |                |                |
| subjects affected / exposed       | 0 / 20 (0.00%) | 0 / 20 (0.00%) | 0 / 21 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |

|   |                      |                      |                     |
|---|----------------------|----------------------|---------------------|
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all) | 2 / 20 (10.00%)<br>2 | 1 / 20 (5.00%)<br>1  | 2 / 21 (9.52%)<br>2 |
| Viral skin infection<br>subjects affected / exposed<br>occurrences (all)    | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Metabolism and nutrition disorders  |                      |                      |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)      | 3 / 20 (15.00%)<br>3 | 7 / 20 (35.00%)<br>7 | 1 / 21 (4.76%)<br>1 |
| Dehydration<br>subjects affected / exposed<br>occurrences (all)             | 0 / 20 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  | 0 / 21 (0.00%)<br>0 |
| Hyperglycaemia<br>subjects affected / exposed<br>occurrences (all)          | 1 / 20 (5.00%)<br>1  | 1 / 20 (5.00%)<br>1  | 1 / 21 (4.76%)<br>1 |
| Hyperkalaemia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 20 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  | 1 / 21 (4.76%)<br>1 |
| Hypermagnesaemia<br>subjects affected / exposed<br>occurrences (all)        | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 0 / 21 (0.00%)<br>0 |
| Hyperuricaemia<br>subjects affected / exposed<br>occurrences (all)          | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 1 / 21 (4.76%)<br>1 |
| Hypoalbuminaemia<br>subjects affected / exposed<br>occurrences (all)        | 0 / 20 (0.00%)<br>0  | 2 / 20 (10.00%)<br>2 | 1 / 21 (4.76%)<br>1 |
| Hypocalcaemia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 20 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  | 1 / 21 (4.76%)<br>1 |
| Hypokalaemia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 20 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  | 1 / 21 (4.76%)<br>1 |
| Hypomagnesaemia   |                      |                      |                     |

|                             |                |                 |                |
|-----------------------------|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0              | 0               | 0              |
| Hyponatraemia               |                |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%) | 3 / 20 (15.00%) | 2 / 21 (9.52%) |
| occurrences (all)           | 0              | 3               | 2              |
| Hypophagia                  |                |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 0 / 21 (0.00%) |
| occurrences (all)           | 0              | 0               | 0              |
| Hypophosphataemia           |                |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%) | 1 / 20 (5.00%)  | 1 / 21 (4.76%) |
| occurrences (all)           | 0              | 1               | 1              |
| Vitamin D deficiency        |                |                 |                |
| subjects affected / exposed | 0 / 20 (0.00%) | 0 / 20 (0.00%)  | 1 / 21 (4.76%) |
| occurrences (all)           | 0              | 0               | 1              |

|   |   |  |  |
|---|---|--|--|
| <b>Non-serious adverse events</b>                                   | Ph II: MCS110@7.5<br>mg/kg Q3W@+<br>PDR001 300@mg<br>Q3W - ME |  |  |
| Total subjects affected by non-serious adverse events               |   |  |  |
| subjects affected / exposed   | 20 / 20 (100.00%)   |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |  |
| Cancer pain   |   |  |  |
| subjects affected / exposed   | 1 / 20 (5.00%)  |  |  |
| occurrences (all)   | 1   |  |  |
| Metastases to central nervous system                                |   |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)  |  |  |
| occurrences (all)   | 0   |  |  |
| Tumour pain   |   |  |  |
| subjects affected / exposed   | 1 / 20 (5.00%)  |  |  |
| occurrences (all)   | 1   |  |  |
| Vascular disorders  |   |  |  |
| Deep vein thrombosis  |   |  |  |
| subjects affected / exposed   | 0 / 20 (0.00%)  |  |  |
| occurrences (all)   | 0   |  |  |
| Hypertension  |   |  |  |



