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	v2 (current)
This version publication date	23 August 2021
First version publication date	12 June 2021
Version creation reason	

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:

Results analysis stage

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

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

Notes:

General information about the trial

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

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.

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	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

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	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
Arm title	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

Arm title	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	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

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	

Arm title	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	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	
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	
Arm title	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	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	
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	
Arm title	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	
Arm title	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	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	
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	
Arm title	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	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	
Arm title	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	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

Arm title	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	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

Arm title	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

Number of subjects in period 1	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

Number of subjects in period 1	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

Number of subjects in period 1	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

Number of subjects in period 1	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 Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	3	9	8
>=65 years	3	3	4
Age Continuous Units: years			
arithmetic mean	64.3	56.9	59.3
standard deviation	± 14.72	± 11.13	± 9.94

Sex: Female, Male Units: Participants			
Female	4	10	6
Male	2	2	6
Race (NIH/OMB) 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 Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	10	5	8
>=65 years	3	1	3
Age Continuous Units: years			
arithmetic mean	55.4	57.3	58.6
standard deviation	± 10.03	± 14.02	± 11.13
Sex: Female, Male Units: Participants			
Female	8	4	6
Male	5	2	5
Race (NIH/OMB) 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 Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	20	11	9
>=65 years	0	9	12

Age Continuous Units: years			
arithmetic mean	50.0	61.5	62.8
standard deviation	± 8.29	± 11.33	± 10.13
Sex: Female, Male Units: Participants			
Female	20	8	21
Male	0	12	0
Race (NIH/OMB) 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

Reporting group values	Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - ME	Total	
Number of subjects	20	141	
Age Categorical Units: Participants			
<=18 years	0	0	
Between 18 and 65 years	12	95	
>=65 years	8	46	
Age Continuous Units: years			
arithmetic mean	60.7		
standard deviation	± 13.15	-	
Sex: Female, Male Units: Participants			
Female	9	96	
Male	11	45	
Race (NIH/OMB) 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[1][2]
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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: 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 grades	0	0	0	0
AEs leading to dose adjust / interrupt-all grades	4	4	4	2
AEs requiring addit. therapy - all grades	6	12	10	12

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: 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 grades	2	1		
AEs leading to dose adjust / interrupt-all 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[3][4]

End point description:

Overall Response Rate (ORR) is defined as the proportion of patients with a best overall response assessed by CT scan or MRI of complete response (CR), disappearance of all measurable and non-measurable lesions or partial response (PR), at least a 30% decrease in the sum of diameter of all measurable lesions, taking as reference the baseline sum of diameters,. based on local Investigator assessment, as per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1).

End point type	Primary

End point timeframe:

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: This endpoint only applied to phase II arms and not phase Ib arms.

[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: This endpoint only applied to phase II arms and not phase Ib arms.

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				
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[5][6]

End point description:

Overall Response Rate (ORR) is defined as the proportion of patients with a best overall response assessed by CT scan or MRI of complete response (CR), disappearance of all measurable and non-measurable lesions or partial response (PR), at least a 30% decrease in the sum of diameter of all measurable lesions, taking as reference the baseline sum of diameters,. based on local Investigator assessment, as per Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1) - mean (FAS).

End point type	Primary

End point timeframe:

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: This endpoint only applied to phase II arms and not phase Ib arms.

[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: This endpoint only applied to phase II arms and not phase Ib arms.

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%)	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[7][8]

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: This endpoint only applied to phase II arms and not phase Ib arms.

[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: This endpoint only applied to phase II arms and not phase Ib arms.

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				
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[9][10]

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: This endpoint only applied to phase II arms and not phase Ib arms.

[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: This endpoint only applied to phase II arms and not phase Ib arms.

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[11][12]

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II. Planned dose intensity for MCS110 is cumulative planned dose (mg/kg)/ number of doses scheduled per protocol during treatment period (i.e., this is equivalent to planned dose level).

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: mg/kg/3wks				
arithmetic mean (standard deviation)	0.86 (± 0.191)	2.74 (± 0.386)	2.66 (± 0.435)	4.85 (± 0.286)

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: mg/kg/3wks				
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[13][14]

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II. Relative dose intensity (%) is 100 × dose intensity (mg/kg/3wks)/planned dose intensity (mg/kg/3wks).

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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 (± 100)	100 (± 100)	100 (± 100)	99.23 (± 2.774)

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 (± 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[15][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. Planned dose intensity for PDR001 (mg/3wks) is planned cumulative dose (mg)/ number of doses scheduled per protocol during treatment period (i.e., this is equivalent to planned dose level).