|  |                 |  |  |
|--|-----------------|--|--|
| subjects affected / exposed                          | 4 / 20 (20.00%) |  |  |
| occurrences (all)                                    | 4               |  |  |
| General disorders and administration site conditions |                 |  |  |
| Adverse reaction                                     |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| Asthenia   |                 |  |  |
| subjects affected / exposed                          | 3 / 20 (15.00%) |  |  |
| occurrences (all)                                    | 3               |  |  |
| Chest discomfort                                     |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| Chills   |                 |  |  |
| subjects affected / exposed                          | 7 / 20 (35.00%) |  |  |
| occurrences (all)                                    | 10              |  |  |
| Face oedema  |                 |  |  |
| subjects affected / exposed                          | 6 / 20 (30.00%) |  |  |
| occurrences (all)                                    | 8               |  |  |
| Fatigue  |                 |  |  |
| subjects affected / exposed                          | 4 / 20 (20.00%) |  |  |
| occurrences (all)                                    | 5               |  |  |
| Gait disturbance                                     |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| General physical health deterioration                |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| Generalised oedema                                   |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| Influenza like illness                               |                 |  |  |
| subjects affected / exposed                          | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                                    | 0               |  |  |
| Non-cardiac chest pain                               |                 |  |  |

|  |  |  |  |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oedema peripheral</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Suprapubic pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 20 (5.00%)</p> <p>1</p> <p>3 / 20 (15.00%)</p> <p>3</p> <p>8 / 20 (40.00%)</p> <p>10</p> <p>0 / 20 (0.00%)</p> <p>0</p> |  |  |
| <p>Immune system disorders</p> <p>Cytokine release syndrome</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>0 / 20 (0.00%)</p> <p>0</p>   |  |  |
| <p>Reproductive system and breast disorders</p> <p>Breast pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Metrorrhagia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Varicocele</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                   | <p>0 / 20 (0.00%)</p> <p>0</p> <p>0 / 20 (0.00%)</p> <p>0</p> <p>0 / 20 (0.00%)</p> <p>0</p>                                   |  |  |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Aphonia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dysphonia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dyspnoea</p>        | <p>0 / 20 (0.00%)</p> <p>0</p> <p>1 / 20 (5.00%)</p> <p>1</p> <p>0 / 20 (0.00%)</p> <p>0</p>                                   |  |  |

|                             |                |  |  |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Epistaxis                   |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Haemoptysis                 |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Lung opacity                |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Nasal congestion            |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Nasal mucosal ulcer         |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Oropharyngeal pain          |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Pleural effusion            |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Pneumonitis                 |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Productive cough            |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Pulmonary embolism          |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Respiratory failure         |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Rhinalgia                   |                |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Rhinorrhoea                                     |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Psychiatric disorders                           |                 |  |  |
| Anxiety   |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Confusional state                               |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Depression                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Disorientation                                  |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Eating disorder                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Insomnia  |                 |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                               | 2               |  |  |
| Investigations                                  |                 |  |  |
| Activated partial thromboplastin time prolonged |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Alanine aminotransferase increased              |                 |  |  |
| subjects affected / exposed                     | 4 / 20 (20.00%) |  |  |
| occurrences (all)                               | 6               |  |  |
| Amylase increased                               |                 |  |  |
| subjects affected / exposed                     | 2 / 20 (10.00%) |  |  |
| occurrences (all)                               | 2               |  |  |
| Aspartate aminotransferase increased            |                 |  |  |

|   |                  |  |  |
|---|------------------|--|--|
| subjects affected / exposed                 | 10 / 20 (50.00%) |  |  |
| occurrences (all)                           | 11               |  |  |
| Blood alkaline phosphatase increased        |                  |  |  |
| subjects affected / exposed                 | 3 / 20 (15.00%)  |  |  |
| occurrences (all)                           | 4                |  |  |
| Blood bilirubin increased                   |                  |  |  |
| subjects affected / exposed                 | 0 / 20 (0.00%)   |  |  |
| occurrences (all)                           | 0                |  |  |
| Blood creatine phosphokinase increased      |                  |  |  |
| subjects affected / exposed                 | 14 / 20 (70.00%) |  |  |
| occurrences (all)                           | 15               |  |  |
| Blood creatinine increased                  |                  |  |  |
| subjects affected / exposed                 | 1 / 20 (5.00%)   |  |  |
| occurrences (all)                           | 3                |  |  |
| Blood lactate dehydrogenase increased       |                  |  |  |
| subjects affected / exposed                 | 5 / 20 (25.00%)  |  |  |
| occurrences (all)                           | 5                |  |  |
| Blood pressure increased                    |                  |  |  |
| subjects affected / exposed                 | 0 / 20 (0.00%)   |  |  |
| occurrences (all)                           | 0                |  |  |
| Blood thyroid stimulating hormone increased |                  |  |  |
| subjects affected / exposed                 | 0 / 20 (0.00%)   |  |  |
| occurrences (all)                           | 0                |  |  |
| C-reactive protein increased                |                  |  |  |
| subjects affected / exposed                 | 0 / 20 (0.00%)   |  |  |
| occurrences (all)                           | 0                |  |  |
| Lipase increased                            |                  |  |  |
| subjects affected / exposed                 | 2 / 20 (10.00%)  |  |  |
| occurrences (all)                           | 3                |  |  |
| Lymphocyte count decreased                  |                  |  |  |
| subjects affected / exposed                 | 1 / 20 (5.00%)   |  |  |
| occurrences (all)                           | 2                |  |  |
| Neutrophil count increased                  |                  |  |  |

|  |                 |  |  |
|--|-----------------|--|--|
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Platelet count decreased                       |                 |  |  |
| subjects affected / exposed                    | 2 / 20 (10.00%) |  |  |
| occurrences (all)                              | 2               |  |  |
| Transaminases increased                        |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Weight decreased                               |                 |  |  |
| subjects affected / exposed                    | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                              | 1               |  |  |
| Injury, poisoning and procedural complications |                 |  |  |
| Abdominal injury                               |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Fall   |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Foot fracture                                  |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Infusion related reaction                      |                 |  |  |
| subjects affected / exposed                    | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                              | 1               |  |  |
| Post procedural haemorrhage                    |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Post procedural inflammation                   |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Procedural pain                                |                 |  |  |
| subjects affected / exposed                    | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                              | 0               |  |  |
| Rib fracture                                   |                 |  |  |

|  |  |  |  |
|--|--|--|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  |  |  |
| Cardiac disorders<br>Tachycardia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  |  |  |
| Nervous system disorders<br>Balance disorder<br>subjects affected / exposed<br>occurrences (all)<br><br>Dizziness<br>subjects affected / exposed<br>occurrences (all)<br><br>Dysgeusia<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)<br><br>Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)<br><br>Neuropathy peripheral<br>subjects affected / exposed<br>occurrences (all)<br><br>Paraesthesia<br>subjects affected / exposed<br>occurrences (all)<br><br>Somnolence<br>subjects affected / exposed<br>occurrences (all) | 0 / 20 (0.00%)<br>0<br><br>1 / 20 (5.00%)<br>1<br><br>0 / 20 (0.00%)<br>0<br><br>1 / 20 (5.00%)<br>1<br><br>0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0<br><br>0 / 20 (0.00%)<br>0 |  |  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)<br><br>Leukocytosis  | 7 / 20 (35.00%)<br>8   |  |  |

|  |                      |  |  |
|--|----------------------|--|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 20 (0.00%)<br>0  |  |  |
| Ear and labyrinth disorders<br>Vertigo<br>subjects affected / exposed<br>occurrences (all) | 1 / 20 (5.00%)<br>1  |  |  |
| Eye disorders<br>Dry eye<br>subjects affected / exposed<br>occurrences (all)               | 1 / 20 (5.00%)<br>1  |  |  |
| Eye pruritus<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 20 (0.00%)<br>0  |  |  |
| Eyelid oedema<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 20 (0.00%)<br>0  |  |  |
| Lacrimation increased<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 20 (5.00%)<br>1  |  |  |
| Panophthalmitis<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 20 (0.00%)<br>0  |  |  |
| Periorbital oedema<br>subjects affected / exposed<br>occurrences (all)                     | 6 / 20 (30.00%)<br>6 |  |  |
| Uveitis<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 20 (0.00%)<br>0  |  |  |
| Visual impairment<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 20 (0.00%)<br>0  |  |  |
| Xerophthalmia<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 20 (0.00%)<br>0  |  |  |
| Gastrointestinal disorders   |                      |  |  |