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: mg/3wks				
arithmetic mean (standard deviation)	86.09 (± 19.058)	91.18 (± 12.873)	265.83 (± 43.528)	293.59 (± 16.013)

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: mg/3wks				
arithmetic mean (standard deviation)	282.12 (± 23.773)	289.04 (± 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[17][18]

End point description:

To characterize the tolerability of MCS110 given in combination with PDR001 and to identify a recommended dose combination for Phase II. Relative dose intensity (%) is 100 × dose intensity (mg/3wks)/planned dose intensity (mg/3wks).

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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 (± 100.00)	100.00 (± 100.00)	100.00 (± 100.00)	100.00 (± 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 (± 100.00)	100.00 (± 100.00)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase Ib: Number of Participants with Dose Reductions

End point title	Phase Ib: Number of Participants with Dose Reductions[19][20]

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:

[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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: Participants				
n of participants with no dose reduction-MCS110	6	12	12	13
n of participants with no dose reduction-PDR001	6	12	12	13

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: Participants				
n of participants with no dose reduction-MCS110	6	9		
n of participants with no dose reduction-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[21][22]

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: Dose interruptions per participant				
arithmetic mean (standard deviation)				
Number of dose interruptions per subject - MCS110	1.3 (± 1.97)	0.3 (± 0.45)	0.3 (± 0.45)	0.0 (± 0.0)
Number of dose interruptions per subject - PDR001	1.3 (± 1.97)	0.3 (± 0.45)	0.3 (± 0.45)	0.0 (± 0.0)

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: Dose interruptions per participant				
arithmetic mean (standard deviation)				
Number of dose interruptions per subject - MCS110	0.3 (± 0.52)	0.1 (± 0.30)		
Number of dose interruptions per 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[23][24]

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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: Participants				
N w/ at least 1 dose interruption - MCS110	3	3	3	0
N w/ at least 1 dose interruption - PDR001	3	3	3	0

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: Participants				
N w/ at least 1 dose interruption - MCS110	2	1		
N w/ at least 1 dose interruption - PDR001	2	1		

Statistical analyses

No statistical analyses for this end point

Primary: Phase Ib: Number of Participants with Dose Limiting Toxicities (DLTs) During the First 2 Cycles of Study Treatment

End point title	Phase Ib: Number of Participants with Dose Limiting Toxicities (DLTs) During the First 2 Cycles of Study Treatment[25][26]

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. (CPK = Creatine Phosphokinase)

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: This endpoint only applied to phase Ib arms and not phase II arms.

[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: This endpoint only applied to phase Ib arms and not phase II arms.

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	5	11	9	7
Units: Participants				
n w/ at least 1 event - all grades(n=5,11,9,7,4,4)	0	0	1	0
n Investigations - all grades (n=5,11,9,7,4,4)	0	0	1	0
n Blood CPK increased (n=5,11,9,7,4,4)	0	0	1	0

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	4	4		
Units: Participants				
n w/ at least 1 event - all grades(n=5,11,9,7,4,4)	0	1		
n Investigations - all grades (n=5,11,9,7,4,4)	0	1		
n Blood CPK increased (n=5,11,9,7,4,4)	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[27]

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: This endpoint only applied to phase II arms and not phase Ib arms.

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				
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)[28]

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: This endpoint only applied to phase Ib arms and not phase II arms.

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

	PDR001 300 mg Q3W	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[29]

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: This endpoint only applied to phase II arms and not phase Ib arms.

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	0[30]	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)[31]

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: This endpoint only applied to phase Ib arms and not phase II arms.

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 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 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 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[32]

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: This endpoint only applied to phase II arms and not phase Ib arms.

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				
number (confidence interval 90%)	20.0 (7.1 to 40.1)	5.0 (0.3 to 21.6)	19.0 (6.8 to 38.4)	30.0 (14.0 to 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[33]

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: This endpoint only applied to phase II arms and not phase Ib arms.

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	0[34]	20	0[35]	0[36]
Units: Percentage of participants				
arithmetic mean (confidence interval 90%)	(to)	5.6 (0.4 to 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 iiRC	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 iiRC	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)

End point values	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: 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	

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%)	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)

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%)	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)

End point values	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: 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

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: 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)

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

End point values	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

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				
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)

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: 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)

End point values	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[37]

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: This endpoint only applied to phase II arms and not phase Ib arms.

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: 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 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: Participants				
Baseline (B/l) positive	0	1	1	1
Baseline negative	6	11	11	12

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

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: Participants				
Baseline (B/l) positive	0	0	0	0
Baseline negative	6	11	19	19
Baseline missing	0	0	1	1
B/l positive, on treatment persistent positive	0	0	0	0
B/l 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/l negative, on treatment persistent positive	0	0	0	0
B/l negative, on treatment only last positive	0	0	0	0
B/l negative, on treatment any positive	0	0	0	0
Baseline negative, on treatment all negative	5	6	12	16
B/l missing, on treatment persistent positive	0	0	0	0
B/l missing, on treatment only last positive	0	0	0	0
B/l missing, on treatment any positive	0	0	0	0
B/l missing, on treatment all negative	0	0	0	0

End point values	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: Participants				
Baseline (B/l) positive	0	0		
Baseline negative	17	18		
Baseline missing	4	2		
B/l positive, on treatment persistent positive	0	0		
B/l 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/l negative, on treatment persistent positive	0	0		
B/l negative, on treatment only last positive	0	0		
B/l negative, on treatment any positive	0	0		
Baseline negative, on treatment all negative	14	17		
B/l missing, on treatment persistent positive	0	0		
B/l missing, on treatment only last positive	0	0		
B/l missing, on treatment any positive	0	0		
B/l 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

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: Participants				
Baseline (B/l) positive	0	2	1	2
Baseline negative	6	10	11	10
Baseline missing	0	0	0	1
B/l positive, on treatment persistent positive	0	1	0	1
B/l positive, on treatment only last positive	0	1	0	0
B/l positive, on treatment any positive	0	0	0	0
Bl/ positive, on treatment all negative	0	0	0	0
B/l negative, on treatment persistent positive	0	1	0	0
B/l negative, on treatment only last positive	1	1	0	0
B/l negative, on treatment any positive	1	3	1	0
B/l negative, on treatment all negative	4	4	8	6
B/l missing, on treatment persistent positive	0	0	0	0
B/l missing, on treatment only last positive	0	0	0	0
B/l missing, on treatment any positive	0	0	0	0
B/l missing, on treatment all negative	0	0	0	1

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: Participants				
Baseline (B/l) positive	1	2	1	1
Baseline negative	5	8	18	17
Baseline missing	0	1	1	2
B/l positive, on treatment persistent positive	0	0	0	0
B/l positive, on treatment only last positive	0	0	0	1
B/l positive, on treatment any positive	1	1	1	0
Bl/ positive, on treatment all negative	0	0	0	0
B/l negative, on treatment persistent positive	0	1	0	0
B/l negative, on treatment only last positive	0	1	0	4
B/l negative, on treatment any positive	0	0	0	1
B/l negative, on treatment all negative	4	2	11	10
B/l missing, on treatment persistent positive	0	0	0	0

B/l missing, on treatment only last positive	0	0	0	0
B/l missing, on treatment any positive	0	0	0	0
B/l missing, on treatment all negative	0	1	1	0

End point values	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: Participants				
Baseline (B/l) positive	0	1		
Baseline negative	19	19		
Baseline missing	2	0		
B/l positive, on treatment persistent positive	0	0		
B/l positive, on treatment only last positive	0	0		
B/l positive, on treatment any positive	0	1		
Bl/ positive, on treatment all negative	0	0		
B/l negative, on treatment persistent positive	0	1		
B/l negative, on treatment only last positive	1	0		
B/l negative, on treatment any positive	0	2		
B/l negative, on treatment all negative	16	13		
B/l missing, on treatment persistent positive	0	0		
B/l missing, on treatment only last positive	0	0		
B/l missing, on treatment any positive	0	0		
B/l 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 (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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*ng/mL				
arithmetic mean (standard deviation)				
AUClast - C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	46900 (± 9080)	343000 (± 142000)	249000 (± 93400)	490000 (± 149000)
AUCinf-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	50100 (± 11600)	383000 (± 178000)	330000 (± 73400)	560000 (± 177000)
AUClast C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	41000 (± 22800)	213000 (± 92200)	232000 (± 99300)	710000 (± 171000)
AUCinf-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	42300 (± 21900)	260000 (± 73500)	253000 (± 114000)	619000 (± 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*ng/mL				
arithmetic mean (standard deviation)				
AUClast - C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	909000 (± 233000)	1090000 (± 231000)	1200000 (± 507000)	1090000 (± 352000)
AUCinf-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	1020000 (± 336000)	988000 (± 116000)	999 (± 999)	999 (± 999)
AUClast C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	1520000 (± 353000)	1200000 (± 1030000)	1200000 (± 389000)	918000 (± 102000)
AUCinf-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (± 999)	769000 (± 999)	999 (± 999)	999 (± 999)

End point values	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: day*ng/mL				
arithmetic mean (standard deviation)				
AUClast - C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	1120000 (± 440000)	1270000 (± 335000)		
AUCinf-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	999 (± 999)	999 (± 999)		

AUClast C4-day 84(n=3,6,4,2,3,3,4,3,4,13) AUCinf-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	1010000 (± 337000) 999 (± 999)	1240000 (± 499000) 999 (± 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:

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 × time × volume-1); and AUCinf, which is the AUC from time zero to infinity (mass × time × volume-1) and AUCinf - PDR001. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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- C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	229 (± 68.3)	271 (± 53.8)	651 (± 322)	604 (± 309)
AUCinf-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	274 (± 999)	610 (± 999)	999 (± 999)
AUClast-C4-day 84((n=3,6,4,2,3,3,5,3,4,13)	369 (± 26.4)	330 (± 182)	1020 (± 526)	2020 (± 1170)
AUCinf -C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	196 (± 999)	999 (± 999)	999 (± 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- C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	581 (± 147)	450 (± 135)	825 (± 402)	782 (± 264)
AUCinf-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	747 (± 999)	710 (± 999)	999 (± 999)	999 (± 999)
AUClast-C4-day 84((n=3,6,4,2,3,3,5,3,4,13)	954 (± 179)	718 (± 288)	1170 (± 388)	1330 (± 555)
AUCinf -C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)

End point values	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: day*ug/mL				
arithmetic mean (standard deviation)				
AUClast- C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	764 (± 311)	782 (± 307)		
AUCinf-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	999 (± 999)		
AUClast-C4-day 84((n=3,6,4,2,3,3,5,3,4,13)	1660 (± 283)	1260 (± 533)		
AUCinf -C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	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-1); and Clast - MCS110. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: ng/mL				

arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	17400 (± 1870)	58800 (± 16900)	56700 (± 17800)	96900 (± 28600)
Clast-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	1120 (± 795)	1290 (± 2760)	6600 (± 6370)	9130 (± 11500)
Cmax-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	13500 (± 5580)	53000 (± 9790)	48900 (± 14100)	76400 (± 24000)
Clast-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	510 (± 457)	5700 (± 10300)	3490 (± 2410)	7350 (± 5870)

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: ng/mL				
arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	122000 (± 17100)	186000 (± 54000)	158000 (± 44800)	130000 (± 38400)
Clast-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	15100 (± 9070)	28700 (± 27800)	33000 (± 21300)	12900 (± 10700)
Cmax-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	176000 (± 19800)	189000 (± 29400)	159000 (± 39800)	152000 (± 58000)
Clast-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	45100 (± 12400)	34100 (± 29800)	57600 (± 45000)	33300 (± 42600)

End point values	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: ng/mL				
arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	134000 (± 64900)	151000 (± 42500)		
Clast-C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	24500 (± 20100)	17500 (± 11400)		
Cmax-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	128000 (± 42600)	147000 (± 38300)		
Clast-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	18600 (± 21700)	29400 (± 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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: ug/mL				
arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	24 (± 9.52)	29.5 (± 6.56)	73.4 (± 22.3)	77 (± 24.3)
Clast -C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	7.73 (± 2.97)	7.24 (± 2.95)	19.4 (± 11.7)	26.4 (± 11.8)
Cmax-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	29.5 (± 9.3)	36.8 (± 10.5)	126 (± 54.6)	153 (± 22.6)
Clast-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	10.7 (± 2.25)	14.5 (± 8.47)	65.1 (± 37.6)	71 (± 6.65)

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: ug/mL				
arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	76.6 (± 36.8)	64.2 (± 20.4)	94.5 (± 27.4)	75.3 (± 23.9)
Clast -C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	22.7 (± 12.8)	17.2 (± 8.67)	34.5 (± 13.3)	24 (± 12)
Cmax-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	92 (± 22.1)	85.9 (± 16.8)	123 (± 56.8)	127 (± 7)
Clast-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	47.5 (± 25.7)	35.6 (± 14.7)	81.4 (± 43.6)	62.1 (± 9.93)

End point values	Ph II: MCS110 7.5 mg/kg Q3W +	Ph II: MCS110 7.5 mg/kg Q3W +		

	PDR001 300 mg Q3W - EC	PDR001 300 mg Q3W - ME		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: ug/mL				
arithmetic mean (standard deviation)				
Cmax-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	80.2 (± 24)	70.3 (± 21.6)		
Clast -C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	22.8 (± 9.44)	24.4 (± 14.6)		
Cmax-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	122 (± 23.6)	108 (± 23.4)		
Clast-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	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:

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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: hour				
median (full range (min-max))				
Tmax -C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	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-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	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 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: hour				
median (full range (min-max))				
Tmax -C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	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-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	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)

End point values	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 -C1-day 21(n=6,9,12,12,6,10,16,16,16,18)	2.09 (2 to 163)	2.08 (1.5 to 188)		
Tmax-C4-day 84(n=3,6,4,2,3,3,4,3,4,13)	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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: hour				
median (full range (min-max))				
Tmax-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	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-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	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)

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: hour				
median (full range (min-max))				
Tmax-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	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-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	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)

End point values	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-C1-day 21(n=6,11,11,13,6,11,20,18,19,18)	1.5 (1.42 to 166)	1.5 (1.45 to 624)		
Tmax-C4-day 84(n=3,6,4,2,3,3,5,3,4,13)	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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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				
median (full range (min-max))				
T1/2-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	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-C4- day 84(n=3,4,4,1,0,1,0,0,0,0)	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)

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				
median (full range (min-max))				
T1/2-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	6.35 (2.17 to 8.05)	4.36 (2.25 to 6.62)	999 (999 to 999)	999 (999 to 999)
T1/2-C4- day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (999 to 999)	4.82 (4.82 to 4.82)	999 (999 to 999)	999 (999 to 999)

End point values	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: day				
median (full range (min-max))				
T1/2-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	999 (999 to 999)	999 (999 to 999)		
T1/2-C4- day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (999 to 999)	999 (999 to 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:

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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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				
median (full range (min-max))				
T1/2 -C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (999 to 999)	8.14 (8.14 to 8.14)	7.71 (7.71 to 7.71)	999 (999 to 999)
T1/2-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (999 to 999)	7.81 (7.81 to 7.81)	999 (999 to 999)	999 (999 to 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				
median (full range (min-max))				
T1/2 -C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	7.13 (7.13 to 7.13)	7.33 (7.33 to 7.33)	999 (999 to 999)	999 (999 to 999)
T1/2-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)	999 (999 to 999)

End point values	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: day				
median (full range (min-max))				
T1/2 -C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (999 to 999)	999 (999 to 999)		
T1/2-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (999 to 999)	999 (999 to 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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: L/h/kg				
arithmetic mean (standard deviation)				
CL -C1- day 21(n=6,7,7,9,5,5,0,0,0,0)	0.000863 (± 0.000158)	0.000388 (± 0.000181)	0.000394 (± 0.0000833)	0.000407 (± 0.000131)
CL-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	0.00117 (± 0.000549)	0.000523 (± 0.000199)	0.000315 (± 0.000218)	0.000337 (± 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: L/h/kg				
arithmetic mean (standard deviation)				
CL -C1- day 21(n=6,7,7,9,5,5,0,0,0,0)	0.000338 (± 0.000117)	0.000427 (± 0.0000558)	999 (± 999)	999 (± 999)
CL-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (± 999)	0.000541 (± 999)	999 (± 999)	999 (± 999)

End point values	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: L/h/kg				
arithmetic mean (standard deviation)				
CL -C1- day 21(n=6,7,7,9,5,5,0,0,0,0)	999 (± 999)	999 (± 999)		
CL-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	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. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: L/h				
arithmetic mean (standard deviation)				
CL-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	0.0152 (± 999)	0.0205 (± 999)	999 (± 999)
CL-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	0.0213 (± 999)	999 (± 999)	999 (± 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: L/h				
arithmetic mean (standard deviation)				
CL-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	0.0167 (± 999)	0.0176 (± 999)	999 (± 999)	999 (± 999)

CL-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)

End point values	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: L/h				
arithmetic mean (standard deviation)				
CL-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	999 (± 999)		
CL-C4-day 84(n=0,1,0,0,0,0,0,0,0,0)	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:	
Phase Ib and Phase II: PK Parameters - Vz, which is the apparent volume of distribution during terminal phase (volume) - MCS110. (C1 = Cycle1; C4 = Cycle 4)	
End point type	Secondary
End point timeframe:	
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: L/kg				
arithmetic mean (standard deviation)				
Vz-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	0.0486 (± 0.00989)	0.0334 (± 0.00783)	0.0423 (± 0.00875)	0.051 (± 0.0206)
Vz-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	0.0684 (± 0.0407)	0.0294 (± 0.0128)	0.045 (± 0.0308)	0.0736 (± 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 -	Ph II: MCS110 7.5 mg/kg Q3W + PDR001 300 mg Q3W - PC

			TNBC	
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-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	0.0651 (± 0.0201)	0.065 (± 0.0267)	999 (± 999)	999 (± 999)
Vz-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (± 999)	0.0904 (± 999)	999 (± 999)	999 (± 999)

End point values	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: L/kg				
arithmetic mean (standard deviation)				
Vz-C1-day 21(n=6,7,7,9,5,5,0,0,0,0)	999 (± 999)	999 (± 999)		
Vz-C4-day 84(n=3,4,4,1,0,1,0,0,0,0)	999 (± 999)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase Ib and Phase II: Pharmacokinetics of PDR001 - Vz

End point title	Phase Ib and Phase II: Pharmacokinetics of PDR001 - Vz

End point description:

Phase Ib and Phase II: PK Parameters - Vz, which is the apparent volume of distribution during terminal phase (volume) - PDR001. (C1 = Cycle1; C4 = Cycle 4)

End point type	Secondary

End point timeframe:

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: Liters (L)				
arithmetic mean (standard deviation)				
Vz-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	4.28 (± 999)	5.47 (± 999)	999 (± 999)
Vz-C4- day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	5.76 (± 999)	999 (± 999)	999 (± 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: Liters (L)				
arithmetic mean (standard deviation)				
Vz-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	4.13 (± 999)	4.47 (± 999)	999 (± 999)	999 (± 999)
Vz-C4- day 84(n=0,1,0,0,0,0,0,0,0,0)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)

End point values	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: Liters (L)				
arithmetic mean (standard deviation)				
Vz-C1-day 21(n=0,1,1,0,1,1,0,0,0,0)	999 (± 999)	999 (± 999)		
Vz-C4- day 84(n=0,1,0,0,0,0,0,0,0,0)	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:

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:

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	3	6	4	2
Units: Ratio of AUC				
arithmetic mean (standard deviation)	0.789 (± 0.232)	0.744 (± 0.307)	0.833 (± 0.0739)	1.14 (± 0.0991)

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	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)

End point values	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)

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	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)

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	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 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	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 ontreatment 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 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: Participants				
Total Deaths	6	12	10	12
On-treatment Deaths	0	1	4	4

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: Participants				
Total Deaths	4	10	11	19
On-treatment Deaths	1	4	1	3

End point values	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: Participants				
Total Deaths	14	11		
On-treatment Deaths	0	2		

Statistical analyses

No statistical analyses for this end point

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 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@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@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

Serious adverse events	Ph Ib: MCS110@1 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
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	4 / 12 (33.33%)	7 / 13 (53.85%)
number of deaths (all causes)	0	4	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 / 13 (0.00%)
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 / 13 (0.00%)
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%)	1 / 12 (8.33%)	0 / 13 (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
Tumour pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (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%)	1 / 13 (7.69%)
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 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 / 13 (0.00%)
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 / 13 (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%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 / 13 (0.00%)
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%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
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 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (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
Pneumonia aspiration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 13 (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
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (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 / 13 (0.00%)
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%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemoperitoneum			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (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 / 13 (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 / 13 (0.00%)
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 / 13 (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 / 13 (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 / 13 (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 / 13 (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 / 13 (0.00%)
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 / 13 (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 / 13 (0.00%)
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%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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%)	1 / 12 (8.33%)	0 / 13 (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
Infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
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 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 100@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	4 / 12 (33.33%)	2 / 6 (33.33%)	5 / 11 (45.45%)
number of deaths (all causes)	1	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 / 12 (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 / 12 (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 / 12 (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 / 12 (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	0 / 12 (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
Hypertensive crisis			
subjects affected / exposed	0 / 12 (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 / 12 (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	0 / 12 (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
Chills			
subjects affected / exposed	0 / 12 (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 / 12 (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	0 / 12 (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

Generalised oedema			
subjects affected / exposed	0 / 12 (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	0 / 12 (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
Ulcer			
subjects affected / exposed	0 / 12 (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	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (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
Pleural effusion			
subjects affected / exposed	0 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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	0 / 12 (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
Haemoperitoneum			
subjects affected / exposed	0 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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	1 / 12 (8.33%)	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
Renal failure			
subjects affected / exposed	0 / 12 (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	1 / 12 (8.33%)	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
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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	0 / 12 (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
Peritonitis			
subjects affected / exposed	0 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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	1 / 12 (8.33%)	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
Urinary tract infection			
subjects affected / exposed	0 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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 / 12 (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

Serious adverse events	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			
Cystitis			
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
Febrile 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
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
Peritonitis			
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
Pneumocystis jirovecii pneumonia			
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
Pneumonia			
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
Sepsis			
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 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
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

Serious adverse events	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				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Gastrointestinal procedural complication				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Infusion related reaction				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebral infarction				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Guillain-Barre syndrome				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to 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 %

Non-serious adverse events	Ph Ib: MCS110@1 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
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	12 / 12 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Adverse reaction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	3 / 6 (50.00%)	3 / 12 (25.00%)	3 / 13 (23.08%)
occurrences (all)	3	3	3
Chest discomfort			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	2 / 13 (15.38%)
occurrences (all)	1	3	2
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	3 / 13 (23.08%)
occurrences (all)	0	2	3
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	5 / 12 (41.67%)	2 / 13 (15.38%)
occurrences (all)	2	5	2
Gait disturbance			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Generalised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Oedema peripheral			
subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	2 / 13 (15.38%)
occurrences (all)	3	2	3
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 12 (25.00%)	1 / 13 (7.69%)
occurrences (all)	1	3	1
Suprapubic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Cytokine release syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Varicocele			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	2	2	1
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lung opacity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal mucosal ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eating disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 6 (66.67%)	3 / 12 (25.00%)	5 / 13 (38.46%)
occurrences (all)	5	3	6
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 12 (25.00%)	2 / 13 (15.38%)
occurrences (all)	0	3	2
Blood bilirubin increased			
subjects affected / exposed	3 / 6 (50.00%)	2 / 12 (16.67%)	2 / 13 (15.38%)
occurrences (all)	5	2	2
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 6 (16.67%)	3 / 12 (25.00%)	3 / 13 (23.08%)
occurrences (all)	1	3	3
Blood creatinine increased			

subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	3	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			

Abdominal injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Dysgeusia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	3 / 12 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 6 (66.67%)	3 / 12 (25.00%)	3 / 13 (23.08%)
occurrences (all)	8	4	4
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			

subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Lacrimation increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Panophthalmitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	3 / 13 (23.08%)
occurrences (all)	2	4	3
Abdominal pain lower			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Colitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 6 (50.00%)	2 / 12 (16.67%)	2 / 13 (15.38%)
occurrences (all)	3	2	2
Diarrhoea			
subjects affected / exposed	3 / 6 (50.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	6	0	1
Dry mouth			
subjects affected / exposed	2 / 6 (33.33%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	2	2	1
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Epigastric discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	3 / 12 (25.00%)	5 / 13 (38.46%)
occurrences (all)	2	3	6
Odynophagia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	3 / 13 (23.08%)
occurrences (all)	2	1	3
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	3 / 12 (25.00%)	5 / 13 (38.46%)
occurrences (all)	2	4	5
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Hair colour changes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Intertrigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Choluria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Ureterolithiasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Groin pain			

subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Joint warmth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Muscle twitching			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Conjunctivitis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Diarrhoea infectious			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Helicobacter infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Respiratory tract infection			
subjects affected / exposed	2 / 6 (33.33%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	6	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral skin infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 6 (50.00%)	4 / 12 (33.33%)	1 / 13 (7.69%)
occurrences (all)	3	5	1
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 12 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 12 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 12 (16.67%)	1 / 13 (7.69%)
occurrences (all)	3	2	1
Hypophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 12 (8.33%)	4 / 13 (30.77%)
occurrences (all)	1	1	4
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 12 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph Ib: MCS110@3 mg/kg Q3W@+ PDR001 100@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	12 / 12 (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 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	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 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	5 / 12 (41.67%)	3 / 6 (50.00%)	5 / 11 (45.45%)
occurrences (all)	5	3	5
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	2	1	1
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)	2 / 6 (33.33%)	0 / 11 (0.00%)
occurrences (all)	3	3	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	1 / 12 (8.33%)	2 / 6 (33.33%)	0 / 11 (0.00%)
occurrences (all)	1	2	0
Generalised oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 12 (25.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Oedema peripheral			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Pyrexia			
subjects affected / exposed	4 / 12 (33.33%)	0 / 6 (0.00%)	5 / 11 (45.45%)
occurrences (all)	6	0	7
Suprapubic pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Varicocele			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	3 / 12 (25.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	4	0	1
Dysphonia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Lung opacity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Nasal mucosal ulcer			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Respiratory failure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rhinalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Disorientation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Eating disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	2 / 11 (18.18%)
occurrences (all)	1	3	2
Amylase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 12 (25.00%)	3 / 6 (50.00%)	4 / 11 (36.36%)
occurrences (all)	3	3	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 12 (25.00%)	4 / 6 (66.67%)	3 / 11 (27.27%)
occurrences (all)	4	4	3
Blood creatinine increased			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Blood pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 12 (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	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	3 / 12 (25.00%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	3	1	1
Post procedural haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Post procedural inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Headache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	3 / 6 (50.00%)	3 / 11 (27.27%)
occurrences (all)	2	3	4
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Eyelid oedema			
subjects affected / exposed	3 / 12 (25.00%)	0 / 6 (0.00%)	2 / 11 (18.18%)
occurrences (all)	3	0	2
Lacrimation increased			
subjects affected / exposed	4 / 12 (33.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
Panophthalmitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	3 / 12 (25.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
Uveitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	3	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Aphthous ulcer			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	2	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 12 (16.67%)	2 / 6 (33.33%)	1 / 11 (9.09%)
occurrences (all)	2	2	1
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	2 / 6 (33.33%)	3 / 11 (27.27%)
occurrences (all)	3	2	4
Dry mouth			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1

Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Epigastric discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	5 / 12 (41.67%)	1 / 6 (16.67%)	6 / 11 (54.55%)
occurrences (all)	6	1	6
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Vomiting			
subjects affected / exposed	5 / 12 (41.67%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	5	1	1

Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hair colour changes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nail dystrophy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Rash			

subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	1 / 11 (9.09%)
occurrences (all)	4	1	1
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Choluria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypopituitarism			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 12 (25.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	6	3	0
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Flank pain			
subjects affected / exposed	4 / 12 (33.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Joint stiffness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Joint warmth			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	2 / 12 (16.67%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Pyuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 12 (16.67%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 6 (33.33%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Viral skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	7 / 12 (58.33%)	0 / 6 (0.00%)	4 / 11 (36.36%)
occurrences (all)	7	0	6
Dehydration			

subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 6 (33.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 6 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Hypophagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 6 (33.33%)	1 / 11 (9.09%)
occurrences (all)	1	2	1
Vitamin D deficiency			

subjects affected / exposed	0 / 12 (0.00%)	1 / 6 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	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			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Renal colic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypopituitarism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 20 (15.00%)	0 / 20 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Arthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	1 / 21 (4.76%)
occurrences (all)	2	2	1
Flank pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	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			
subjects affected / exposed	2 / 20 (10.00%)	1 / 20 (5.00%)	2 / 21 (9.52%)
occurrences (all)	2	1	2
Viral skin infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 20 (15.00%)	7 / 20 (35.00%)	1 / 21 (4.76%)
occurrences (all)	3	7	1
Dehydration			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hypermagnesaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	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

Non-serious adverse events	Ph II: MCS110@7.5 mg/kg Q3W@+ PDR001 300@mg 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			

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

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

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Eye pruritus			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Panophthalmitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	6 / 20 (30.00%)		
occurrences (all)	6		
Uveitis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Xerophthalmia			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	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 occurrences (all)	0 / 20 (0.00%) 0		
Flatulence subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Gastritis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Gingival bleeding subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Haematochezia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Melaena subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4		
Odynophagia subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Stomatitis subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3		
Vomiting subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 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			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Rash pruritic			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Choluria			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Pollakiuria			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	3		
Renal colic			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Ureterolithiasis			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypopituitarism			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	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: 1. Increase the number of pancreatic cancer patients to be enrolled in the Phase II part of the study from 20 to 40 2. Change the primary endpoint for antitumor activity in pancreatic cancer from ORR to CBR 3. Add the assessment of cfDNA as a complementary method to evaluate tumor mutational burden 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