|                             |                 |  |  |
|-----------------------------|-----------------|--|--|
| Abdominal discomfort        |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Abdominal distension        |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Abdominal pain              |                 |  |  |
| subjects affected / exposed | 1 / 20 (5.00%)  |  |  |
| occurrences (all)           | 1               |  |  |
| Abdominal pain lower        |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Abdominal pain upper        |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Aphthous ulcer              |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Ascites                     |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Colitis                     |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Constipation                |                 |  |  |
| subjects affected / exposed | 5 / 20 (25.00%) |  |  |
| occurrences (all)           | 5               |  |  |
| Diarrhoea                   |                 |  |  |
| subjects affected / exposed | 1 / 20 (5.00%)  |  |  |
| occurrences (all)           | 1               |  |  |
| Dry mouth                   |                 |  |  |
| subjects affected / exposed | 0 / 20 (0.00%)  |  |  |
| occurrences (all)           | 0               |  |  |
| Dyspepsia                   |                 |  |  |
| subjects affected / exposed | 1 / 20 (5.00%)  |  |  |
| occurrences (all)           | 1               |  |  |

|                                  |                 |  |  |
|----------------------------------|-----------------|--|--|
| Epigastric discomfort            |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Flatulence                       |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Gastritis                        |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Gastrooesophageal reflux disease |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Gingival bleeding                |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Haematochezia                    |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Melaena                          |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Nausea                           |                 |  |  |
| subjects affected / exposed      | 4 / 20 (20.00%) |  |  |
| occurrences (all)                | 4               |  |  |
| Odynophagia                      |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Stomatitis                       |                 |  |  |
| subjects affected / exposed      | 3 / 20 (15.00%) |  |  |
| occurrences (all)                | 3               |  |  |
| Vomiting                         |                 |  |  |
| subjects affected / exposed      | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                | 0               |  |  |
| Hepatobiliary disorders          |                 |  |  |
| Cholestasis                      |                 |  |  |

|  |                 |  |  |
|--|-----------------|--|--|
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Hyperbilirubinaemia                    |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Portal vein thrombosis                 |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Skin and subcutaneous tissue disorders |                 |  |  |
| Alopecia                               |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Dry skin                               |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Hair colour changes                    |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Hyperhidrosis                          |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Intertrigo                             |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Nail dystrophy                         |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Petechiae                              |                 |  |  |
| subjects affected / exposed            | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                      | 0               |  |  |
| Pruritus                               |                 |  |  |
| subjects affected / exposed            | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                      | 1               |  |  |
| Rash                                   |                 |  |  |
| subjects affected / exposed            | 4 / 20 (20.00%) |  |  |
| occurrences (all)                      | 6               |  |  |

|   |                      |  |  |
|---|----------------------|--|--|
| Rash maculo-papular<br>subjects affected / exposed<br>occurrences (all) | 2 / 20 (10.00%)<br>2 |  |  |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all)       | 0 / 20 (0.00%)<br>0  |  |  |
| Renal and urinary disorders   |                      |  |  |
| Choluria<br>subjects affected / exposed<br>occurrences (all)            | 0 / 20 (0.00%)<br>0  |  |  |
| Dysuria<br>subjects affected / exposed<br>occurrences (all)             | 0 / 20 (0.00%)<br>0  |  |  |
| Haematuria<br>subjects affected / exposed<br>occurrences (all)          | 1 / 20 (5.00%)<br>1  |  |  |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)         | 0 / 20 (0.00%)<br>0  |  |  |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)         | 2 / 20 (10.00%)<br>3 |  |  |
| Renal colic<br>subjects affected / exposed<br>occurrences (all)         | 0 / 20 (0.00%)<br>0  |  |  |
| Renal failure<br>subjects affected / exposed<br>occurrences (all)       | 0 / 20 (0.00%)<br>0  |  |  |
| Ureterolithiasis<br>subjects affected / exposed<br>occurrences (all)    | 0 / 20 (0.00%)<br>0  |  |  |
| Endocrine disorders   |                      |  |  |
| Hypopituitarism<br>subjects affected / exposed<br>occurrences (all)     | 0 / 20 (0.00%)<br>0  |  |  |
| Hypothyroidism  |                      |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Musculoskeletal and connective tissue disorders |                 |  |  |
| Arthralgia                                      |                 |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                               | 1               |  |  |
| Arthritis                                       |                 |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                               | 1               |  |  |
| Back pain                                       |                 |  |  |
| subjects affected / exposed                     | 2 / 20 (10.00%) |  |  |
| occurrences (all)                               | 2               |  |  |
| Flank pain                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Groin pain                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Joint stiffness                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Joint warmth                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Muscle spasms                                   |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Muscle twitching                                |                 |  |  |
| subjects affected / exposed                     | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                               | 0               |  |  |
| Muscular weakness                               |                 |  |  |
| subjects affected / exposed                     | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                               | 1               |  |  |
| Musculoskeletal chest pain                      |                 |  |  |

|                             |                |  |  |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Myalgia                     |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Neck pain                   |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Pain in extremity           |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Infections and infestations |                |  |  |
| Abscess                     |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Cellulitis                  |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Conjunctivitis              |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Diarrhoea infectious        |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Helicobacter infection      |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Infection                   |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Influenza                   |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Nasopharyngitis             |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |

|                                    |                 |  |  |
|------------------------------------|-----------------|--|--|
| Otitis media                       |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Peritonitis                        |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Pneumonia                          |                 |  |  |
| subjects affected / exposed        | 3 / 20 (15.00%) |  |  |
| occurrences (all)                  | 3               |  |  |
| Pyuria                             |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Respiratory tract infection        |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Skin infection                     |                 |  |  |
| subjects affected / exposed        | 2 / 20 (10.00%) |  |  |
| occurrences (all)                  | 2               |  |  |
| Upper respiratory tract infection  |                 |  |  |
| subjects affected / exposed        | 1 / 20 (5.00%)  |  |  |
| occurrences (all)                  | 1               |  |  |
| Urinary tract infection            |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Viral skin infection               |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Metabolism and nutrition disorders |                 |  |  |
| Decreased appetite                 |                 |  |  |
| subjects affected / exposed        | 4 / 20 (20.00%) |  |  |
| occurrences (all)                  | 4               |  |  |
| Dehydration                        |                 |  |  |
| subjects affected / exposed        | 0 / 20 (0.00%)  |  |  |
| occurrences (all)                  | 0               |  |  |
| Hyperglycaemia                     |                 |  |  |

|                             |                |  |  |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hyperkalaemia               |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hypermagnesaemia            |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hyperuricaemia              |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hypoalbuminaemia            |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Hypocalcaemia               |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hypokalaemia                |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 2              |  |  |
| Hypomagnesaemia             |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hyponatraemia               |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Hypophagia                  |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |
| Hypophosphataemia           |                |  |  |
| subjects affected / exposed | 1 / 20 (5.00%) |  |  |
| occurrences (all)           | 1              |  |  |
| Vitamin D deficiency        |                |  |  |
| subjects affected / exposed | 0 / 20 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |





## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment   |
|------------------|---|
| 11 July 2016     | Amendment 01 - The main reason for this amendment was to add more specific guidance for dose modifications and to revise definitions for (DLTs), following HA feed-back.  |
| 07 February 2017 | Amendment 02 - The main reasons for this amendment were to make changes requested by the HA, to prepare the protocol for inclusion of Japanese patients and to update safety monitoring. Furthermore, clarifications and correction of typos have been made to the protocol.  |
| 14 February 2018 | Amendment 03 - The main purpose for this amendment was to:<br>1. Increase the number of pancreatic cancer patients to be enrolled in the Phase II part of the study from 20 to 40<br>2. Change the primary endpoint for antitumor activity in pancreatic cancer from ORR to CBR<br>3. Add the assessment of cfDNA as a complementary method to evaluate tumor mutational burden<br>4. Mention that statins should be used with caution.   |
| 20 July 2018     | Amendment 04 - The main purpose for this amendment was to allow exploration of an additional, lower dose of MCS110 in patients with pancreatic cancer. Data generated in the dose escalation part of the study show preliminary signals of efficacy (1 PR, 2 SD >1 year) at the lowest dose level of MCS110 (1 mg/kg, Q3W) in combination with PDR001 in pancreatic cancer patients. In order to further explore this, 2 additional groups, each consisting of up to 20 patients with PDAC may be enrolled at either 1 mg/kg Q3W or the RP2D (7.5mg/kg, Q3W) of MCS110 in combination with PDR001 (300 mg, Q3W) respectively. Recruitment into these 2 groups was contingent upon evidence of clinical benefit in the first 20 PDAC patients treated at the RP2D. |
| 23 July 2019     | Amendment 05 - This protocol amendment revised the definition of end of study to include the option for patients still on study treatment and who, in the opinion of the investigator, were still deriving clinical benefit at the time of end of study, to transfer to another study to continue providing study treatment to these patients or to an alternative treatment option.  |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported